WHA47/1994/REC/1

WORLD HEALTH ORGANIZATION

FORTY-SEVENTH WORLD HEALTH ASSEMBLY

GENEVA, 2-12 MAY 1994

RESOLUTIONS AND DECISIONS
ANNEXES

GENEVA
1994

WHA47/1994/REC/1

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ABBREVIATIONS

Abbreviations used in WHO documentation include the following:

ACC - Administrative Committee on Coordination
ACHR - Advisory Committee on Health Research
AGFUND - Arab Gulf Programme for United Nations Development Organizations
ASEAN - Association of South-East Asian Nations
CIDA - Canadian International Development Agency
CIOMS - Council for International Organizations of Medical Sciences
DANIDA - Danish International Development Agency
ECA - Economic Commission for Africa
ECE - Economic Commission for Europe
ECLAC - Economic Commission for Latin America and the Caribbean
ESCAP - Economic and Social Commission for Asia and the Pacific
ESCWA - Economic and Social Commission for Western Asia
FAO - Food and Agriculture Organization of the United Nations
FINNIDA - Finnish International Development Agency
IAEA - International Atomic Energy Agency
IARC - International Agency for Research on Cancer
ICAO - International Civil Aviation Organization
IFAD - International Fund for Agricultural Development
ILO - International Labour Organisation (Office)
IMO - International Maritime Organization
ITU - International Telecommunication Union
NORAD - Norwegian Agency for International Development
OAU - Organization of African Unity
OECD - Organisation for Economic Co-operation and Development
PAHO - Pan American Health Organization
SAREC - Swedish Agency for Research Cooperation with Developing Countries
SIDA - Swedish International Development Authority
UNCTAD - United Nations Conference on Trade and Development
UNDCP - United Nations International Drug Control Programme
UNDP - United Nations Development Programme
UNEP - United Nations Environment Programme
UNESCO - United Nations Educational, Scientific and Cultural Organization
UNFPA - United Nations Population Fund
UNHCR - Office of the United Nations High Commissioner for Refugees
UNICEF - United Nations Children's Fund
UNIDO - United Nations Industrial Development Organization
UNRWA - United Nations Relief and Works Agency for Palestine Refugees in the Near East
UNSCEAR - United Nations Scientific Committee on the Effects of Atomic Radiation
USAID - United States Agency for International Development
WFP - World Food Programme
WIPO - World Intellectual Property Organization
WMO - World Meteorological Organization

PREFACE

The Forty-seventh World Health Assembly was held at the Palais des Nations, Geneva, from 2 to 12 May 1994, in accordance with the decision of the Executive Board at its ninety-second session. Its proceedings are published in three volumes, containing, in addition to other relevant material:

Resolutions and decisions,[1] annexes and list of participants - document WHA47/1994/REC/1

Verbatim records of plenary meetings - document WHA47/1994/REC/2

Summary records and reports of committees - document WHA47/1994/REC/3

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[1] The resolutions, which are reproduced in the order in which they were adopted, have been cross-referenced to the relevant sections of the WHO *Handbook of Resolutions and Decisions,* volumes I, II and III (third edition), which contain most of the resolutions adopted by the Health Assembly and the Executive Board between 1948 and 1992. A list of the dates of sessions, indicating resolution symbols and the volumes in which the resolutions and decisions were first published, is given in volume III (third edition) of the *Handbook* (page XIII).

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[1] The agenda was adopted at the third plenary meeting.

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    Implementation of WHO's revised drug strategy

    Elimination of neonatal tetanus and control of measles

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[1] Item referred to Committee B.

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A47/5	Report on progress in implementing resolution WHA45.24: health and development
A47/6	Infant and young child nutrition (progress and evaluation report; and status of implementation of the International Code of Marketing of Breast-milk Substitutes) (report by the Director-General)[4]
A47/7	WHO ethical criteria for medicinal drug promotion (report by the Director-General)[5]
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A47/9	Elimination of neonatal tetanus and control of measles (report by the Director-General)
A47/10	Eradication of dracunculiasis (report by the Director-General)
A47/11	Elimination of leprosy as a public health problem (progress report by the Director-General)
A47/12	Tuberculosis programme (progress report by the Director-General)
A47/13	Onchocerciasis control through ivermectin distribution (report by the Director-General)
A47/14	Implementation of the global AIDS strategy (report by the Director-General)

[1] Issued in Arabic, Chinese, English, French, Russian and Spanish.

[2] See page ix.

[3] To be published in 1994 as No. 11 in WHO's "Health for All" Series.

[4] See Annex 1.

[5] See Annex 4.

[6] See Annex 3.

A47/15	Joint and cosponsored United Nations programme on HIV/AIDS (report by the Director-General)
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A47/18	Consideration of the situation of certain Member States falling under the purview of Article 7 of the Constitution: Members in arrears in the payment of their contributions to an extent which would justify invoking Article 7 of the Constitution (second report of the Committee of the Executive Board to Consider Certain Financial Matters prior to the Forty-seventh World Health Assembly)
A47/19	Financial Report and audited financial statements for the financial period 1 January 1992 - 31 December 1993 and Report of the External Auditor to the World Health Assembly
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A47/20	Implementation of recommendations of the External Auditor 1990-1991 (report by the Director-General)
A47/21	Status of collection of assessed contributions and status of advances to the Working Capital Fund (report by the Director-General)
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A47/23	Scale of assessments - Assessment of new Members and Associate Members: assessments of the Czech Republic and Slovakia (report by the Director-General)
A47/24	Real Estate Fund (report by the Director-General)[3]
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A47/28	Collaboration within the United Nations system: International Year of the Family (1994) (summary of WHO's contribution to the International Year of the Family) (report by the Director-General)

[1] See Annex 2, part 1.

[2] See Annex 2, part 2.

[3] See Annex 5.

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A47/30	Health conditions of the Arab population in the occupied Arab territories, including Palestine: special technical support to improve the health conditions of the Palestinian people in the occupied Arab territories (report by the Director-General)
A47/31	United Nations Joint Staff Pension Fund (annual report of the United Nations Joint Staff Pension Board)
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A47/36	Admission of new Members and Associate Members: application by the Republic of Nauru for admission to membership
A47/37	Consideration of the situation of certain Member States falling under the purview of Article 7 of the Constitution: Cambodia's request for restoration of voting rights and waiver of arrears (report by the Director-General)
A47/38	Consideration of the situation of certain Member States falling under the purview of Article 7 of the Constitution: arrears of contributions of South Africa (report by the Director-General)
A47/39	Committee on Nominations: first report
A47/40	Committee on Nominations: second report
A47/41	Committee on Nominations: third report
A47/42	Financial report and audited financial statements for the financial period 1 January 1992 - 31 December 1993 and Report of the External Auditor to the World Health Assembly (first report of the Committee of the Executive Board to Consider Certain Financial Matters prior to the Forty-seventh World Health Assembly)
A47/43	Committee on Credentials: first report
A47/44	Election of Members entitled to designate a person to serve on the Executive Board
A47/45	Committee on Credentials. Second report

[1] See Annex 2, part 3.

A47/46	Scale of assessments - assessment of new Members and Associate Members: assessment of Niue (report by the Director-General)
A47/47	Scale of assessments - assessment of new Members and Associate Members: assessment of the Republic of Nauru (report by the Director-General)
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A47/INF.DOC./3	Health conditions of the Arab population in the occupied Arab territories, including Palestine (report of the Director of Health of UNRWA)
A47/INF.DOC./4	Health conditions of the Arab population in the occupied Arab territories, including Palestine (report of Palestine)[2]
A47/INF.DOC./5	Health conditions of the Arab population in the occupied Arab territories, including Palestine (report of Ministry of Health of Israel)
A47/INF.DOC./6	WHO response to global change
A47/INF.DOC./7	Collaboration within the United Nations system: International Year of the Family (1994) - the concept of family health (report by the Director-General)

[1] Issued in English and French.

[2] Also available in Arabic.

FORTY-SEVENTH WORLD HEALTH ASSEMBLY

Geneva, 2-12 May 1994

RESOLUTIONS AND DECISIONS
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Committee A

Secretary: *delete* Mr A. K. ASAMOAH, Chief, Administration and Staff Support Service

insert Dr B.-I. THYLEFORS, Chief, Programme for the Prevention of Blindness

Committee B

Secretary: *delete* Dr B.-I. THYLEFORS, Chief, Programme for the Prevention of Blindness

insert Mr A. K. ASAMOAH, Chief, Administration and Staff Support Service

OFFICERS OF THE HEALTH ASSEMBLY AND MEMBERSHIP OF ITS COMMITTEES

President
Mr B. K. TEMANE (Botwsana)

Vice-Presidents
Dr A. L. PICO (Argentina)
Dr A. ABDEL FATTAH EL MAKHZANGI (Egypt)[1]
Dr B. VOLJČ (Slovenia)
Dr A. OURAIRAT (Thailand)
Professor V. RAJPHO (Lao People's Democratic Republic)

Secretary
Dr H. NAKAJIMA, Director-General

Committee on Credentials

The Committee on Credentials was composed of delegates of the following Member States: Bulgaria, Canada, Chile, Côte d'Ivoire, Namibia, Nepal, Netherlands, Portugal, Samoa, Seychelles, Tunisia, and United Arab Emirates.

Chairman: Dr M. HAMDAN (United Arab Emirates)
Vice-Chairman: Professor Y. G. LOUKOU (Côte d'Ivoire)
Rapporteur: Dr C. SHAMLAYE (Seychelles)
Secretary: Mr T. S. R. TOPPING, Senior Legal Officer, Office of the Legal Counsel

Committee on Nominations

The Committee on Nominations was composed of delegates of the following Member States: Angola, Australia, Bangladesh, Barbados, Bolivia, Ecuador, Fiji, France, Iceland, Jordan, Kenya, Kyrgyzstan, Morocco, Mozambique, Myanmar, Oman, Pakistan, Panama, Philippines, Russian Federation, Senegal, Swaziland, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania, and United States of America.

Chairman: Mr A. DIOP (Senegal)
Secretary: Dr H. NAKAJIMA, Director-General

General Committee

The General Committee was composed of the President and Vice-Presidents of the Health Assembly and the Chairmen of the main committees, together with delegates of the following Member States: Bahrain, Burkina Faso, Cape Verde, China, Cuba, France, Gabon, Guatemala, Guinea, Iran (Islamic Republic of), Israel, Japan, Nigeria, Russian Federation, United Kingdom of Great Britain and Northern Ireland, United States of America, and Venezuela.

Chairman: Mr B. K. TEMANE (Botswana)
Secretary: Dr H. NAKAJIMA, Director-General

MAIN COMMITTEES

Under Rule 35 of the Rules of Procedure of the World Health Assembly, each delegation was entitled to be represented on each main committee by one of its members.

Committee A

Chairman: Dr N. K. RAI (Indonesia)
Vice-Chairmen: Mr D. VAN DAELE (Belgium) and Dr B. VAITHINATHAN (Singapore)
Rapporteur: Dr N. H. A. AL-SHABANDAR (Iraq)
Secretary: Mr A. K. ASAMOAH, Chief, Administration and Staff Support Service

Committee B

Chairman: Dr M. S. E. ASAAD (Saudi Arabia)
Vice-Chairmen: Dr F. CHÁVEZ PEÓN (Mexico) and Mr A. ZANE-FE TOUAM-BONA (Central African Republic)
Rapporteur: Dr T. PYAKALYIA (Papua New Guinea)
Secretary: Dr B.-I. THYLEFORS, Chief, Programme for the Prevention of Blindness

[1] Having noted that Dr El Makhzangi had to return to his country, the Health Assembly, at its fourth plenary meeting, on 3 May, decided that Dr M. Zahran should replace him as Vice-President.

RESOLUTIONS

WHA47.1 Rights and privileges of South Africa

The Forty-seventh World Health Assembly,

Noting the democratic elections which took place in South Africa from 26 to 29 April 1994 with a view to the installation of a Government of National Unity to represent the whole population of South Africa;

Noting further the coming into force of a new constitution in South Africa on 27 April 1994 which now regulates governmental action at all levels;

Considering the desire of South Africa to participate henceforth in the activities of the World Health Organization and its Assembly and thereby to fulfil its obligations and assume its rights in accordance with the WHO Constitution;

1. RESCINDS resolution WHA17.50;

2. DECIDES that all rights and privileges associated with full membership of the World Health Organization be restored with immediate effect to South Africa at the Forty-seventh World Health Assembly.

Hbk Res., Vol. III (3rd ed.), 5.2.5 (Second plenary meeting, 2 May 1994)

WHA47.2 Admission of a new Member: Niue

The Forty-seventh World Health Assembly

ADMITS Niue as a Member of the World Health Organization, subject to the deposit of a formal instrument with the Secretary-General of the United Nations in accordance with Article 79 of the Constitution.

Hbk Res., Vol. III (3rd ed.), 5.2.1.1 (Eighth plenary meeting, 5 May 1994)

WHA47.3 Admission of a new Member: Nauru

The Forty-seventh World Health Assembly

ADMITS Nauru as a Member of the World Health Organization, subject to the deposit of a formal instrument with the Secretary-General of the United Nations in accordance with Article 79 of the Constitution.

Hbk Res., Vol. III (3rd ed.), 5.2.1.1 (Eighth plenary meeting, 5 May 1994)

WHA47.4 Ninth General Programme of Work covering a specific period (1996-2001)

The Forty-seventh World Health Assembly,

Having considered the draft Ninth General Programme of Work covering a specific period (1996-2001), submitted to it by the Executive Board, in accordance with Article 28(g) of the Constitution;

Aware of the progress made towards the goals and targets of the Eighth General Programme of Work, and recognizing the challenges ahead;

Recognizing that the Ninth General Programme of Work provides the policy framework for world health action by all partners in health development and for WHO programme development in the context of overall reform of the work of the Organization;

Emphasizing that the goals and targets set in the Ninth General Programme of Work reiterate the commitment of the world health community to tackling existing and emerging health problems and thus to achieving greater equity in health status everywhere;

Aware that at regional, national and even subnational levels targets will be set in the light of the most prevalent or otherwise important health problems and priorities taking into account the policy framework of the Ninth General Programme of Work;

Stressing that the targets of the Ninth General Programme of Work are the minimum to be attained by the end of the period, but that the pace of and capacity for achievement will vary in different situations;

Emphasizing therefore that expertise, resources and efforts will have to be focused on those countries and population groups in which the targets are furthest from being reached;

Aware that detailed planning of WHO's work will be undertaken through the proposed programme budgets closer to the time of implementation in order to ensure flexibility in responding to emerging health problems and opportunities, taking into account ongoing reform activities within WHO;

Recognizing the need for the Ninth General Programme of Work to be accessible to a wide audience such as decision-makers and health professionals, as well as to the public at large,

1. APPROVES the Ninth General Programme of Work;[1]

2. CALLS ON the world health community to continue working together in a concerted way in order to mobilize the commitment, resources and expertise needed to reach the targets set in the Ninth General Programme of Work, recognizing that this is the minimum to be achieved in accelerating progress towards health for all;

3. CALLS ON Member States:

(1) to set targets which address specific problems at national and/or subnational levels while also ensuring efforts to strengthen the infrastructure for the delivery and maintenance of health services, taking account of affordable technology, skill, knowledge and resources that can be applied in a sustainable way;

(2) to use the priorities in the "WHO programme framework" of the Ninth General Programme of Work as the basis for their cooperative activities with WHO;

[1] To be published in 1994 as No. 11 in WHO's "Health for All" Series.

4. REQUESTS the Executive Board:

(1) to continue to review the progress made and difficulties encountered in improving the health situation, since such information is the basis for establishing and updating health policy;

(2) to continue to monitor and evaluate the implementation of WHO's own work, especially on the basis of results achieved in countries, and to use the results of such evaluation to improve planning of WHO's work for each successive programme budget;

(3) to periodically review the implementation of the Ninth General Programme of Work and to adapt it as necessary to take into account emerging issues and the progress made in the reform process in WHO;

5. REQUESTS the Director-General:

(1) to ensure that the Organization's programme budgets reflect the ways in which WHO can best support countries and the international health community in reaching the targets set by the Ninth General Programme of Work;

(2) to establish clear priorities and strengthen the integration of programmes, starting from the programme budget for the financial biennium 1996-1997;

(3) to ensure that the programme budgets are properly monitored and evaluated and that the results are used to adapt activities already being implemented and plan the following programme budget;

(4) to ensure that WHO's information systems are adapted best to meet evolving needs for information on health and programme management;

(5) to strengthen interagency coordination in all relevant programmes involving appropriate agencies in the process;

(6) to continue to implement the recommendations of the Executive Board Working Group on the WHO Response to Global Change in order to improve WHO's capacity to reflect fully the vision of the Ninth General Programme of Work in carrying out the Organization's activities.

Hbk Res., Vol. III (3rd ed.), 1.3.1.1

(Eleventh plenary meeting, 9 May 1994 - Committee A, first report)

WHA47.5 Infant and young child nutrition

The Forty-seventh World Health Assembly,

Having considered the report by the Director-General on infant and young child nutrition;[1]

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34 and WHA46.7 concerning infant and young child nutrition, appropriate feeding practices and related questions;

Reaffirming its support for all these resolutions and reiterating the recommendations to Member States contained therein;

[1] See Annex 1.

Bearing in mind the superiority of breast-milk as the biological norm for the nourishment of infants, and that a deviation from this norm is associated with increased risks to the health of infants and mothers,

1. THANKS the Director-General for his report;

2. URGES Member States to take the following measures:

(1) to promote sound infant and young child nutrition, in keeping with their commitment to the World Declaration and Plan of Action for Nutrition,[1] through coherent effective intersectoral action, including:

(a) increasing awareness among health personnel, nongovernmental organizations, communities and the general public of the importance of breast-feeding and its superiority to any other infant feeding method;

(b) supporting mothers in their choice to breast-feed by removing obstacles and preventing interference that they may face in health services, the workplace, or the community;

(c) ensuring that all health personnel concerned are trained in appropriate infant and young child feeding practices, including the application of the principles laid down in the joint WHO/UNICEF statement on breast-feeding and the role of maternity services;[2]

(d) fostering appropriate complementary feeding practices from the age of about six months, emphasizing continued breast-feeding and frequent feeding with safe and adequate amounts of local foods;

(2) to ensure that there are no donations of free or subsidized supplies of breast-milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system;

(3) to exercise extreme caution when planning, implementing or supporting emergency relief operations, by protecting, promoting and supporting breast-feeding for infants, and ensuring that donated supplies of breast-milk substitutes or other products covered by the scope of the International Code are given only if all the following conditions apply:

(a) infants have to be fed on breast-milk substitutes, as outlined in the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes;[3]

(b) the supply is continued for as long as the infants concerned need it;

(c) the supply is not used as a sales inducement;

(4) to inform the labour sector, and employers' and workers' organizations, about the multiple benefits of breast-feeding for infants and mothers, and the implications for maternity protection in the workplace;

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[1] *World Declaration and Plan of Action for Nutrition.* FAO/WHO, International Conference on Nutrition, Rome, December 1992.

[2] *Protecting, promoting and supporting breast-feeding: the special role of maternity services.* A joint WHO/UNICEF statement. Geneva, World Health Organization, 1989.

[3] Document WHA39/1986/REC/1, Annex 6, part 2.

3. REQUESTS the Director-General:

(1) to use his good offices for cooperation with all parties concerned in giving effect to this and related resolutions of the Health Assembly in their entirety;

(2) to complete development of a comprehensive global approach and programme of action to strengthen national capacities for improving infant and young child feeding practices, including the development of methods and criteria for national assessment of breast-feeding trends and practices;

(3) to support Member States, at their request, in monitoring infant and young child feeding practices and trends in health facilities and households, in keeping with new standard breast-feeding indicators;

(4) to urge Member States to join in the Baby-friendly Hospital Initiative and to support them, at their request, in implementing this Initiative, particularly in their efforts to improve educational curricula and in-service training for all health and administrative personnel concerned;

(5) to increase and strengthen support to Member States, at their request, in giving effect to the principles and aim of the International Code and all relevant resolutions, and to advise Member States on a framework which they may use in monitoring their application, as appropriate to national circumstances;

(6) to develop, in consultation with other concerned parties and as part of WHO's normative function, guiding principles for the use in emergency situations of breast-milk substitutes or other products covered by the International Code which the competent authorities in Member States may use, in the light of national circumstances, to ensure the optimal infant-feeding conditions;

(7) to complete, in cooperation with selected research institutions, collection of revised reference data and the preparation of guidelines for their use and interpretation, so as to assess the growth of breast-fed infants;

(8) to seek additional technical and financial resources for intensifying WHO's support to Member States in infant feeding and in the implementation of the International Code and subsequent relevant resolutions.

Hbk Res., Vol. III (3rd ed.), 1.12.1

(Eleventh plenary meeting, 9 May 1994 - Committee A, first report)

WHA47.6 WHO response to global change: Programme Development Committee

The Forty-seventh World Health Assembly,

Recalling the requests and recommendations of the Forty-sixth World Health Assembly to the Executive Board and the Director-General in its resolutions WHA46.16 and WHA46.21;

Having considered the progress reports by the Director-General;[1]

Aware that the Director-General, in collaboration with the Regional Directors and Assistant Directors-General, programme directors and other WHO staff, has embarked on a comprehensive, ongoing process of managerial and administrative reform;

[1] See Annex 2.

Welcoming the decision of the Executive Board in resolution EB93.R13 at its ninety-third session to establish a Programme Development Committee;

Noting with satisfaction the creation by the Director-General of a Global Policy Council and Management Development Committee to improve the management of WHO and to implement reform, and of development teams to assist the process of reform in six priority areas;

Noting that the Executive Board will decide at its ninety-fourth session the composition, objectives and work programmes of its Programme Development Committee;

Convinced that substantive reform of the Organization in response to global political, social and economic change should result in improved health in all Member States, particularly the developing countries,

1. COMMENDS the action of the Director-General and his staff in their response thus far to resolution WHA46.16;

2. REQUESTS the Executive Board to make full use of the Programme Development Committee in implementing the comprehensive plan for managerial and administrative reform endorsed by the Health Assembly that should, in the longer term, bring about fundamental improvements in WHO's operations;

3. REQUESTS the Director-General:

(1) to continue to pursue the reform process;

(2) to report regularly to the Executive Board on plans and implications for progress in implementing, and impact of WHO's initiatives in, the reform process in response to resolutions WHA46.16 and WHA46.21;

4. REQUESTS the Board to report to the Forty-eighth World Health Assembly on progress.

Hbk Res., Vol. III (3rd ed.), 3.2.4

(Twelfth plenary meeting, 10 May 1994 - Committee B, first report)

WHA47.7 Budgetary reform: Administration, Budget and Finance Committee

The Forty-seventh World Health Assembly,

Having considered the Director-General's report on progress achieved in implementing resolution WHA46.35 on budgetary reform;[1]

Welcoming the decision of the Executive Board in resolution EB93.R13 at its ninety-third session to establish an Administration, Budget and Finance Committee to assist the Board and, through it, the Health Assembly in their deliberations on budgetary matters;

Noting that the Board will decide at its ninety-fourth session the composition, objectives and work programmes of its Administration, Budget and Finance Committee,

REQUESTS the Executive Board:

1. to take whatever steps are necessary to guarantee the effectiveness of the Administration, Budget and Finance Committee by ensuring that its members have specific expertise in

[1] See Annex 2, part 2.

administrative, budgetary and financial matters, and that it is given sufficient meeting time to fulfil the expectations of its role;

2. to assign to the Committee the tasks previously assigned to the Programme Committee under resolution EB79.R9;

3. to make full use of the Committee:

(1) to assist the Director-General's continuing efforts to simplify and clarify the programme budgeting process;

(2) to monitor the impact of administrative and budgetary measures introduced so far on the preparation of the programme budget for the biennium 1996-1997;

(3) to recommend as necessary further measures to improve the efficiency of the budget preparation process;

(4) to advise the Executive Board on the administrative, budgetary and financial implications of proposed biennial programme budgets;

4. to report to the Forty-eighth World Health Assembly on progress.

Hbk Res., Vol. III (3rd ed.), 3.2.4

(Twelfth plenary meeting, 10 May 1994 - Committee B, first report)

WHA47.8 Budgetary reform

The Forty-seventh World Health Assembly,

Recalling resolution WHA46.35 which set out a number of matters of concern to Member States relating to budgetary reform;

Reiterating the request to the Director-General in the operative paragraphs of that resolution;

Reiterating, also, the obligation of all Member States to pay their assessed contributions in full and on time;

Considering the Director-General's report to the Executive Board[1] and his report to the Health Assembly on budgetary reform,[2] describing the steps taken to introduce improved budget and accounting procedures;

Welcoming the measures taken since the Forty-sixth World Health Assembly to simplify and clarify the budget, to reduce the lead time for its preparation, and to take into account the United Nations common accounting standards;

Recognizing that other aspects of resolution WHA46.35 remain to be addressed,

REQUESTS the Director-General:

1. to continue and accelerate the development and implementation of improved budget and accounting by

[1] See document EB93/1994/REC/1, Annex 2, part 1.

[2] See Annex 2, part 2, in this volume.

(1) determining the resources required and reallocating them as necessary to meet priorities and targets;

(2) establishing regular evaluation of progress towards agreed targets;

(3) including data on actual cost increases during the last complete financial period and comparing these with forecasts;

(4) taking measures to achieve a more appropriate ratio of staff and staff-related costs to all other programme costs;

2. to report to the Executive Board at its ninety-fifth session in January 1995 and to the Forty-eighth World Health Assembly on progress achieved in implementing resolution WHA46.35 and this resolution.

Hbk Res., Vol. III (3rd ed.), 2.1

(Twelfth plenary meeting, 10 May 1994 - Committee B, first report)

WHA47.9 Maternal and child health and family planning: quality of care

The Forty-seventh World Health Assembly,

Noting the report by the Director-General to the Executive Board on maternal and child health and family planning: current needs and future orientation;[1]

Recalling resolutions WHA32.42 on maternal and child health, including family planning; WHA32.30 on primary health care and monitoring health for all; WHA45.5 on strengthening nursing and midwifery services; and WHA46.18 on maternal and child health and family planning for health;

Noting that the Organization has successfully developed and adapted a number of management and evaluation methods that involve the participation of all levels of the health system and community, that can be rapidly applied to a wide range of service delivery problems, and that may provide guidance on action needed to improve the functioning and performance of maternal and child health and family planning services;

Noting also that several divisions and programmes within WHO are engaged in these fields and that there is a need for a comprehensive, unifying strategy for action and research in the broad area of reproductive health;

Recognizing that enormous progress has been made in many aspects of maternal and child health, as evidenced by the great increase in immunization coverage, accessibility and use of family planning services and numbers of trained attendants at childbirth;

Concerned nonetheless that in many countries such increases in coverage are not having the expected effect because of poor quality of care and performance of health systems;

Emphasizing that rapid progress in the health of mothers and the newborn and in family planning can be assured by improving the quality of care and the performance of the existing services and staff;

Recognizing that a number of different international and national governmental and nongovernmental organizations are providing technical and financial support at country level,

[1] See document EB93/1994/REC/1, Annex 5.

1. URGES all Member States:

(1) to give priority to assessing and improving the quality of care for women and children in district-based health systems, as part of a global approach to family health;

(2) to adapt and apply standard protocols for the diagnosis and clinical management of the common problems encountered in services for the health of mothers, infants and children;

(3) to strengthen health centres so as to ensure a high level of nursing and midwifery care, and to provide regular supervisory, managerial and logistic support to peripheral health posts, community health workers and trained traditional birth attendants applying local strategies for the health of mothers and the newborn;

(4) to give priority to assessing and improving the quality of basic and continuing nursing and midwifery education;

(5) to reorient training curricula to community-based and problem-solving approaches, and to ensure that health workers are made aware of the attitudes and needs of women and other members of the community within a context of coherent implementation of population policies;

2. REQUESTS the Director-General:

(1) to continue to provide technical support and guidance to Member States in the further development, adaptation and application of indicators of quality of care in maternal and child health and family planning and other aspects of primary health care;

(2) to continue to prepare guidelines and training material and devise approaches that improve the quality of care through standardized case definition, diagnosis and case management for the major health problems affecting mothers, the newborn, infants and children, and providing the necessary supervisory support, including monitoring and evaluation;

(3) to ensure that the components of maternal and child health care and family planning are promoted and provided to Member States in a coherent and integrated manner, and that they correspond to national priorities and demand;

(4) to seek to improve mechanisms in countries, where appropriate, for coordination between all concerned agencies and organizations, in order to support national leadership and make optimal use of available human and material resources;

(5) to report to the Executive Board and to the Health Assembly in 1995 on ongoing activities to develop a comprehensive strategy for action and research in the broad field of sexual and reproductive health.

Hbk Res., Vol. III (3rd ed.), 1.8; 1.12.1

(Twelfth plenary meeting, 10 May 1994 - Committee A, second report)

WHA47.10 Maternal and child health and family planning: Traditional practices harmful to the health of women and children

The Forty-seventh World Health Assembly,

Noting the report by the Director-General to the Executive Board on maternal and child health and family planning: current needs and future orientation;[1]

Recalling resolutions WHA32.42 on maternal and child health, including family planning; WHA38.22 on maturity before childbearing and promotion of responsible parenthood; and WHA46.18 on maternal and child health and family planning for health;

Reaffirming its support for the United Nations Convention on the Rights of the Child, and United Nations Economic and Social Council resolution 1992/251 on traditional practices affecting the health of women and children;

Recognizing that, although some traditional practices may be beneficial or harmless, others, particularly those relating to female genital mutilation and early sexual relations and reproduction, cause serious problems in pregnancy and childbirth and have a profound effect on the health and development of children, including child care and feeding, creating risks of rickets and anaemia;

Acknowledging the important role that nongovernmental organizations have played in bringing these matters to the attention of their social, political and religious leaders, and in establishing programmes for the abolition of many of these practices, particularly female genital mutilation,

1. WELCOMES the initiative taken by the Director-General in drawing international attention to these matters in relation to health and human rights in the context of a comprehensive approach to women's health in all countries, and the policy declarations to the United Nations Special Rapporteur on traditional practices by governments in countries where female genital mutilation is practised;

2. URGES all Member States:

(1) to assess the extent to which harmful traditional practices affecting the health of women and children constitute a social and public health problem in any local community or sub-group;

(2) to establish national policies and programmes that will effectively, and with legal instruments, abolish female genital mutilation, childbearing before biological and social maturity, and other harmful practices affecting the health of women and children;

(3) to collaborate with national nongovernmental groups active in this field, draw upon their experience and expertise and, where such groups do not exist, encourage their establishment;

3. REQUESTS the Director-General:

(1) to strengthen WHO's technical support to and cooperation with Member States in implementing the measures specified above;

(2) to continue global and regional collaboration with the networks of nongovernmental organizations, United Nations bodies, and other agencies and organizations concerned in order to establish national, regional and global strategies for the abolition of harmful traditional practices;

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[1] See document EB93/1994/REC/1, Annex 5.

(3) to mobilize additional extrabudgetary resources in order to sustain the action at national, regional and global levels.

Hbk Res., Vol. III (3rd ed.), 1.12.1

(Twelfth plenary meeting, 10 May 1994 - Committee A, second report)

WHA47.11 Revision and amendment of WHO's Good Manufacturing Practices for Pharmaceutical Products

The Forty-seventh World Health Assembly,

Recalling resolutions WHA20.34 and WHA22.50 on quality control of drugs and resolution WHA28.65 on good practices in the manufacture and quality control of drugs and certification scheme on the quality of pharmaceutical products moving in international commerce;

Recognizing the importance for the purpose of facilitating international trade in pharmaceutical products of the WHO Certification Scheme;

Noting that the implementation of the WHO Certification Scheme is dependent on promulgation of Good Manufacturing Practices for Pharmaceutical Products that meet contemporary requirements;

Aware that pharmaceutical technology is currently passing through a phase of rapid development which it is anticipated will continue over many years, and that frequent amendments to Good Manufacturing Practices are likely to be proposed in future expert committee reports as a consequence of regular consultations with national drug regulatory authorities and discussions within the biennial International Conferences of Drug Regulatory Authorities,

1. APPROVES the revision of the Good Manufacturing Practices for Pharmaceutical Products as contained in the thirty-second and thirty-third reports of the WHO Expert Committee on Specifications for Pharmaceutical Preparations;[1]

2. AUTHORIZES the Executive Board, as the executive organ of the Health Assembly, to approve such technical amendments to the Good Manufacturing Practices for Pharmaceutical Products as may be proposed in subsequent reports of meetings of the Expert Committee, and to keep the Health Assembly informed.

Hbk Res., Vol. III (3rd ed.), 1.15.3

(Twelfth plenary meeting, 10 May 1994 - Committee A, second report)

WHA47.12 Role of the pharmacist in support of the WHO revised drug strategy

The Forty-seventh World Health Assembly,

Noting the report of the Director-General on implementation of WHO's revised drug strategy;[2]

Recalling resolutions WHA37.33, WHA39.27 and WHA41.16 on the rational use of drugs;

Noting in particular the need to encourage the fulfilment by all concerned parties, including health personnel involved in prescription, dispensing, supply and distribution of medicines, of their responsibilities with respect to rational use of drugs as specified in WHO's revised drug strategy;

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[1] See WHO Technical Report Series, No. 823, 1992; and No. 834, 1993.

[2] See Annex 3.

Recognizing the economic benefits and the therapeutic advantage of advocating and reinforcing the rational use of drugs;

Recognizing that the pharmacist can play a key role in public health and particularly in the field of medicines, and that the rational use of drugs is contingent upon the availability to the whole population at all times of essential drugs of good quality at affordable prices;

Emphasizing the need for the utmost vigilance to ensure the detection and prevention of the manufacture, export or smuggling of falsely-labelled, spurious, counterfeit or substandard pharmaceutical preparations;

Concerned about the continued poor state of development of pharmaceutical services in many countries as emphasized in WHO meetings on the role of the pharmacist held in New Delhi in 1988 and Tokyo in 1993;

Appreciating the contribution made by organizations representing pharmacists, in collaboration with WHO, in pursuit of the goal of health for all;

Stressing the importance of collaboration between pharmacists and all other health professionals involved in patient care and the safe and effective administration of medicines,

1. CALLS UPON pharmacists and their professional associations everywhere, through their contributions to regulatory control, pharmaceutical manufacture and community service, to support WHO's policies as embodied in WHO's revised drug strategy and develop the profession at all levels in accordance with the reports of the above-mentioned meetings, and, in particular:

(1) to provide the supervision necessary to assure the quality of pharmaceutical products and services at the time of manufacture, importation or exportation and at all stages of the distribution chain;

(2) to manage drug procurement and supply systems and in so doing, to cooperate in efforts to detect and prevent the distribution of falsely-labelled, spurious, counterfeit or substandard pharmaceutical preparations;

(3) to provide informed and objective advice on medicines and their use to the public, and provide technical advice to other health professionals, to drug regulatory bodies, health planners and policy-makers;

(4) to promote, in collaboration with other health professionals, the concept of pharmaceutical care as a means of furthering the rational use of drugs and of actively participating in illness prevention and health promotion;

(5) to support relevant research and training programmes;

2. URGES all Member States, in collaboration with national organizations representing pharmacists, where such exist:

(1) to define the role of the pharmacist in the promotion and implementation of the national drug policy within the framework of health-for-all strategy;

(2) to make full use of the expertise of the pharmacist at all levels of the health care system and particularly in the development of national drug policies;

(3) to provide training facilities to equip pharmacists to assume responsibilities for all activities cited in 1(1) to 1(4) above;

3. REQUESTS the Director-General:

(1) to support Member States in their efforts to develop drug regulatory and pharmaceutical services;

(2) to encourage Member States to assess their needs for pharmaceutical services and manpower, and for relevant training facilities;

(3) to encourage regular publication of the *World Directory of Schools of Pharmacy*;

(4) to report on progress made to the Executive Board at its ninety-seventh session in January 1996.

Hbk Res., Vol. III (3rd ed.), 1.15.2

(Twelfth plenary meeting, 10 May 1994 - Committee A, second report)

WHA47.13 Rational use of drugs; and the WHO Action Programme on Essential Drugs

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General on the implementation of WHO's revised drug strategy;[1]

Recalling resolutions WHA39.27 and WHA41.16 on the rational use of drugs, and resolutions WHA43.20 and WHA45.27 on the WHO Action Programme on Essential Drugs;

Noting the activities of WHO in pursuance of the revised drug strategy and its intensified direct collaboration and support to countries in drug policy formulation, standard-setting, regulation, procurement and use as well as the related logistics, financing, information, operational research, and education and training of human resources, including capacity-building and institution-strengthening;

Recognizing the efforts of WHO in collaboration with governments and other bodies to improve access to essential drugs and the rational use of drugs, within the framework of national drug policies;

Aware of the role of the community in the rational use of drugs;

Recognizing also the need for continued action by all interested parties to achieve all the objectives of a comprehensive national drug policy;

Appreciating that the Action Programme on Essential Drugs will be subject to a detailed review by the Executive Board at its ninety-fifth session in 1995, with a view to optimizing the collaboration between all technical programmes in this field;

Emphasizing the need for an adequate response to new economic challenges and the changing balance of the public and private sectors in health care, including the provision of drugs, and assessment of the viability and long-term effects of new financing strategies and other measures;

Mindful of problems with counterfeit drugs and drugs of poor quality,

1. REAFFIRMS the crucial importance of WHO's leadership and coordination, through its Action Programme on Essential Drugs, in the development, support and evaluation of national drug policies within the framework of national health policies;

[1] See Annex 3.

2. URGES Member States:

(1) to commit themselves to the development and implementation of national drug policies to improve equitable access to essential drugs of good quality at affordable cost, and to intensify efforts to promote the rational use of drugs;

(2) to accelerate the education and training of the necessary human resources, and to strengthen the implementation of drug policies and programmes;

(3) to evaluate progress regularly using performance indicators developed by the Action Programme on Essential Drugs or other suitable mechanisms;

3. CALLS ON bilateral and multilateral agencies, nongovernmental organizations and other collaborators to strengthen their technical and financial support to the Action Programme;

4. REQUESTS the Director-General:

(1) further to strengthen the leadership and advocacy by the Action Programme in mobilizing and coordinating a global collaborative effort to improve access to essential drugs and ensure the rational use of drugs;

(2) to encourage contacts with organizations and bodies of the United Nations system, bilateral and multilateral agencies and nongovernmental organizations, and with consumers, industry, and other collaborators;

(3) to ensure that the concept of the revised drug strategy is fully reflected in WHO's work towards reform in the health sector;

(4) to ensure that adequate financial and human resources are provided under the regular budget and from extrabudgetary sources, as necessary, to implement the Action Programme, and to meet increased demands from Member States;

(5) to support Member States in their efforts to ensure that available drugs are of good quality, and in combating the use of counterfeit drugs;

(6) to report on the current state and the progress made in the drug sector throughout the world by publishing periodically up-to-date information on the world drug situation;

(7) to report to the Forty-ninth World Health Assembly, and subsequently biennially, on progress achieved and problems encountered in the implementation of WHO's revised drug strategy, with recommendations for action.

Hbk Res., Vol. III (3rd ed.), 1.15.2

(Twelfth plenary meeting, 10 May 1994 - Committee A, second report)

WHA47.14 WHO response to global change: Health Assembly resolutions

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General to the Executive Board,[1] as well as the report and recommendations of the Executive Board Working Group on the WHO Response to Global Change,[2]

[1] Document EB93/1994/REC/1, Annex 1, Part 2, section III.

[2] Document EB92/1993/REC/1, Part I, Annex 1, section 4.2.1.1.

concerning mechanisms and procedures for the development, review and follow-up of resolutions of the Health Assembly;

Bearing in mind Article XIII of the Financial Regulations of WHO and Rule 13 of the Rules of Procedure of the Health Assembly, as well as resolutions WHA31.9 and WHA44.30 on the method of work of the Health Assembly;

Considering the desirability of more systematic prior review of all resolutions proposed to the Health Assembly that have potential impact on the objectives, policy and orientation of WHO or that have implications in terms of staffing, costs, budgetary resources and administrative support,

1. REITERATES the general principle that, in order to ensure that the Health Assembly has sufficient information before considering proposals, resolutions should be considered by the Executive Board before submission to the Health Assembly;

2. AUTHORIZES the Executive Board, in coordination with the Director-General, to establish a routine procedure for prior review of resolutions designed to ensure that sufficient information is available to the Health Assembly in accordance with recommendation 5 of the Working Group on the WHO Response to Global Change;

3. REQUESTS:

(1) the Director-General to ensure that the necessary background information, including information about the implications of adopting resolutions proposed, is provided as a matter of routine to the Executive Board and subsequently transmitted in an appropriate manner to the Health Assembly;

(2) the Chairman of the Executive Board, supported by the Director-General, to help to ensure that, when appropriate, draft resolutions that are first introduced in the Board clearly set out a realistic time-limit for validity of the resolution and an appropriate mechanism and interval for following up and reporting on implementation;

4. RECOGNIZES nonetheless that the Health Assembly may decide to consider a resolution not transmitted to it by the Executive Board, and that in such a case the Director-General shall provide a statement of its programme and budget implications before the approval of the resolution in Committee;

5. REQUESTS that, when a resolution is first initiated and presented at the Health Assembly without prior review by the Executive Board:

(1) the Chairmen of Committees A and B of the Health Assembly consult their respective officers, supported by the Director-General, and, depending on whether the committee concerned has sufficient information or not, (a) request it to consider the resolution directly, or (b) refer the matter to the General Committee;

(2) the General Committee in such cases, and in consultation with the Director-General, makes a recommendation as to whether the draft resolution should be considered by the Health Assembly and what further information (if any) would be needed or whether any other appropriate course of action should be taken;

(3) the Chairmen of Committees A and B endeavour to ensure that, when appropriate, draft resolutions that are introduced in their committees clearly set a realistic time-limit for validity of the resolution and establish an appropriate mechanism and interval for following up and reporting on implementation;

6. RECOMMENDS that these mechanisms and approaches be tested over a period of two years by the Executive Board and the Health Assembly, with effect from January 1995;

7. FURTHER REQUESTS the Director-General to review the results and to report to the Fiftieth World Health Assembly through the Executive Board in 1997.

Hbk Res., Vol. III (3rd ed.), 1.4; 3.1.3; 3.2.4

(Thirteenth plenary meeting, 11 May 1994 - Committee B, second report)

WHA47.15 Financial report and audited financial statements for the financial period 1 January 1992 - 31 December 1993 and report of the External Auditor to the Health Assembly

The Forty-seventh World Health Assembly,

Having examined the financial report and audited financial statements for the financial period 1 January 1992 to 31 December 1993 and the report of the External Auditor to the Health Assembly;[1]

Having considered the first report of the Committee of the Executive Board to Consider Certain Financial Matters prior to the Forty-seventh World Health Assembly;[2]

Noting that the External Auditor had qualified his opinion and report by a "scope limitation" in relation to the Regional Office for Africa and the reasons therefor;

Appreciating the concern of the Director-General and his initiative in expediting an audit review of the Regional Office for Africa by WHO internal auditors,

1. NOTES the report of the internal auditors on the Regional Office for Africa;

2. ACCEPTS the Director-General's financial report and audited financial statements for the financial period 1 January 1992 to 31 December 1993 and the report of the External Auditor to the Health Assembly;

3. REQUESTS the Director-General to report to the ninety-fifth session of the Executive Board and to the Forty-eighth World Health Assembly in 1995 on progress made in the implementation of the recommendations of the External Auditor.

Hbk Res., Vol. III (3rd ed.), 6.1.10.3

(Thirteenth plenary meeting, 11 May 1994 - Committee B, second report)

WHA47.16 WHO Ethical Criteria for Medicinal Drug Promotion

The Forty-seventh World Health Assembly,

Recalling resolutions WHA41.17 and WHA45.30 on ethical criteria for medicinal drug promotion and resolution WHA43.20 on WHO Action Programme on Essential Drugs;

Noting the continued need to improve the quality of drug promotion through the use of the concepts embodied in the WHO Ethical Criteria for Medicinal Drug Promotion;

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[1] Documents A47/19 and Add.1.

[2] Document A47/42.

Having considered the report of the Director-General[1] on the outcome of the CIOMS/WHO consultation on the WHO Ethical Criteria,

1. THANKS the Council for International Organizations of Medical Sciences (CIOMS) for having convened the consultation in collaboration with WHO, and for the valuable report adopted by consensus and which covers a wide range of issues and the action to be taken;

2. APPRECIATES the commitment of the participants - drug regulatory authorities, pharmaceutical manufacturers and distributors, health professionals, universities and other teaching institutions, professional associations, patient and consumer groups, and the professional and general media - to a common responsibility, based on fundamental ethical principles, for the well-being of patients individually and the public collectively;

3. ENDORSES the report of the consultation and reaffirms:

(1) that the regulation of drugs must ensure not only the safety, efficacy and quality of drugs but also the accuracy of the information provided pursuant to their regulation;

(2) that patients, pharmacists and prescribers should have access to appropriate and understandable information about drugs and their side-effects;

(3) that the promotion of drugs must be accurate, fair and objective, and presented in such a way as to conform to legal requirements and also to high ethical standards;

(4) that promotional claims should not be stronger than valid, up-to-date scientific evidence warrants, every effort being made to avoid ambiguity;

(5) that the same information for patients and prescribers that appears in leaflets accompanying drugs in the manufacturing country should be supplied by the manufacturer to the countries to which they are exported;

4. CALLS UPON all concerned parties to continue to collaborate in order to promote further and implement the principles embodied in the WHO Ethical Criteria for Medicinal Drug Promotion, by rapidly adopting, as appropriate, measures based on the recommendations of the CIOMS/WHO consultation;

5. URGES Member States to develop and implement national mechanisms, where relevant, to control drug promotion in accordance with the principles embodied in the WHO Ethical Criteria, and as proposed in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce;

6. REQUESTS the Director-General:

(1) to implement the recommendations of the CIOMS/WHO consultation applicable to WHO, giving special attention to:

(a) wide dissemination of the WHO Ethical Criteria to all Member States and all other concerned parties;

(b) measures to develop and disseminate educational material on the WHO Ethical Criteria, and methods to monitor their implementation;

(c) monitoring of the implementation of the WHO Ethical Criteria and collection of information on voluntary, self-regulatory national and international codes and guidelines that relate to the promotion of medicinal drugs, in consultation with all concerned parties;

[1] See Annex 4.

(d) the carrying-out of studies or surveys of current promotional practices as necessary, and analysis of the effectiveness of the WHO Ethical Criteria;

(e) support to Member States, as appropriate, in strengthening drug regulatory capacity and mechanisms for the labelling and promotion of medicinal drugs;

(f) dissemination of national experience in the promotion of medicinal drugs;

(g) alerting Member States to the importance of the role of universities and other educational institutions and assisting them in the development of educational programmes;

(h) periodical review of the WHO Ethical Criteria in consultation with interested parties;

(2) to report regularly, through the Executive Board, on progress made and problems encountered by WHO and Member States, as part of the reporting on the implementation of the revised drug strategy.

Hbk Res., Vol. III (3rd ed.), 1.15.2

(Thirteenth plenary meeting, 11 May 1994 - Committee A, third report)

WHA47.17 Safety, efficacy and quality of pharmaceuticals

The Forty-seventh World Health Assembly,

Having reviewed the report of the Director-General on the implementation of WHO's revised drug strategy;[1]

Recalling resolutions WHA37.33, WHA39.27 and WHA41.16 on rational use of drugs;

Noting that pharmaceutical trade is becoming more complex as more countries manufacture and export pharmaceutical and biological products and active ingredients, and as new technology is applied to their production;

Aware, therefore, that countries need to develop the capability to assure the quality of all such products - whether brand-name or generic, domestically manufactured or imported - on their national markets;

Aware, moreover, of an unacceptable prevalence of substandard and counterfeit pharmaceutical products in international trade that threatens to erode confidence in the health care system because such products may be inefficacious or toxic;

Aware also of the important role of the community in drug control,

1. REAFFIRMS the principles embodied in WHO's Guiding Principles for Small National Drug Regulatory Authorities and the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce;

2. URGES Member States to provide the resources and manpower needed to strengthen their national regulatory capability;

3. REQUESTS governments and pharmaceuticals manufacturers to cooperate in order to ensure complementary support of public health goals;

[1] See Annex 3.

4. REQUESTS the Director-General:

(1) to maintain the normative activities that provide standards to assure the quality, safety and efficacy of pharmaceutical and biological products, including vaccine and sera, having regard to the evolution of new technology;

(2) to ensure the continued and timely provision of independent information to support effective registration, to control excessive claims in advertising and to promote the rational use of drugs;

(3) to provide complementary support and training at country level to assist in strengthening regulatory capacity;

(4) to promote and support the biennial International Conference of Drug Regulatory Authorities as a means of fostering understanding and collaboration between officials in countries at all stages of development.

Hbk Res., Vol. III (3rd ed.), 1.15.2; 1.15.3

(Thirteenth plenary meeting, 11 May 1994 - Committee A, third report)

WHA47.18 Consideration of the situation of certain Member States falling under the purview of Article 7 of the Constitution

The Forty-seventh World Health Assembly,

Having considered the second report of the Committee of the Executive Board to Consider Certain Financial Matters prior to the Forty-seventh World Health Assembly, on Members in arrears in the payment of their contributions to an extent which would justify invoking Article 7 of the Constitution;[1]

Noting that, at the time of opening of the Forty-seventh World Health Assembly, the voting rights of Antigua and Barbuda, Burundi, Cambodia, Comoros, Congo, Dominican Republic, Equatorial Guinea, Iraq, Liberia, Niger and Somalia remained suspended, such suspension to continue until the arrears of the Member State concerned have been reduced, at the present or future Health Assemblies, to a level below the amount which would justify invoking Article 7 of the Constitution;

Having been informed that as a result of a payment received after the opening of the Forty-seventh World Health Assembly, the arrears of contributions of Niger have been reduced to a level below the amount which would justify invoking Article 7 of the Constitution, and thus the voting rights of Niger have been automatically restored;

Noting that, in accordance with resolution WHA46.10, the voting privileges of Chad, Guinea-Bissau, Haiti and Zaire have been suspended as from 2 May 1994, such suspension to continue until the arrears of the Member State concerned have been reduced, at the present or future Health Assemblies, to a level below the amount which would justify invoking Article 7 of the Constitution;

Noting that, since Romania had made payments prior to the opening of the Forty-seventh World Health Assembly that reduced its unpaid arrears of contributions to a level below the amount which would justify invoking Article 7 of the Constitution, the decision taken with respect to Romania by the Forty-sixth World Health Assembly in resolution WHA46.10 is no longer applicable and the suspension of its voting rights has not taken effect;

Noting that Burkina Faso, Central African Republic, Guatemala, Senegal, Ukraine, Yemen and Yugoslavia were in arrears at the time of the opening of the Forty-seventh World Health Assembly to such

[1] Document A47/18.

an extent that it is necessary for the Health Assembly to consider, in accordance with Article 7 of the Constitution, whether or not the voting privileges of these Members should be suspended at the opening of the Forty-eighth World Health Assembly;

Having been informed that as a result of payments received from the Central African Republic and Ukraine after the opening of the Forty-seventh World Health Assembly, the arrears of contributions of these Members have been reduced to a level below the amount which would justify invoking Article 7 of the Constitution,

1. EXPRESSES serious concern at the large number of Members that have been in arrears in the payment of their contributions in recent years to an extent which would justify invoking Article 7 of the Constitution;

2. URGES the Members concerned to regularize their position at the earliest possible date;

3. FURTHER URGES Members that have not communicated their intention to settle their arrears to do so as a matter of urgency;

4. REQUESTS the Director-General to approach the Members in arrears to an extent which would justify invoking Article 7 of the Constitution, with a view to pursuing the question with the governments concerned;

5. REQUESTS the Executive Board, in the light of the Director-General's report to the Board at its ninety-fifth session and after the Members concerned have had an opportunity to explain their situation to the Board, to report to the Forty-eighth World Health Assembly on the status of payment of contributions;

6. DECIDES:

(1) that in accordance with the statement of principles in resolution WHA41.7 if, by the time of the opening of the Forty-eighth World Health Assembly, Burkina Faso, Guatemala, Senegal, Yemen and Yugoslavia are still in arrears in the payment of their contributions to an extent which would justify invoking Article 7 of the Constitution, their voting privileges shall be suspended as from the said opening;

(2) that any suspension which takes effect as aforesaid shall continue at the Forty-eighth and subsequent Health Assemblies, until the arrears of the Member concerned have been reduced to a level below the amount which would justify invoking Article 7 of the Constitution;

(3) that this decision shall be without prejudice to the right of any Member to request restoration of its voting privileges in accordance with Article 7 of the Constitution.

Hbk Res., Vol. III (3rd ed.), 6.1.2.4

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.19 Status of collection of assessed contributions and status of advances to the Working Capital Fund

The Forty-seventh World Health Assembly,

Noting with concern that, as at 31 December 1993:

(a) the rate of collection in 1993 of contributions to the effective working budget for that year amounted to 79.03%, leaving US$ 74 517 451 unpaid;

(b) only 95 Members had paid their contributions to the effective working budget for that year in full, and 71 Members had made no payment;

(c) unpaid contributions to the effective working budget in respect of the financial period 1992-1993 amounted to US$ 106 million,

1. EXPRESSES concern at the level of outstanding contributions, which has had a deleterious effect on programmes and on the financial situation;

2. CALLS THE ATTENTION of all Members to Financial Regulation 5.6, which provides that instalments of contributions and advances shall be considered as due and payable in full by the first day of the year to which they relate, and to the importance of paying contributions as early as possible to enable the Director-General to implement the programme budget in an orderly manner;

3. REMINDS Members that, as a result of the adoption, by resolution WHA41.12, of an incentive scheme to promote the timely payment of assessed contributions, those that pay their assessed contributions early in the year in which they are due will have their contributions payable for a subsequent programme budget reduced appreciably, whereas those paying later will have their contributions payable for that subsequent programme budget reduced only marginally or not at all;

4. URGES Members that are regularly late in the payment of their contributions to take as rapidly as possible all steps necessary to ensure prompt and regular payment;

5. REQUESTS the Director-General to draw this resolution to the attention of all Members.

Hbk Res., Vol. III (3rd ed.), 6.1.2.4

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.20 Review of the Working Capital Fund

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General[1] and the recommendations of the Executive Board on the Working Capital Fund;

Bearing in mind the recommendations of the Joint Inspection Unit in its report,[2]

A

1. DECIDES that the level of Part II of the Working Capital Fund shall be increased from US$ 6 000 000 to US$ 26 000 000 by transfers of funds from the Casual Income Account during the financial period 1994-1995 and, if necessary, in 1996-1997, as and when arrears of contributions in respect of the financial period 1992-1993 are credited to the Casual Income Account;

2. DECIDES also that Part II of the Working Capital Fund shall continue to be financed by appropriations by the Health Assembly from casual income as recommended by the Executive Board after considering the report of the Director-General; such appropriations shall be voted separately from the appropriations for the relevant financial period;

3. AUTHORIZES the Director-General to effect the necessary transfers as in paragraph A.1 above.

[1] Document EB93/1994/REC/1, Annex 8.

[2] Document JIU/REP/89/9 (Vol. 1) dated 1989.

B

1. DECIDES that henceforth the Working Capital Fund shall be used solely for the purpose of financing any regular budget income deficit pending the receipt of assessed contributions from Members and Associate Members.

C

1. REQUESTS Members and Associate Members to make every effort to pay their contributions on the dates on which they are due in order to enable the Director-General to implement in an orderly manner the programmes approved by the Health Assembly;

2. REQUESTS the Director-General to continue his efforts to secure early payment of Members' and Associate Members' assessed contributions.

D

1. REQUESTS the Director-General to review the implications of consolidating Parts I and II of the Working Capital Fund, refunding the amount standing to the credit of each Member or Associate Member in Part I with a simultaneous transfer from casual income to the Fund to compensate for this refund and to report to the ninety-fifth session of the Executive Board in January 1995 and the Forty-eighth World Health Assembly.

Hbk Res., Vol. III (3rd ed.), 6.1.3

(Fourteenth plenary meeting, 12 May 1994 - Committee B - third report)

WHA47.21 Assessments of the Czech Republic and Slovakia

The Forty-seventh World Health Assembly,

Considering that the rates of assessments for the Czech Republic and Slovakia under resolution WHA46.15 were provisional and subject to amendment, if necessary, to take into account the United Nations rates of assessment for these Members to be established by the United Nations General Assembly at a later date;

Noting that the United Nations General Assembly, in resolution 48/223, adopted in December 1993, established assessment rates applicable to the Czech Republic and Slovakia in the United Nations scale of assessment of 0.42% and 0.13%, respectively;

Recalling the principles and criteria established by resolutions WHA24.12 and WHA26.21 to apply to the basis for calculating the WHO scale of assessments,

DECIDES that the rates applicable to the Czech Republic and Slovakia in the WHO scale of assessments for the financial period 1994-1995 should be adjusted from the provisional rates of 0.36% and 0.18%, respectively, to definitive rates of 0.41%[1] and 0.13%.

Hbk Res., Vol. III (3rd ed.), 6.1.2.2

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

[1] The difference of 0.01% between the assessment rate of 0.42% in the United Nations and the suggested rate of 0.41% in WHO is due to the difference in membership of the two organizations.

WHA47.22 Assessment of Eritrea

The Forty-seventh World Health Assembly,

Noting that Eritrea, a Member of the United Nations, became a Member of the World Health Organization by depositing with the Secretary-General of the United Nations a formal instrument of acceptance of the WHO Constitution on 24 July 1993;

Noting that the United Nations General Assembly, in resolution 48/223, established the assessment of Eritrea at the rate of 0.01% for the years 1993 and 1994;

Recalling the principle established in resolution WHA8.5, and confirmed in resolution WHA24.12, that the latest available United Nations scale of assessments should be taken as a basis for determining the scale of assessments to be used by WHO;

Recalling further that the Twenty-sixth World Health Assembly, in resolution WHA26.21, affirmed its belief that the scale of assessments in WHO should follow as closely as possible that of the United Nations,

DECIDES:

(1) that Eritrea shall be assessed at the rate of 0.01% for the year 1993 and for the financial period 1994-1995;

(2) that Eritrea's assessment relating to the year 1993 shall be reduced to five-twelfths of 0.01%.

Hbk Res., Vol. III (3rd ed.), 6.1.2.2 (Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.23 Assessment of Niue

The Forty-seventh World Health Assembly,

Noting the admission of Niue to membership in the Organization;

Recalling that the Twenty-second World Health Assembly, in resolution WHA22.6, decided that from 1968 new Members shall be assessed in accordance with the practice followed by the United Nations in assessing new Members for their year of admission,

DECIDES:

(1) that Niue shall be assessed for the financial period 1994-1995 and for future financial periods at a rate to be fixed by the Health Assembly, as and when an assessment rate for this country has been established by the United Nations General Assembly;

(2) that Niue shall be assessed at the provisional rate of 0.01% for the financial period 1994-1995 and for future financial periods, to be adjusted to the definitive assessment rate when established by the Health Assembly;

(3) that the 1994 instalment of the assessment shall be reduced to seven-twelfths of 0.01%.

Hbk Res., Vol. III (3rd ed.), 6.1.2.2 (Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.24 Assessment of Nauru

The Forty-seventh World Health Assembly,

Noting the admission of Nauru to membership in the Organization;

Recalling that the Twenty-second World Health Assembly, in resolution WHA22.6, decided that from 1968 new Members shall be assessed in accordance with the practice followed by the United Nations in assessing new Members for their year of admission,

DECIDES:

(1) that Nauru shall be assessed for the financial period 1994-1995 and for future financial periods at a rate to be fixed by the Health Assembly, as and when an assessment rate for this country has been established by the United Nations General Assembly;

(2) that Nauru shall be assessed at the provisional rate of 0.01% for the financial period 1994-1995 and for future financial periods, to be adjusted to the definitive assessment rate when established by the Health Assembly;

(3) that the 1994 instalment of the assessment shall be reduced to seven-twelfths of 0.01%.

Hbk Res., Vol. III (3rd ed.), 6.1.2.2 (Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.25 Real Estate Fund

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General on the status of projects financed from the Real Estate Fund and the estimated requirements of the Fund for the period 1 June 1994 to 31 May 1995;[1]

Recognizing that certain estimates must remain provisional because of the fluctuation of exchange rates,

1. AUTHORIZES the financing from the Real Estate Fund of the expenditures summarized in part III of the Director-General's report, at an estimated cost of US$ 1 965 250;

2. APPROPRIATES to the Real Estate Fund, from casual income, the sum of US$ 1 721 250.

Hbk Res., Vol. III (3rd ed.), 6.1.7 (Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.26 Cooperation Agreement with the African Development Bank and the African Development Fund

The Forty-seventh World Health Assembly,

Having considered the report of the Director-General on the Cooperation Agreement between WHO and the African Development Bank and the African Development Fund;

[1] See Annex 5.

Taking into consideration Article 70 of the WHO Constitution,

APPROVES the attached Cooperation Agreement between WHO and the African Development Bank and the African Development Fund.

Annex

COOPERATION AGREEMENT BETWEEN THE AFRICAN DEVELOPMENT BANK AND THE AFRICAN DEVELOPMENT FUND AND THE WORLD HEALTH ORGANIZATION

THIS COOPERATION AGREEMENT (hereinafter called the "Agreement") is entered into this 21st day of April 1994 by and between the African Development Bank (hereinafter called the "Bank"), the African Development Fund (hereinafter called the "Fund"), of the one part, and the World Health Organization (hereinafter called "WHO"), of the other part.

RECALLING the provisions of the Agreement concluded on 1 November 1974 between the Bank and WHO, and those of the Expanded Memorandum of Understanding concluded on 29 August 1978 for cooperation in the provision of assistance in the field of health and related fields to the African countries having common membership in the Bank and WHO (hereinafter called the "regional Member countries");

DESIROUS of revising the aforesaid Agreement with the aim of further strengthening, fostering and consolidating their cooperative programme and creating a proper framework through which assistance may be channelled in an effective manner to regional Member countries;

THE PARTIES HEREBY AGREE AS FOLLOWS:

Article I

Purpose

The purpose of this Agreement shall be to provide an expanded framework of cooperation and facilitate collaboration between the parties hereto in providing assistance in the fields of health and related fields to regional Member countries for the improvement of health conditions and for raising the standards of health in regional Member countries, having regard to the respective objectives and functions of the parties.

Article II

Areas of cooperation

The parties hereto agree to cooperate in the following areas of activity:

(i) identification, preparation, appraisal, implementation and post-evaluation of development projects and programmes sponsored by the Bank or the Fund in the field of health and in health-related areas such as education programmes, food and nutrition, supply of essential drugs and vaccines, water and sanitation, population growth, women in development, environmental issues and poverty alleviation;

(ii) participation in the mobilization of resources for and the financing of such projects and programmes in regional Member countries and identification of complementary sources of finance;

(iii) assistance by WHO in the planning, organization and implementation of projects and programmes sponsored by the Bank or the Fund, through the provision of technical expertise and any other support;

(iv) supervision of on-going projects and programmes and post-evaluation of completed projects and programmes, financed by the Bank or the Fund;

(v) undertaking, by WHO in collaboration with, or on behalf of, the Bank and/or the Fund, of pre-investment, sectoral and other economic and technical studies, particularly those concerning the assessment of performance and development potential in the fields and areas referred to in paragraph (i) of this Article;

(vi) assisting regional Member countries in undertaking health data collection and analysis and in carrying out research activities in the health sector;

(vii) jointly engaging in dialogue with regional Member countries with a view to assisting them in health planning and in formulating and implementing policies and strategies aimed at improving health conditions and raising the standards of health of their populations;

(viii) providing orientation and training to professional and technical personnel of the Bank, as well as cooperating in the organization and conduct of courses, research, seminars, workshops and symposia related to matters of common interest in regional Member countries;

(ix) exchange of experience and relevant documents, data and other information on health conditions in regional Member countries;

(x) other related activities as may be agreed upon by the parties from time to time.

Article III

Consultation and exchange of information

1. The parties to this Agreement shall, on a regular basis, keep each other informed of their respective sectoral priorities, policy approaches and programmes and, where necessary, consult on matters of common interest which in their opinion are likely to lead to mutual collaboration.

2. The parties hereto shall, at such intervals as they deem fit, convene meetings to agree on programmes of activities, the means and responsibilities for carrying out and managing such activities, and to review the progress of activities being carried out under the present Agreement.

3. Consultation and exchange of documents, data and information under this Agreement shall be without prejudice to arrangements which may be required to safeguard the confidential and restricted character of certain documents and information.

Article IV

Representation

The parties to this Agreement shall make the necessary arrangements for ensuring reciprocal representation at appropriate meetings or conferences convened by them or under their auspices in which, in the opinion of either party, the other may have an interest, subject to such procedures as may be applicable to the respective meeting or conference.

Article V

Implementation of the Agreement

The President of the Bank and the Fund and the Director-General of WHO shall make the arrangements necessary for ensuring the satisfactory implementation of this Agreement.

Article VI

Financial provision

Costs or expenses relating to, or arising from, an activity undertaken pursuant to this Agreement shall be borne by one or both of the parties hereto in accordance with an agreement previously reached by the parties in regard to the activity concerned.

Article VII

Duration

1. The present Agreement shall be concluded for an indefinite period; it being understood that each party shall have the right to terminate it at any time by giving six months' advance notice to the other party.

2. In the event of termination of the Agreement pursuant to paragraph 1 of this Article, the parties shall take all necessary steps to ensure that such a decision is not prejudicial to any activities then in progress within the framework of this Agreement.

Article VIII

Supplementary arrangements and amendment

1. The parties may enter into such supplementary arrangements or agreements within the scope of this Agreement as may be appropriate.

2. The provisions of the present Agreement may be amended at any time by the mutual written agreement of the parties.

Article IX

Notices and addresses

Any notice or request required or permitted to be given or made under this Agreement shall be in writing. Such notice or request shall be deemed to have been duly given or made when it shall have been delivered by hand, mail, telex, cable, or telefax to the party to which it is required to be given or made at the address specified below or such other address as shall be hereafter notified.

For the Bank and the Fund	Mail address: African Development Bank and African Development Fund 01 B.P. 1387 ABIDJAN 01 Côte d'Ivoire Cable address: AFDEV Abidjan Telex address: 23717/23498 Fax: (225) 227004/331917
For WHO	Mail address: World Health Organization CH-1211 GENEVA 27 Switzerland Cable address: UNISANTE-GENEVA Telex address: 415416 OMS CH Fax: (022) 791-0746

Article X

Entry into force and effect

1. This Agreement shall enter into force upon signature thereof by the President of the Bank and the Fund and the Director-General of WHO, and, after approval by the competent bodies of the Bank and the Fund and of WHO.

2. Upon its entry into force, the present Agreement shall supersede the Agreement for Cooperation concluded between the Bank and WHO on 1 November 1974 and all working arrangements concluded thereunder; it being understood that all commitments entered into prior to the effective date of this Agreement shall, not withstanding the foregoing, be governed by the Agreement for Cooperation dated 1 November 1974, and the Expanded Memorandum of Understanding on Working Arrangements between the parties concluded on 29 August 1978.

IN WITNESS WHEREOF the Bank, the Fund and WHO, each acting through its duly authorized representative, have signed this Agreement on the date first above written in two original texts, in the English and French languages each text being equally authentic.

For the African Development Bank
For the African Development Fund

Babacar Ndiaye
President

For the World Health Organization

Hiroshi Nakajima
Director-General

Hbk Res., Vol. III (3rd ed.), 7.3

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.27 International Decade of the World's Indigenous People

The Forty-seventh World Health Assembly,

Recalling United Nations General Assembly resolution 48/163 of 21 December 1993 which proclaimed the International Decade of the World's Indigenous People, commencing on 10 December 1994, and requested specialized agencies to consider with governments and indigenous people how they can contribute to the success of the Decade;

Recalling also that the resolution appealed to the specialized agencies to increase their efforts and, in particular, to take into account the needs of indigenous people in their budgeting and programming;

Noting that a goal of the Decade should be the strengthening of international cooperation for the solution of problems faced by indigenous people in such areas as health;

Mindful of WHO's objective of health for all by the year 2000, which seeks to help all citizens of the world to attain a level of health that will permit them to lead a socially and economically productive life;

Recalling resolution WHA45.24, which urged Member States to take specific steps to improve the health status of the most vulnerable population groups;

Recalling also the discussion on health and indigenous people which took place in Committee B at the Forty-sixth World Health Assembly;

Concerned that due recognition should be given to the value of indigenous people's knowledge and expertise in traditional medicines and practices and that indigenous health care should be based on practical, socially and culturally acceptable methods and technology made universally accessible to individuals and families in their communities;

Noting the efforts already undertaken by the WHO Regional Office for the Americas;

Recalling resolution 1994/26 of the Commission of Human Rights of 4 March 1994 urging United Nations bodies and specialized agencies to designate focal points for liaison with the Centre for Human Rights on activities related to the Decade and to work in partnership with governments and indigenous people to develop and improve programmes that are beneficial to indigenous communities;

Concerned that WHO's expertise should benefit all people,

1. AGREES that WHO should participate in planning for, and implement the objectives of, the International Decade of the World's Indigenous People;

2. REQUESTS the appropriate regional office to work alongside the governments of the Member States concerned, with indigenous people, including the establishment of a core advisory group of indigenous representatives with special knowledge of the health needs and resources of their communities;

3. CALLS on the Director-General:

(1) to increase cooperation between WHO and other organizations of the United Nations system, including the Centre for Human Rights, to help to meet health needs of indigenous people in the context of the Decade;

(2) to provide Member States with technical support to enable them to accelerate the implementation of their programmes for indigenous people;

(3) to assist governments and indigenous people to address indigenous health needs in a culturally effective manner;

(4) to consider the contribution WHO might make to promoting respect for, and maintenance of, indigenous knowledge, traditions and remedies, in particular in their pharmacopoeia;

(5) to ensure that relevant research projects undertaken by WHO and other specialized agencies and organizations of the United Nations system are conducted in consultation with, and for the benefit of, indigenous people and communities, such projects being undertaken by indigenous people themselves where appropriate;

4. INVITES Member States with indigenous populations to consider, where appropriate, designating a focal point for cooperation with their communities in all health-related decisions that will have an impact on indigenous people.

Hbk Res., Vol. III (3rd ed.), 7.1.1

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.28 Collaboration within the United Nations system and with other intergovernmental organizations: health assistance to specific countries

The Forty-seventh World Health Assembly,

Recalling and confirming the previous resolutions of the Health Assembly on health assistance to specific countries, and the most recent resolution WHA46.29, which includes reference to earlier resolutions WHA44.37 (Health and medical assistance to Lebanon); WHA44.38 (Health assistance to refugees and displaced persons in Cyprus); WHA44.39 (Assistance to Lesotho and Swaziland); WHA44.40 (Reconstruction and development of the health sector in Namibia); and WHA44.43 (Health and medical assistance to Somalia); and also resolution WHA41.33 (Health assistance to the people of Afghanistan);

Noting the increasing number of countries and areas stricken by natural and man-made disasters and the subsequent numerous reports submitted for discussion during the Health Assembly;

Taking note of United Nations General Assembly resolution 46/182, "Strengthening of the coordination of humanitarian assistance of the United Nations";

Recalling resolution WHA35.1 on method of work of the Health Assembly, which draws attention to the desirability of a full discussion at regional level of all matters dealing with specific countries before such items are referred to the Health Assembly, and the recent decision on this matter by the Regional Committee for the Eastern Mediterranean (resolution EM/RC39/R.11);

Having examined the Director-General's report on the action taken by WHO for health assistance to specific countries and to drought-affected countries,[1]

1. EXPRESSES its appreciation to the Director-General for his continuous efforts to strengthen the Organization's capacity to respond promptly and efficiently to country-specific emergencies;

2. URGES the Director-General to continue to give high priority to countries mentioned in the above resolution and to coordinate these and other WHO efforts in emergency preparedness and humanitarian assistance with the humanitarian affairs programmes of the United Nations system, including mobilization of extrabudgetary resources;

3. CALLS UPON the Director-General to report to the Forty-eighth World Health Assembly on the implementation of this resolution.

Hbk Res., Vol. III (3rd ed.), 1.2.2.2; 1.2.2.3; 7.1.4.5

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.29 Rwanda

The Forty-seventh World Health Assembly,

Noting with the gravest concern the wanton massacre of innocent civilians in Rwanda following the tragic deaths of Mr Juvenal Habyarimana, President of Rwanda and Mr Cyprien Ntaryamira, President of Burundi;

Noting the very heavy flow of refugees into neighbouring countries and the burden placed on those countries,

[1] Documents A47/29 Rev.1 and Add.1.

1. EXPRESSES its concern at the continuing massacre, which constitutes a tragedy in terms of human suffering and loss of life and health;

2. EXPRESSES its solidarity with the people of Rwanda and neighbouring countries;

3. THANKS all governments for the assistance provided and, in particular, the governments of the neighbouring countries of Burundi, Uganda, United Republic of Tanzania and Zaire for the assistance that they have provided for the refugees;

4. THANKS the World Health Organization and other organizations of the United Nations system for their concern as well as health and humanitarian assistance, including the support provided to the refugees;

5. CALLS on Member States, national and international organizations and agencies to provide urgent financial, material and technical support to the neighbouring States in their efforts to provide emergency help to the refugee populations;

6. URGES the Director-General to bring to the attention of the Secretary-General of the United Nations the short- and long-term health effects of this tragedy;

7. REQUESTS the Director-General to mobilize adequate efforts and resources, in cooperation with other international organizations and agencies, to succour the civilian populations affected and to assist the neighbouring countries in their efforts to provide emergency assistance to the refugees;

8. REQUESTS the Director-General to determine programmes and resources that will assist in the re-establishment of health services in Rwanda once peace has been restored;

9. URGES all parties concerned to bring all efforts to bear in order to ensure an immediate cessation of the killing of innocent men, women and children.

Hbk Res., Vol. III (3rd ed.), 1.2.2.2; 1.2.2.3

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.30 Health conditions of the Arab populations in the occupied Arab territories, including Palestine

The Forty-seventh World Health Assembly,

Mindful of the basic principle established in the WHO Constitution, which affirms that the health of all peoples is fundamental to the attainment of peace and security;

Recalling the convening of the International Peace Conference on the Middle East at Madrid on 30 October 1991, on the basis of Security Council resolutions 242 (1967) of 22 November 1967 and 338 (1973) of 22 October 1973, and the subsequent bilateral negotiations;

Expressing the hope that the peace talks among the parties concerned in the Middle East will lead to a just and comprehensive peace in the area;

Noting the signing in Washington D.C. on 13 September 1993 of the Declaration of Principles on Interim Self-Government Arrangements between Israel and the Palestine Liberation Organization, which provides for the transfer of authority to the Palestinian people during the interim period and in particular the responsibility for health services;

Recognizing the need for increased support and health assistance to the Arab populations in the occupied territories including the Palestinians as well as the Syrian Arab population;

Recognizing that the Palestinian people will have to make strenuous efforts to improve their health infrastructure;

Aware that health development is difficult under occupation and best promoted in circumstances of peace and stability;

Recognizing the need for providing support and health assistance to the Arab populations in the occupied territories including the occupied Golan;

Having considered the report of the Director-General,[1]

1. EXPRESSES the hope that the peace talks will lead to the establishment of a just, lasting and comprehensive peace in the Middle East so that the Palestinian people can be responsible for their health services and develop their health plans and projects in order to participate with the people of the world in the achievement of WHO's objective of health for all by the year 2000;

2. AFFIRMS that the transfer of responsibility for health to the Palestinian people will lead to the development of their health system, thereby enabling them to meet their needs by managing their own affairs and supervising their health services;

3. URGES Member States, international intergovernmental and nongovernmental organizations and regional and interregional organizations to assist rapidly and generously in the health development of the Palestinian people in the West Bank and Gaza, and to do so in close cooperation with the Palestine Liberation Organization;

4. THANKS the Director-General for his efforts, and requests him:

(1) to provide the required technical assistance for facilitating the transfer of responsibility for health to the Palestinian people in the interim period, especially in the following:

(a) the carrying out of a comprehensive survey in order to identify the basic health issues to be dealt with;

(b) the development of an appropriate health system;

(c) the establishment of a comprehensive health insurance scheme;

(d) the development and strengthening of programmes for environmental health and protection;

(2) to take action and make the necessary contacts in order to provide the required funds from various existing and extrabudgetary sources of funding for meeting the urgent health needs of the Palestinian people during the transitional period;

(3) to continue his efforts to implement the special health assistance programme, gearing it to the requirements of meeting the health needs of the Palestinian people, taking into consideration the development of the comprehensive health plan for the Palestinian people;

(4) to strengthen the role of the organizational unit at WHO headquarters responsible for health of the Palestinian people, and to follow up the provision of health assistance in order to improve the health conditions of the Palestinian people;

(5) to report to the Forty-eighth World Health Assembly on the aspects of health assistance to the populations covered by this resolution;

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[1] Document A47/30.

5. EXPRESSES its gratitude to all Member States and to international governmental and nongovernmental organizations and invites them to provide the necessary assistance to meet the health needs of the Palestinian people.

Hbk Res., Vol. III (3rd ed.), 7.1.4.4

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.31 Salaries for ungraded posts and the Director-General

The Forty-seventh World Health Assembly,

Noting the recommendations of the Executive Board with regard to remuneration of staff in the ungraded posts and of the Director-General,

1. ESTABLISHES the salary for the posts of Assistant Directors-General and Regional Directors at US$ 125 677 per annum before staff assessment, resulting in a modified net salary of US$ 82 586 (dependency rate) or US$ 74 721 (single rate);

2. ESTABLISHES the salary for the post of Deputy Director-General at US$ 138 759 per annum before staff assessment, resulting in a modified net salary of US$ 90 043 (dependency rate) or US$ 80 922 (single rate);

3. ESTABLISHES the salary for the Director-General at US$ 171 709 per annum before staff assessment, resulting in a modified net salary of US$ 108 824 (dependency rate) or US$ 96 540 (single rate);

4. DECIDES that these adjustments in remuneration shall come into effect on 1 March 1994.

Hbk Res., Vol. III (3rd ed.), 6.2.4.3

(Fourteenth plenary meeting, 12 May 1994 - Committee B, third report)

WHA47.32 Onchocerciasis control through ivermectin distribution

The Forty-seventh World Health Assembly,

Noting the report by the Director-General on onchocerciasis control through ivermectin distribution;[1]

Aware of the threat to health from onchocerciasis in endemic countries in the African Region, the Region of the Americas and the Eastern Mediterranean Region in which some 18 million people suffer from the disease, including one million blind or severely visually disabled persons;

Recognizing with appreciation the success achieved by the Onchocerciasis Control Programme in West Africa, at present operating in 11 countries, with vector control and, in recent years, ivermectin distribution to selected populations;

Concerned that onchocerciasis is still a public health problem with serious socioeconomic consequences in the remaining endemic countries in the three regions concerned;

Appreciating that the disease can be brought under control through single annual doses of ivermectin, the drug provided free of charge by the manufacturer to countries where onchocerciasis is endemic;

[1] Document A47/13.

Noting the recent initiatives for the control of onchocerciasis in the Americas, and the creation of an international nongovernmental organizations coordination group for ivermectin distribution, collaborating with WHO,

1. REQUESTS the Member States concerned:

(1) to prepare national plans, if they do not already exist, for the control of onchocerciasis through vector control, where applicable, and the regular distribution of ivermectin to populations in need;

(2) to take advantage of ivermectin distribution to strengthen primary health care, including appropriate health and public information;

(3) to consider setting up mechanisms for collaboration with nongovernmental or other organizations through national coordinators, national committees or similar bodies, for support to, and coordination of, ivermectin distribution schemes;

(4) to make full use of the existing application procedure for obtaining ivermectin for public health purposes free of charge from the manufacturer;

2. REQUESTS the Director-General:

(1) to pursue actively the initiatives taken for onchocerciasis control through ivermectin distribution, in consultation with collaborating nongovernmental and other organizations and interested institutions;

(2) to develop further and disseminate rapid epidemiological methods for assessment and mapping of onchocerciasis in the remaining countries where it is endemic;

(3) to determine the most appropriate sustainable modalities of delivery, including evaluation of the cost-effectiveness in relation to vector control;

(4) to ensure technical cooperation with those countries for the development of national plans for onchocerciasis control;

(5) to promote further and coordinate potential support for ivermectin distribution to combat onchocerciasis with other specialized agencies and bodies of the United Nations system, such as UNICEF and the World Bank;

(6) to report back to the Executive Board and the Health Assembly on further progress made, as appropriate.

Hbk Res., Vol. III (3rd ed.), 1.16.3.3

(Fourteenth plenary meeting, 12 May 1994 - Committee A, fourth report)

DECISIONS

WHA47(1) Composition of the Committee on Credentials

The Forty-seventh World Health Assembly appointed a Committee on Credentials consisting of delegates of the following 12 Member States: Bulgaria, Canada, Chile, Côte d'Ivoire, Namibia, Nepal, Netherlands, Portugal, Samoa, Seychelles, Tunisia and United Arab Emirates.

(First plenary meeting, 2 May 1994)

WHA47(2) Composition of the Committee on Nominations

The Forty-seventh World Health Assembly elected a Committee on Nominations consisting of delegates of the following 25 Member States: Angola, Australia, Bangladesh, Barbados, Bolivia, Ecuador, Fiji, France, Iceland, Jordan, Kenya, Kyrgyzstan, Morocco, Mozambique, Myanmar, Oman, Pakistan, Panama, Philippines, Russian Federation, Senegal, Swaziland, United Kingdom of Great Britain and Northern Ireland, United Republic of Tanzania and United States of America.

(First plenary meeting, 2 May 1994)

WHA47(3) Election of officers of the Forty-seventh World Health Assembly

The Forty-seventh World Health Assembly, after considering the recommendations of the Committee on Nominations, elected the following officers:

President: Mr B. K. Temane (Botswana)

Vice-Presidents: Professor V. Rajpho (Lao People's Democratic Republic)
Dr A. Abdel Fattah El Makhzangi (Egypt)
Dr A. Ourairat (Thailand)
Dr B. Voljč (Slovenia)
Dr A. L. Pico (Argentina)

Having noted that Dr El Makhzangi had to return to his country, the Health Assembly, on 3 May, decided that Dr M. Zahran should replace him as Vice-President.

(Second and fourth plenary meetings, 2 and 3 May 1994)

WHA47(4) Election of officers of the main committees

The Forty-seventh World Health Assembly, after considering the recommendations of the Committee on Nominations, elected the following officers of the main committees:

Committee A: **Chairman,** Dr N. K. Rai (Indonesia)

Committee B: **Chairman,** Dr M. S. E. Asaad (Saudi Arabia)

(Second plenary meeting, 2 May 1994)

The main committees subsequently elected the following officers:

Committee A: **Vice-Chairmen,** Mr D. Van Daele (Belgium) and Dr B. R. Vaithinathan (Singapore)
Rapporteur, Dr N. H. A. Al-Shabandar (Iraq)

Committee B: **Vice-Chairmen,** Dr F. Chávez Peón (Mexico) and Mr A. C. Zane-Fe Touam-Bona (Central African Republic)
Rapporteur, Dr T. Pyakalyia (Papua New Guinea)

(First meetings of Committees A and B, 4 and 6 May 1994)

WHA47(5) Establishment of the General Committee

The Forty-seventh World Health Assembly, after considering the recommendations of the Committee on Nominations, elected the delegates of the following 17 countries as members of the General Committee: Bahrain, Burkina Faso, Cape Verde, China, Cuba, France, Gabon, Guatemala, Guinea, Iran (Islamic Republic of), Israel, Japan, Nigeria, Russian Federation, United Kingdom of Great Britain and Northern Ireland, United States of America and Venezuela.

(Second plenary meeting, 2 May 1994)

WHA47(6) Adoption of the agenda

The Forty-seventh World Health Assembly adopted the provisional agenda prepared by the Executive Board at its ninety-third session with the deletion of one item and a change in title of one item.

(Third plenary meeting, 3 May 1994)

WHA47(7) Verification of credentials

The Forty-seventh World Health Assembly recognized the validity of the credentials of the following delegations: Afghanistan; Albania; Algeria; Angola; Antigua and Barbuda; Argentina; Armenia; Australia; Austria; Bahamas; Bahrain; Bangladesh; Barbados; Belgium; Belize; Benin; Bhutan; Bolivia; Bosnia and Herzegovina; Botswana; Brazil; Brunei Darussalam; Bulgaria; Burkina Faso; Burundi; Cambodia; Cameroon; Canada; Cape Verde; Central African Republic; Chile; China; Colombia; Comoros; Congo; Costa Rica; Côte d'Ivoire; Croatia; Cuba; Cyprus; Czech Republic; Democratic People's Republic of Korea; Denmark; Djibouti;[1] Dominican Republic; Ecuador; Egypt; El Salvador; Equatorial Guinea; Eritrea; Estonia; Ethiopia; Fiji; Finland; France; Gabon; Gambia; Georgia; Germany; Ghana; Greece; Guatemala; Guinea; Guinea-Bissau; Guyana; Haiti; Honduras; Hungary; Iceland; India; Indonesia; Iran (Islamic Republic of); Iraq; Ireland; Israel; Italy; Jamaica; Japan; Jordan; Kazakhstan; Kenya; Kiribati; Kuwait; Kyrgyzstan; Lao People's Democratic Republic; Latvia; Lebanon; Lesotho; Liberia; Libyan Arab Jamahiriya; Lithuania; Luxembourg; Madagascar; Malawi; Malaysia; Maldives; Mali; Malta; Mauritania; Mauritius; Mexico; Micronesia (Federated States of); Monaco; Mongolia; Morocco; Mozambique; Myanmar; Namibia; Nauru; Nepal; Netherlands; New Zealand; Nicaragua; Niger; Nigeria; Niue; Norway; Oman; Pakistan; Panama; Papua New Guinea; Paraguay; Peru; Philippines; Poland; Portugal; Qatar; Republic of Korea;

[1] Credentials provisionally accepted.

Republic of Moldova; Romania; Russian Federation; Rwanda;[1] Saint Kitts and Nevis; Saint Lucia; Samoa; San Marino; Sao Tome and Principe; Saudi Arabia; Senegal; Seychelles; Sierra Leone; Singapore; Slovakia; Slovenia; Solomon Islands; South Africa; Spain; Sri Lanka; Sudan; Suriname; Swaziland; Sweden; Switzerland; Syrian Arab Republic; Tajikistan;[1] Thailand; The Former Yugoslav Republic of Macedonia; Togo; Tonga; Trinidad and Tobago; Tunisia; Turkey; Tuvalu; Uganda; Ukraine; United Arab Emirates; United Kingdom of Great Britain and Northern Ireland; United Republic of Tanzania; United States of America; Uruguay; Uzbekistan; Vanuatu; Venezuela; Viet Nam; Yemen; Zaire; Zambia; Zimbabwe.

(Fifth and eleventh plenary meetings, 4 and 9 May 1994)

WHA47(8) Report of the Director-General on the work of WHO in 1992-1993

The Forty-seventh World Health Assembly, after reviewing the Director-General's report on the work of WHO in 1992-1993,[2] noted with satisfaction the manner in which the Organization's programme for that biennium had been implemented.

(Tenth plenary meeting, 6 May 1994)

WHA47(9) Election of Members entitled to designate a person to serve on the Executive Board

The Forty-seventh World Health Assembly, after considering the recommendations of the General Committee,[3] elected the following as Members entitled to designate a person to serve on the Executive Board: China, Cuba, Finland, France, Kuwait, Pakistan, Russian Federation, Thailand, United States of America and Zambia.

(Eleventh plenary meeting, 9 May 1994)

WHA47(10) Annual report of the United Nations Joint Staff Pension Board

The Forty-seventh World Health Assembly noted the status of the operations of the United Nations Joint Staff Pension Fund, as indicated in the annual report of the United Nations Joint Staff Pension Board, and as reported by the Director-General.[4]

(Fourteenth plenary meeting, 12 May 1994)

WHA47(11) Appointment of representatives to the WHO Staff Pension Committee

The Forty-seventh World Health Assembly appointed Professor Béat Andreas Roos, in his personal capacity, as a member of the WHO Staff Pension Committee, and the member of the Board designated by the Government of Kuwait as alternate member of the Committee, the appointments being for a period of three years.

(Fourteenth plenary meeting, 12 May 1994)

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[1] Credentials provisionally accepted.

[2] *The Work of WHO, 1992-1993*, Geneva, World Health Organization, 1994.

[3] For report of the General Committee, see document WHA47/1994/REC/3.

[4] Document A47/31.

WHA47(12) Selection of the country in which the Forty-eighth World Health Assembly will be held

The Forty-seventh World Health Assembly, in accordance with Article 14 of the Constitution, decided that the Forty-eighth World Health Assembly would be held in Switzerland.

(Fourteenth plenary meeting, 12 May 1994)

WHA47(13) Reports of the Executive Board on its ninety-second and ninety-third sessions

The Forty-seventh World Health Assembly, after reviewing the Executive Board's reports on its ninety-second[1] and ninety-third[2] sessions, approved the reports.

(Fifteenth plenary meeting, 12 May 1994)

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[1] Document EB92/1993/REC/1.

[2] Documents EB93/1994/REC/1 and EB93/1994/REC/2.

ANNEXES

ANNEX 1

Infant and young child nutrition (progress and evaluation report; and status of implementation of the International Code of Marketing of Breast-milk Substitutes)[1]

Report by the Director-General

[A47/6 - 23 March 1994]

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[1] See resolution WHA47.5.

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INTRODUCTION

International Conference on Nutrition

1. The International Conference on Nutrition (ICN, Rome, December 1992) was the culmination of more than two years of joint efforts by WHO and FAO to increase awareness of the extent and seriousness of nutrition- and diet-related problems and to achieve consensus on the way forward in dealing with them. ICN was attended by more than 1300 participants from 159 Member States and the European Community, as well as representatives of 15 organizations and bodies of the United Nations system and over 150 intergovernmental and nongovernmental organizations. It was thus a vital step in the direction of a truly global commitment to confronting all forms of malnutrition, to relating them to inequitable social and economic development, and to eliminating or substantially reducing many of them before the year 2000 (see box below).

WORLD DECLARATION ON NUTRITION[1]

(excerpt)

As a basis for the Plan of Action for Nutrition and guidance for formulation of national plans of action, including the development of measurable goals and objectives within time frames, we [the Ministers and Plenipotentiaries] pledge to make all efforts to eliminate before the end of this decade:

- *famine and famine-related deaths;*
- *starvation and nutritional deficiency diseases in communities affected by natural and man-made disasters;*
- *iodine and vitamin A deficiencies.*

We also pledge to reduce substantially within this decade:

- *starvation and widespread chronic hunger;*
- *undernutrition, especially among children, women and the aged;*
- *other important micronutrient deficiencies, including iron;*
- *diet-related communicable and noncommunicable diseases;*
- *social and other impediments to optimal breast-feeding;*
- *inadequate sanitation and poor hygiene, including unsafe drinking-water.*

PLAN OF ACTION FOR NUTRITION

Strategies and actions

1. Incorporating nutritional objectives, considerations and components into development policies and programmes.
2. Improving household food security.
3. Protecting consumers through improved food quality and safety.
4. Preventing and managing infectious diseases.
5. Promoting breast-feeding.
6. Caring for the socio-economically deprived and nutritionally vulnerable.
7. Preventing and controlling specific micronutrient deficiencies.
8. Promoting appropriate diets and healthy lifestyles.
9. Assessing, analysing and monitoring nutrition situations.

[1] International Conference on Nutrition: World Declaration and Plan of Action for Nutrition. Rome, FAO/WHO, December 1992.

2. The World Declaration emphasizes the unacceptability of malnutrition and the determination of all governments to eliminate hunger and to reduce malnutrition significantly. It points to poverty and lack of education, rooted in underdevelopment, as fundamental causes, and identifies social and economic inequality and disparities between the sexes, as well as wars and occupations, as other major contributors. The Declaration affirms the need for major universal policy changes if malnutrition is to be radically reduced. The Declaration considers nutritional well-being to be a key objective of human development; it focuses on programmes for those most in need, and on the right of women to adequate nutrition, health and education, participation in decision-making and access to and control of resources. As a basis for the Plan of Action for Nutrition, the Declaration reiterates the world community's commitment to the nutrition goals of the Fourth United Nations Development Decade and of the World Summit for Children (see box below). The Plan of Action for Nutrition, in turn, highlights nine action-oriented themes (see excerpt above), which involve various sectors and levels of responsibility, and under which crucial activities are listed for reducing or eliminating all types of malnutrition and promoting nutritional well-being. All are directly relevant to meeting the nutrition needs of infants and young children.

NUTRITION GOALS OF THE WORLD SUMMIT FOR CHILDREN[1]
(to be reached by the year 2000)

- *Reduction in severe, as well as moderate, malnutrition among under-five children by half of 1990 levels;*
- *Reduction of the rate of low birth weight (2.5 kg or less) to less than 10 percent;*
- *Reduction of iron deficiency anaemia in women by one third of the 1990 levels;*
- *Virtual elimination of iodine deficiency disorders;*
- *Virtual elimination of vitamin A deficiency and its consequences, including blindness;*
- *Empowerment of all women to breast-feed their children exclusively for four to six months and to continue breast-feeding, with complementary food, well into the second year;*
- *Growth promotion and its regular monitoring to be institutionalized in all countries by the end of the 1990s;*
- *Dissemination of knowledge and supporting services to increase food production to ensure household food security.*

3. As a global consensus about the nature and causes of nutritional problems, the World Declaration and Plan of Action for Nutrition serve as the platform for WHO's continuing technical support to countries, including those with high levels of malnutrition, for example dietary deficiency of protein and energy that is frequently complicated by infectious diseases; deficiencies of iron, vitamin A and iodine, which are among the world's most widespread health problems; and excessive intakes of energy and nutrients which, combined with unhealthy lifestyles, are taking an increasing toll in all countries in terms of chronic diseases that result in premature disability and death. Meeting the health and nutrition needs of the family, particularly of mothers, infants and young children, is at the centre of WHO's strategy for support to nutrition activities at all levels.

4. The Forty-sixth World Health Assembly, in May 1993, considered the report[2] of the Director-General on ICN and the consequent proposed WHO strategy for supporting nutrition action at all levels. In endorsing in their entirety the World Declaration and Plan of Action for Nutrition in resolution WHA46.7, the Health Assembly requested the Director-General to reinforce WHO's capacity for food and nutrition action in all relevant programmes, so that increased emphasis could be given as a priority to:

- maternal, infant and young-child nutrition, including breast-feeding;

[1] Plan of Action for Implementing the World Declaration on the Survival, Protection and Development of Children in the 1990s. United Nations, New York, 30 September 1990.

[2] Document WHA46/1993/REC/1, Annex 3.

- micronutrient malnutrition;
- nutrition emergencies, particularly training in preparedness and management;
- monitoring of nutritional status;
- control of diet-related chronic diseases;
- food safety control and the prevention of foodborne diseases;
- research and training in subjects related to food and nutrition.

5. In response to the recommendations of ICN, the Director-General had already decided in advance of the Health Assembly to create a new Division of Food and Nutrition composed of the nutrition, food safety, and food aid programmes. Meanwhile, the interprogramme working group on infant feeding,[1] which was established in 1991 under a global nutrition task force, continued to serve as the focus for indispensable collaboration in developing and implementing a comprehensive programme in infant and young child feeding. To ensure a common position that reflects fully the Organization's policy in the light of the World Declaration and Plan of Action for Nutrition, the working group reviewed WHO's overall approach to infant and young child feeding, in collaboration with regional staff and other programmes and agencies concerned.[2] Lastly, global working groups have also been established in related areas; they include "protecting consumers through improved food quality and safety", "preventing and controlling specific nutrient deficiencies", "preventing and managing infectious diseases", "promoting appropriate diets and healthy life-styles", and "assessing, analysing and monitoring nutrition situations" (see box, below paragraph 1).

PART I. MALNUTRITION AMONG INFANTS AND YOUNG CHILDREN: SUMMARY OF THE CURRENT GLOBAL SITUATION

PROTEIN-ENERGY MALNUTRITION

6. More than a third of the world's under-five-year-old children are still malnourished (underweight). The WHO global database on child growth[3] covers 87% of the total population of infants and young children in developing countries. Data from a cross-section of the population in each of 86 of these countries indicate both regional and global trends in malnutrition, and a baseline against which to assess the decade goal of the World Summit for Children (paragraph 2) that aims at halving malnutrition by the year 2000.

7. Currently over two-thirds (80%) of the world's malnourished children live in Asia - especially southern Asia - 15% in Africa, and 5% in Latin America. The prevalence of malnutrition has decreased worldwide; this is also true of the regions, except for Africa where the absolute number of malnourished children has increased due to population growth. Table 1 shows the prevalence and number of malnourished (underweight) children under five years of age, the trend since 1975 and a projection for the year 2005.

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[1] The working group on infant feeding is composed of the programmes for nutrition, maternal and child health, control of diarrhoeal diseases, food safety, human reproduction, and food aid.

[2] "Infant and young child feeding: global approach and plan of action" was reviewed by the Sub-Committee on Nutrition of the United Nations Administrative Committee on Coordination (ACC/SCN) in March 1994.

[3] See *Bulletin of the World Health Organization*, 1993, 71(6): 703-712.

TABLE 1. GLOBAL AND REGIONAL ESTIMATES OF MALNOURISHED (UNDERWEIGHT) CHILDREN IN DEVELOPING COUNTRIES

	1975		1990		2005	
	%	million	%	million	%	million
Africa	30.4	22.9	27.4	31.6	24.7	39.2
Asia	47.8	164.6	42.0	154.1	37.5	144.4
Americas[a]	12.8	8.5	9.6	7.2	8.0	6.2
Near East	39.7	5.6	26.4	5.3	18.8	4.8
Less developed countries[b]	42.6	195.6	35.8	192.5	31.9	189.9

[a] Includes North America.

[b] Comprises all regions of Africa and Latin America, all regions of Asia (excluding Japan), Melanesia, Micronesia and Polynesia.

MICRONUTRIENT MALNUTRITION

8. **Iodine deficiency disorders** (IDD) are the greatest worldwide cause of preventable brain damage in infants and young children. WHO has just completed an assessment of the global magnitude of the problem in terms of the numbers of children affected with goitre. Currently, IDD is a significant public health problem in 118 countries. A total of 1571 million people live in iodine-deficient environments and are therefore at risk of IDD, and 655 million people actually have goitre (Table 2). Approximately half the global total of those affected by IDD lives in Asia (South-East Asia and Western Pacific regions), but there are also 86 million affected by goitre in the African Region, and even 11.4% of Europe's population is still affected. Tangible progress in salt iodization is being made in many countries - for example in China and in countries of South-East Asia and Africa. Despite the magnitude of the problem, it seems realistic to expect that IDD will indeed be eliminated as a major public health problem by the year 2000.[1]

9. **Vitamin A deficiency.** It is estimated that more than a quarter of a million children go blind every year due to a deficiency of vitamin A, and some 14 million currently exhibit signs of clinical xerophthalmia. At least 50 million more children have deficient vitamin A body stores, which compromises health and reduces chances of survival. Meta-analyses of all available large-scale, controlled community trials show that improving the vitamin A status of deficient child populations six months to six years of age contributes significantly to decreasing the risk of mortality. The primary intervention strategies to achieve the vitamin A goals are the improvement of vitamin A status by promoting exclusive breast-feeding for the first four to six months of life, and regular consumption of vitamin A-containing foods during the complementary and post-complementary feeding periods. Continued breast-feeding has been shown to offer an important measure of protection for children even beyond the second year of life. Also, universal or geographically limited distribution of vitamin A supplements at appropriate dosages and intervals should be encouraged where clinical deficiency is an important public health problem.

[1] Micronutrient Deficiency Information System, Working Paper No. 1: Global prevalence of iodine deficiency disorders. WHO/UNICEF/International Council for the Control of Iodine Deficiency Disorders, 1993.

TABLE 2. NUMBERS OF PEOPLE AND PERCENTAGE OF REGIONAL POPULATION LIVING IN AREAS AT RISK OF IODINE DEFICIENCY DISORDERS, AND NUMBERS AFFECTED BY GOITRE (TOTAL GOITRE RATE >5%)

WHO region	Population	Population at risk			Population affected by goitre		
	million	million	% of region	% of global total	million	% of region	% of global total
Africa	550	181	32.9	11.5	89	16.2	13.6
Americas	735	167	22.7	10.6	63	8.6	9.6
South-East Asia	1 355	486	35.9	30.9	175	12.9	26.7
Europe	858	141	16.4	9.0	97	11.3	14.8
Eastern Mediterranean	411	173	42.1	11.0	93	22.6	14.2
Western Pacific	1 553	423	27.2	26.9	139	8.9	21.2
Total	5 462	1 571	28.7	100.0	655	12.0	100.0

10. The goal of virtual elimination of vitamin A deficiency and all its consequences, including blindness, adopted at the World Summit for Children (paragraph 2) was reiterated by ICN. As a step in assessing progress towards this goal by the year 2000, WHO has determined what should be done to meet the WHO/UNICEF intermediate goal in this regard by 1995:

> *Ensure that at least 80% of all children under 24 months of age living in areas with inadequate vitamin A intake receive adequate vitamin A through a combination of breast-feeding, dietary improvement, fortification and supplementation.*[1]

Little more than two years remain to reach the mid-decade goal, and seven years to achieve sustainable programmes for the virtual elimination of vitamin A deficiency in children. For years WHO and UNICEF have been promoting distribution of vitamin A supplements to this age group, but they have only limited experience with advocating and monitoring results of increased intake of food sources of this vitamin. Based on available evidence, however, WHO and UNICEF have concluded that an initial focus on alleviating vitamin A deficiency in children under two years of age would result in the greatest number of lives being saved and the most cases of child-blindness prevented, given the susceptibilities of this age group. An educational component designed to improve child-feeding practices and a plan for monitoring its effectiveness should be an integral part of any strategy adopted for this purpose.

11. WHO has drawn up guidelines for the use and interpretation of new indicators for identifying sub-clinically vitamin A-deficient populations for which intervention programmes would be appropriate. The indicators should also prove useful in determining the extent to which relevant decade goals have been achieved. In 1992 WHO organized two consultations on vitamin A, one with the International Vitamin A Consultative Group on using immunization contacts to combat vitamin A deficiency,[2] and another to examine the impact of vitamin A supplementation on the incidence and severity of respiratory infections.[3] Lastly, WHO coordinated a multi-centre trial to assess the impact of vitamin A supplementation on morbidity.

[1] Document JCHPSS/94/2.8.

[2] Document WHO/NUT/EPI/93.1 (English only).

[3] Document WHO/CDR/93.2 (English only).

12. **Iron deficiency.** Directly related to the truly massive problem of iron deficiency anaemia in women is iron deficiency anaemia in infants and young children. Some 58% of pregnant women in developing countries are anaemic, with the result that infants are born with low birth weight and depleted iron stores. An earlier (1985) WHO global assessment of anaemia indicated that 51% of under-five-year-old children in developing countries are anaemic. Breast milk contains enough iron for infants up to four months of age. Artificial feeding and weaning diets, however, are often very low in iron, and the iron from vegetable sources is very poorly absorbed partly owing to inhibiting substances or low levels of vitamin C in the diet. Iron deficiency in early childhood is associated with higher mortality and impairment of cognitive development. The World Declaration and Plan of Action on Nutrition, apart from setting decade goals for reducing substantially iron deficiency anaemia in women, provides guidelines for countries to combat anaemia in children. WHO, in collaboration with other organizations and bodies in the United Nations system, is pursuing new approaches for defining this problem more accurately and dealing with it more effectively.

PART II. INFANT AND YOUNG CHILD FEEDING

13. This progress report is the eighth in a series prepared since 1981 in accordance with resolution WHA33.32, which requested the Director-General to submit to the Health Assembly in even years a report on the steps taken to promote breast-feeding and to improve infant and young child feeding.

14. The five-theme framework of past progress reports serves as the basic outline. Information on the fifth theme - Appropriate marketing and distribution of breast-milk substitutes - is presented in accordance with Article 11, paragraph 7, of the International Code of Marketing of Breast-milk Substitutes, which provides for reporting to the Health Assembly in even years on the status of its implementation.

ENCOURAGEMENT AND SUPPORT OF BREAST-FEEDING

Examples from countries

15. In September 1993 the Department of Health Services of **Chuuk State (Federated States of Micronesia)** issued its first policy statement on breast-feeding "as a way of working towards exclusive breast-feeding for all Micronesian babies" during the first four to six months of life. The policy governs the prenatal, birth and postnatal periods, and closely follows the principles laid down in the joint WHO/UNICEF statement on breast-feeding and maternity services (see paragraph 58). World Breastfeeding Week (see paragraph 29) was celebrated with the aid of a variety of lectures, leaflets, posters, etc. intended to reach health professionals and the general public alike.

16. Among steps taken to prepare for a national conference on breast-feeding in **Croatia** in November 1993, the authorities formulated a national breast-feeding strategy; prepared booklets for parents and health workers, and audiovisual and other information materials for the mass media; and organized regional seminars in Rijeka, Osijek and Split.

17. By Order No. 95 of 23 May 1991 the Government of **Mexico** established the National Committee on Breast-feeding[1] in order to help reduce infant morbidity and mortality through the promotion of breast-feeding. Functions include proposing amendments to existing legislation and regulations in order to promote breast-feeding; proposing the inclusion of information on breast-feeding in study plans and programmes within the framework of elementary, secondary and, particularly, medical, nursing, and social welfare studies; establishing permanent breast-feeding promotion campaigns; and ensuring compliance with the existing regulations governing advertising for breast-milk substitutes (paragraph 90).

[1] *International Digest of Health Legislation*, 1993, 44(1): 63-64.

18. The *Association nigérienne pour la protection de l'allaitement au sein* (**Niger** Association for the Protection of Breast-feeding) was established in May 1992 to counter negative influences on infant-feeding practices. Its aims include raising awareness of the importance of breast-feeding among political leaders, health authorities and mothers, revising labour legislation relative to breast-feeding women (see also paragraphs 63 to 67), and proposing a law governing breast-milk substitutes and complementary foods.

19. Alarmed by evidence suggesting that artificial feeding is increasing, the Government of **Papua New Guinea** in December 1992 issued instructions to all provincial and district health authorities on action they should take to promote national policy. Main points include promoting exclusive breast-feeding during the first four to six months of life; helping mothers initiate breast-feeding early and teaching them how to express their milk and feed it with a cup and a spoon; and encouraging on-demand feeding and rooming-in while discouraging supplementary feeding and prelacteal feeds, i.e. feeds given shortly after birth before breast-feeding has been initiated.

20. The President of the **Philippines** signed into law on 2 June 1992 the Rooming-in and Breastfeeding Act[1] adopting rooming-in as national policy to encourage, protect and support breast-feeding. The intention is to "create an environment where basic physical, emotional and psychological needs of mothers and infants are fulfilled" by "placing the newborn in the same room as the mother right after delivery up to discharge to facilitate mother-infant bonding and initiate breast-feeding". The Act applies to all private and government health institutions and to infants born of "normal spontaneous deliveries". Provisions cover breast-milk collection, storage and use; information and education; and incentives and sanctions applied to institutions contravening it. The Secretary of Health signed in 1993 a memorandum of agreement with the Philippine Hospital Association for the promotion of breast-feeding in some 1200 private hospitals in the country.

21. The Government of the **Republic of Korea** has produced and distributed widely pamphlets promoting breast-feeding intended for the general public and a poster featuring WHO/UNICEF's "Ten steps to successful breast-feeding" (see paragraph 26) for use in all health centres and hospitals.

22. The Child Nutrition Act of 1966 in the **United States of America** was amended in 1992[2] to establish a new programme to promote breast-feeding as the best method of infant nutrition, foster wider public acceptance of breast-feeding, and assist in the distribution of breast-feeding equipment to breast-feeding women. Activities under the programme may include the developing and distribution of appropriate educational materials, including public service announcements, promotional publications and press kits, and the provision of funds to physicians, health professional organizations, hospitals, community-based health organizations, and employers to assist in the distribution of breast pumps and similar equipment to breast-feeding women.

23. In March 1993 the State of **Florida** adopted an Act[3] encouraging breast-feeding, authorizing breast-feeding in public, and affirming that breast-feeding a baby does not violate prohibitions against obscenity, is not harmful to minors, and does not constitute unlawful nudity or sexual conduct. The Act includes references to the United States Surgeon General's recommendation that, unless medically contraindicated, babies from birth to one year of age should be breast-fed, and to the establishment by WHO and UNICEF of breast-feeding as a major goal of the decade. Describing breast-feeding as "an important and basic act of nurture which must be encouraged in the interests of maternal and child health and family values", the Act provides that "A mother may breast feed her baby in any location, public or private, where the mother is otherwise authorized to be, irrespective of whether the nipple of the mother's breast is uncovered during or incidental to the breast feeding".

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[1] *International Digest of Health Legislation*, 1992, 43(4): 770-772.

[2] *International Digest of Health Legislation*, 1993, 44(1): 64.

[3] *International Digest of Health Legislation*, 1993, 44(3): 466.

24. In **Venezuela**, Presidential Decree[1] No. 2717 of 22 December 1992 established a permanent national commission on breast-feeding, which is responsible for formulating and coordinating national breast-feeding policy. Participants include representatives of national associations of paediatricians and obstetricians and gynaecologists, the milk and pharmaceutical industries, and UNICEF and PAHO/WHO.

The Baby-friendly Hospital Initiative

25. The Baby-friendly Hospital Initiative was launched by WHO and UNICEF in June 1991 at a meeting in Ankara of the International Pediatric Association. In September 1991 the Director-General of WHO and the Executive Director of UNICEF addressed a joint letter to all heads of State calling on them to help reverse the global move away from breast-feeding. Protecting, promoting and supporting breast-feeding in maternity wards and hospitals means ending practices that are obstacles to initiating and continuing breast-feeding, including separating healthy babies from their mothers, giving babies sugar-water, and furnishing free or low-price supplies of infant formula to maternity wards and hospitals (see paragraphs 142 to 151).

TEN STEPS TO SUCCESSFUL BREAST-FEEDING

Every facility providing maternity services and care for newborn infants should:

1. *Have a written breast-feeding policy that is routinely communicated to all health care staff.*
2. *Train all health care staff in skills necessary to implement this policy.*
3. *Inform all pregnant women about the benefits and management of breast-feeding.*
4. *Help mothers initiate breast-feeding within a half-hour of birth.*
5. *Show mothers how to breast-feed, and how to maintain lactation even if they should be separated from their infants.*
6. *Give newborn infants no food or drink other than breast milk, unless* ***medically*** *indicated.*
7. *Practise rooming-in - allow mothers and infants to remain together - 24 hours a day.*
8. *Encourage breast-feeding on demand.*
9. *Give no artificial teats or pacifiers (also called dummies or soothers) to breast-feeding infants.*
10. *Foster the establishment of breast-feeding support groups and refer mothers to them on discharge from the hospital or clinic.*

26. WHO and UNICEF are supporting competent national authorities responsible for designating maternity wards and hospitals "baby-friendly", by issuing international assessment criteria, providing programme guidelines, developing training manuals and other materials, and supporting related training activities (see paragraphs 49 to 52). The Initiative is based on the principles described in the joint WHO/UNICEF statement on breast-feeding and maternity services (see paragraph 58), which are synthesized in the "Ten steps to successful breast-feeding" (see box above). The strategy WHO and UNICEF are using to help achieve the global breast-feeding goals and targets of the Innocenti Declaration (see box below) draws upon the two organizations' technical and programme strengths, the commitment

[1] *International Digest of Health Legislation*, 1993, **44**(4): 642.

of world leaders to the goals of the World Summit for Children[1] and to the Convention on the Rights of the Child, and the cooperation of a large number of nongovernmental organizations.

OPERATIONAL TARGETS OF THE INNOCENTI DECLARATION

A meeting of government policy-makers from over 30 developed and developing countries (Florence, Italy, July 1990) adopted the Innocenti Declaration on the Protection, Promotion and Support of Breastfeeding. The Forty-fifth World Health Assembly, in resolution WHA45.34, urged Member States to give full expression to the Declaration's operational targets, namely that, by 1995:

- all governments should have appointed a national breast-feeding coordinator and established a multisectoral breast-feeding committee;
- ensured that every facility providing maternity services applies the principles laid down in the joint WHO/UNICEF statement on the subject;
- taken action to give effect to the principles and aim of the International Code of Marketing of Breast-milk Substitutes;
- enacted legislation, and adopted means for its enforcement, to protect the breast-feeding rights of working women.

27. According to available information, by December 1992 the competent authorities in all developing countries had assessed the general situation and 860 hospitals had been singled out for achieving "baby-friendly" status. Of this number, 142 had achieved this designation, and 142 had been awarded certificates of commitment. By September 1993 nearly 800 had received certificates. Asian countries are leading the world in transforming maternity services according to the criteria of the Initiative, including **China**[2] with 207 hospitals, **Indonesia** 97, **Philippines** 102 and **Thailand** 45. The **Republic of Korea** intends to make accreditation of new hospitals subject to their introducing rooming-in for mothers and babies, while older institutions will be offered fiscal incentives to alter their premises accordingly. The Government expects to have 60 baby-friendly hospitals by the end of 1993 and 500 by the year 2000. At the urging of the Coalition for Protection of Women and Children, the Government of **Tamil Nadu State** (India), with a population of 40 million, issued instructions in January 1993 that all State maternity hospitals (accounting for 65% to 70% of births) implement the Initiative. The Children's Hospital in Tallinn, **Estonia**, is expanding and adapting the principles to include the special needs of low-birth-weight and sick infants. Similarly, in **Uganda** the decision was taken to add two steps to the original ten - concerning BCG and poliomyelitis vaccination and the issuing of child-health cards before discharge. Seven hospitals in **Poland** have begun making the organizational changes required to comply with the Initiative's standards. The Witwatersrand Breastfeeding Liaison Group in **South Africa** organized the sixth national breast-feeding week (March 1993) on the theme of the Initiative and promotion of the "ten steps", which the national health authorities adopted as official policy in 1990. Promotional material included 300 copies of the South African reprint of the joint WHO/UNICEF statement on breast-feeding and maternity services. In the **United States** the Healthy Mothers, Healthy Babies Coalition, with a grant from the Department of Health and Human Services, is examining the criteria and assessment process of the Initiative. An expert group composed of representatives of key organizations of health-care providers and hospital administration, and

[1] The Forty-fourth World Health Assembly, having discussed action to follow up the World Summit for Children (New York, September 1990), requested the Director-General to monitor achievements in child health in all countries, including those relating to the targets of the Innocenti Declaration (resolution WHA44.33).

[2] See Making hospitals "baby-friendly": an example from China. *Weekly Epidemiological Record*, 1993, **68**(20): 145-146. The figure in December 1992 was 21; a further 186 were announced at the "Baby-friendly Hospital Initiative" Award Ceremony during the International Congress on Maternal and Child Health/Family Planning (Beijing, October 1993), sponsored by the Chinese Ministry of Public Health, UNICEF, UNFPA and WHO.

technical experts in breast-feeding, is deciding what, if any, revisions are necessary to implement the Initiative in the United States. Although no reviews of hospitals will be conducted or awards given until the expert group has completed its work in 1994, hospitals are being encouraged to work towards improving breast-feeding practices by requesting a Certificate of Intent based on self-designation.

28. In a remarkably short time, the Initiative has mobilized national leaders, health professionals, nongovernmental organizations, the news media, mothers, and the public at large in at least 125 countries and territories. This attests to the universality of its principles, applicable as they are **anywhere** that maternity services are offered. Recording and reporting on the impressive accomplishments in so many countries is a challenge in itself, given the volume of information being generated. UNICEF is issuing a monthly newsletter, BFHI News, and WHO is collecting information to prepare a summary of worldwide action during the Initiative's first two years.

World Breastfeeding Week

29. The World Alliance for Breastfeeding Action is a global nongovernmental network of organizations - several of which in official relations with WHO - that was established in 1991 to protect the right of all children and mothers to breast-feed. It functions through a number of task forces dealing with interrelated programme approaches, including social mobilization, research, health care practices, education and training (see paragraphs 49 to 61), mother support groups, women and work (paragraphs 63 to 67), and compliance with the International Code of Marketing of Breast-milk Substitutes (paragraphs 68 to 156). As part of its global mobilization strategy to increase public awareness of breast-feeding's importance and to help achieve the goals of the Innocenti Declaration, the Alliance has twice organized World Breastfeeding Week (1 to 7 August). The themes for 1992 and 1993 were, respectively, the Baby-friendly Hospital Initiative, and women, work and breast-feeding. In recognition of the importance of this event and its emphasis on stimulating worldwide awareness and action in communities, the Director-General addressed to all concerned special messages on the relevant themes. WHO also participated in local action marking the week in a number of countries - more than 70 were reported to have celebrated it in 1993 - and helped with the worldwide distribution through its six regional offices of the Alliance's action folders, in English, French and Spanish. The Alliance has chosen the International Code and how it serves to protect breast-feeding as the theme for World Breastfeeding Week in 1994.

Action by other concerned parties

Consumer groups

30. **La Leche League International**, through its volunteer network of more than 7500 leaders and 30 000 members in 48 countries, is striving to increase the worldwide incidence and duration of breast-feeding and attainment of the operational targets of the Innocenti Declaration, the plan of action of the World Summit for Children, and the World Declaration and Plan of Action for Nutrition. The League, in the best of self-help traditions, is dedicated to aiding mothers support each other in breast-feeding. It has contributed for many years to appropriate WHO programmes, including nutrition, maternal and child health, and diarrhoeal disease control; it was admitted into official relations with WHO in January 1993. WHO is cooperating with La Leche League (Europe) in planning its first regional meeting (Vienna, July 1994).

Professional and other technical bodies

31. In response to growing concern about a decline in the practice of breast-feeding, the **International Confederation of Midwives** (a nongovernmental organization in official relations with WHO) adopted a policy at its international congress (Sydney, Australia, 1984) that spelled out the "great and urgent need for midwives to work much harder to increase the number of babies being breast-fed". Particular emphasis was given to the right of all babies to be breast-fed for at least the first six months of life; the right of all mothers to proper advice, help, encouragement and counselling for successful breast-feeding; the right of all families to accurate information about all aspects of breast-feeding; and the unique and vital role of the midwife in promoting breast-feeding. The Confederation's Executive Committee reiterated these principles (Vancouver, Canada, May 1993) as forming an important child survival strategy with significant health

advantages for the mother. It urged midwives to promote breast-feeding and assist mothers in successful breast-feeding through education and practical advice; encouraged provision of facilities for women to continue breast-feeding; and advocated education of other health care professionals, students of midwifery and auxiliary health workers about the art and practice of breast-feeding.

32. The nearly 3000 members of the **International Lactation Consultant Association** in 25 countries on five continents are lactation consultants, lay breast-feeding counsellors, and professionals in various fields that provide continuing education in breast-feeding. The Association was admitted into official relations with WHO in January 1993 in view of its continuing collaboration with a number of technical programmes, in particular, nutrition and diarrhoeal disease control. It is collaborating in the activities of the Baby-friendly Hospital Initiative, particularly in training and assessment; it also contributes to WHO documents and publications, and acts as an advocate for universal implementation of the International Code.

33. Since 1984 many members of both the Association and La Leche League International - but also physicians in private practice, nurses, midwives and others - have achieved formal certification as lactation consultants by the **International Board of Lactation Consultant Examiners** (a non-profit corporation established to develop and administer a voluntary certification programme for lactation consultants). This title conveys not only the message that the individual is supportive of breast-feeding but also that she or he is skilled in the technical management of the non-medical breast-feeding problems that are the primary causes of lactation failure. By September 1993 a total of nearly 4000 people in 30 countries had been certified. In July 1994 the certification examination is to be offered in some 40 sites in the United States, seven in Canada, five in Europe, 10 in Australia, two in New Zealand, and one each in Colombia, Hong Kong, Singapore, South Africa and Zimbabwe, either in Dutch, English, French, German, or Spanish.

Breast-feeding and child-spacing[1]

34. WHO and the Institute for Reproductive Health at Georgetown University, Washington, D.C., a WHO collaborating centre, are preparing a consolidated review of studies on breast-feeding and fertility undertaken in 10 countries, based on WHO's simplified methodology.[2] The objectives are to report on experiences in using the methodology and to determine what changes might be required in the light of experience. With the assistance of the Institute and the financial support of UNFPA, WHO has prepared a booklet for health workers responsible for educating and counselling women and couples about natural methods of fertility regulation for family planning.[3]

Exploring the economics of breast-feeding

35. Instituting universal breast-feeding and rooming-in in the maternity ward of the Jose Fabella Memorial Hospital in Manila, with its daily newborn census of 320 babies and daily average of 100 deliveries, resulted during the first year in savings equal to 8% of the hospital's entire budget. This and other examples of cost-effective changes in health care routines, in keeping with the principles of the Baby-friendly Hospital Initiative, suggest the usefulness of assessing the financial costs and direct savings related to breast-feeding practices in maternity wards and hospitals. WHO proposes that this should be done by developing a simple framework for assessing the direct monetary costs of breast-feeding practices in relation to the costs of "standard" nursery and bottle-feeding facilities. The primary target would be administrators and managers of individual facilities, and the overall objective would be to provide health managers with a tool to assist operational decision-making and organizational planning. Data collection for intra- and inter-country comparisons of the costs and direct savings of breast-feeding practices would be a secondary

[1] See also "Breastfeeding and child-spacing". Facts about infant feeding, November 1992, No. 2 (English, French and Spanish). Facts is a medium for conveying the results of the collaborative activities of WHO's global working group on infant feeding (see paragraph 5) to both the international health community and the general public.

[2] WHO simplified methodology for community-based calculation of the proportion of mothers at risk of conception by breast-feeding status (document MCH/85.15 Rev.1).

[3] Natural family planning: what health workers need to know (document WHO/MCH/FPP/93.2, English only).

objective. To the extent that resources permit, WHO is prepared to draw up guidelines for this purpose, in consultation with UNICEF and others concerned.

36. As epidemiologists hone their tools and improve their skills for understanding the effects of feeding mode on child health and development, health economists should increase their contribution by incorporating this experience in their calculations. Analyses of costs relating to infant-feeding mode too frequently stop at counting cans of formula and the value of related paraphernalia and calculating the time it takes a mother or child-minder to prepare and feed a breast-milk substitute. Information from developed and developing countries alike indicates that the cost-effectiveness equation of breast-feeding versus artificial feeding is considerably more complex.

37. Significantly lower infectious-disease morbidity and reduced allergies in children with a family history of atopic disease are two of breast-feeding's numerous advantages demonstrated in developed countries. Mounting evidence of breast-feeding's positive effect on health points to a practical but neglected means of lowering health care costs in these same environments. According to the United States National Center for Health Statistics, every year children in the United States make an estimated 87.4 million visits to paediatricians. More than 23 million of these are for just three symptoms - cough, fever and earache - which are among the conditions that breast-feeding helps to prevent or diminish. Health authorities in the State of Florida estimate that as much as US$ 25 million can be saved annually in health- and welfare-payments to mothers and children if the State's new breast-feeding support legislation (see paragraph 23) meets its objective. One can only begin to speculate about the implications of better development, at different ages, among breast-fed children born pre-term compared with a control fed artificially.[1] The fact that whole generations of infants in industrialized countries are being nourished "successfully" on infant formula does not mean that the effects on their health and development, and the related costs to all concerned, have been fully understood.

38. As noted in the *Eighth report on the world health situation*,[2] of the 140 million babies born each year, almost 4 million die within hours or days from perinatal causes. Approximately 95% of these deaths occur in developing countries. Acute respiratory infections are estimated to be the first cause of childhood mortality, claiming 4.3 million lives of children under the age of five annually. Almost 20%, or 800 000, of these deaths are due to pneumonia in the neonatal period. Diarrhoeal diseases remain a major cause of morbidity and mortality in infants and young children, resulting in 1500 million episodes of illness and more than 3 million deaths each year in children under five years of age. The terrible waste in human lives and resulting anguish to families are among the several "costs" to which inappropriate feeding practices greatly contribute. WHO estimates that some 1.5 million infant deaths every year could be averted through effective breast-feeding.

39. There are also a number of important short- and longer-term economic implications of breast-feeding where mothers are concerned. Breast-feeding protects a mother's health by reducing the risk of after-birth bleeding when suckling starts within the first hour, by helping to protect her against ovarian and breast cancer, by reducing her risk of anaemia, and by helping to space births when she fully breast-feeds and thus remains amenorrhoeic. An analysis of what these multiple advantages - or their absence - mean in purely economic terms would do much to enhance understanding about the relative advantages of infant-feeding modes and their financial and other implications, as much for the individual parent, child, family and employer (see paragraphs 63 to 67), as for society as a whole.

Breast-feeding and human immunodeficiency virus (HIV)

40. With the increasing prevalence of HIV infection around the world, more and more women of child-bearing age are becoming infected and hence are capable of passing the infection on to their unborn or

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[1] Lucas, A. et al. Breast milk and subsequent intelligence quotient in children born preterm. *Lancet*, 1992, **339**: 261-264.

[2] *Implementation of the Global Strategy for Health for All by the Year 2000, second evaluation: eighth report on the world health situation*. Volume 1: Global Review. Geneva, World Health Organization, 1993.

newborn babies. Roughly one-third of babies born to HIV-infected mothers become infected. Much of this mother-to-baby transmission occurs during pregnancy and delivery, although recent data confirm that some of it occurs through breast-feeding.

41. WHO and UNICEF jointly convened a technical consultation in 1992 to consider all available data on HIV transmission and breast-feeding. The consultation concluded[1] that where infectious disease and malnutrition are the main cause of infant deaths and the infant mortality rate is high, the usual advice given to mothers should be that they breast-feed their babies. This is because their baby's risk of HIV infection through breast milk is likely to be lower than the risk of death from other causes if the baby is not breast-fed. Women in these circumstances who know they are HIV-infected, and for whom alternative feeding might be an appropriate option, should seek advice from their health-care providers in making their decision on how to feed their infants most safely. On the other hand, in circumstances where the main cause of death during infancy is not infectious disease and the infant mortality rate is low, the consultation concluded that the usual advice to pregnant women known to be infected with HIV should be to use a safe feeding alternative for their baby rather than to breast-feed; voluntary and confidential HIV testing, including pre- and post-testing counselling, should be available to the women, and they should be encouraged to seek testing before delivery.

PROMOTION AND SUPPORT OF APPROPRIATE AND TIMELY COMPLEMENTARY FEEDING (WEANING) PRACTICES WITH THE USE OF LOCAL FOOD RESOURCES

Exclusive breast-feeding as an infant-feeding ideal: understanding better the scientific basis

42. The concept of "exclusive breast-feeding" - giving an infant no other food or liquid than breast milk, not even water, during the first four to six months of life[2] - is anchored in the Innocenti Declaration (see paragraph 26). However, exclusive breast-feeding during the first half-year of life remains an elusive goal in many of the environments even most favourable to breast-feeding (Table 3). Parents and health workers alike, even when convinced that this is the theoretical norm, may have considerable difficulty in applying it in everyday behaviour, whether because tradition dictates that infants receive other liquids or foods during this period, out of ignorance of an infant's true nutritional requirements, or owing to other limiting social or economic factors. The result, at any rate, is greater - often significantly greater - infant morbidity and mortality in this age group than would be expected if infants were exclusively breast-fed during the entire four- to six-month period.

43. Important additional scientific evidence is now available based on two years of preparatory work by an expert committee on the use and interpretation of anthropometry, which WHO convened (Geneva, 1-8 November 1993) to consider major outstanding questions, including reference data on pregnant and lactating women, fetal growth, infants, children, adolescents, adults, and the elderly, and guidelines for their use and interpretation.[3] The work of the committee's subcommittee on infants strongly suggests that the present WHO growth reference for infants, which is based on a predominantly bottle-fed population, is inappropriate and that its application interferes with the promotion of exclusive breast-feeding for the first four to six months of life.

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[1] Consensus Statement from the WHO/UNICEF Consultation on HIV Transmission and Breast-feeding. *Weekly Epidemiological Record*, 1992, **67**(24): 177-179.

[2] For a summary of WHO recommendations on breast-feeding and the giving of supplementary fluids, see "Breast-feeding and the use of water and teas". Facts about infant feeding, August 1992, No. 1. See also Recommended length of exclusive breastfeeding, age of introduction of complementary foods and the weanling dilemma (document WHO/CDD/EDP/92.5, English only).

[3] Physical status: the use and interpretation of anthropometry. Report of an expert committee. Geneva, World Health Organization (in preparation).

TABLE 3. PERCENTAGE OF INFANTS EXCLUSIVELY BREAST-FED FOR UP TO THREE MONTHS, IN SELECTED DEVELOPING COUNTRIES

		%
Burundi	-	89
Uganda	-	70
Bolivia	-	59
Morocco	-	48
Botswana	-	41
Indonesia	-	39
Mexico	-	38
Egypt	-	38
Jamaica	-	35
Jordan	-	32
Peru	-	32

Source: Demographic and Health Surveys and WHO.

44. In reviewing published growth data on infants for whom WHO feeding recommendations are followed and who live under favourable conditions, the subcommittee found significant differences between the growth patterns of these infants and the pattern reflected in the current international reference. One of the negative consequences of such comparisons is that breast-feeding mothers and health-care providers can easily misinterpret as faltering growth the normal pattern of growth of breast-fed infants. This can lead to the premature introduction of solid foods and the erroneous information of mothers that their breast milk is not adequate to meet their infants' nutritional requirements. The result is a twofold risk to children: increased morbidity and mortality from infectious diseases, particularly where living conditions are characterized by poor environmental sanitation and overcrowding; and compromised nutritional status. Alternatively, health practitioners may misinterpret true growth failure in a breast-fed infant as the "normal negative deviation" in growth expected when breast-fed infants are compared to the present reference population. Given the short- and long-term consequences of growth failure, the dangers both of the premature introduction of other foods and their undue delay - often described as the "weanling dilemma" - merit continued close investigation. Use of the present WHO reference data appears to accentuate the difficulties of avoiding both these extremes rather than helping to ensure optimal infant nutritional management. The need for a revised reference thus seems clear; collection of the information needed to complete its development should proceed with all deliberate speed.

Food safety issues in infant and young child feeding

45. In order to raise awareness of the importance of food safety for preventing diarrhoea, WHO has prepared a comprehensive review[1] of the role of food in transmitting diarrhoeal agents. A recent WHO document provides basic principles for safe preparation of foods for infants and young children.[2] Following up a 1987 consultation on health education in food safety, a methodology to ensure food-safety-conscious behaviour has been tested in pilot projects in Argentina, Guatemala, Indonesia, Pakistan, Peru and Venezuela.[3] Within the framework of the Joint FAO/WHO Food Standards Programme, the Codex

[1] Motarjemi Y. et al. Contaminated weaning food: a major risk factor for diarrhoea and associated malnutrition. *Bulletin of the World Health Organization*, 1993, 71(1): 79-92. Facts about infant feeding, April 1993, No. 2, also presents a summary of the main points.

[2] Motarjemi Y. et al. Contaminated food: a hazard for the very young. *World Health Forum*, 1994, 15(1): 69-71.

[3] Application of the hazard analysis critical control point (HACCP) system for the improvement of food safety: WHO-supported case studies on food prepared in homes, at street-vending operations, and in cottage industries (document WHO/HPP/FNU/93.1, English only).

Alimentarius Commission in 1991 adopted Guidelines for formulated supplementary foods for older infants and young children.

46. Monitoring the presence of mycotoxins, pesticide residues and industrial pollutants in breast milk and other foods for children is important in view of the association between ingestion of contaminants, to which infants and children may be particularly sensitive, and acute and chronic noncommunicable diseases. WHO, in collaboration with UNEP and FAO, is implementing the Food Contamination Monitoring and Assessment Programme (GEMS/Food). The objective is to provide governments, and institutions and bodies concerned, with accurate up-to-date information on levels and trends of contaminants in food, their contribution to total human exposure, and their significance for public health and trade.[1] WHO is also preparing a review of the level of chemical contaminants in breast milk to provide governments with a basis for taking appropriate action to protect infants and children.

47. Interest in traditional food-processing technology, as it relates to weaning foods, lies in the potential for reducing contamination by pathogens and for increasing energy density. WHO has prepared a critical review[2] of existing knowledge in this regard. It refers particularly to malting and fermentation, and includes an examination of their prevalence, their effectiveness in increasing energy density, and their acceptability. A WHO-supported study in north-eastern Brazil examined infant-feeding practices in a poor, periurban population, and their relation to the prevention and control of diarrhoea.

Research on infant and young child feeding

48. WHO supports a geographically broad and technically varied programme of research on approaches to promoting improved feeding practices and nutrition. Studies have been completed, or are under way, in the areas of breast-feeding, complementary feeding practices, and supplementation with vitamin A and other micronutrients. For example, a review[3] of available information on the timing of complementary feeding, completed in 1992, confirmed the validity of the recommendation of a four to six month range based on the growth and development needs of the individual infant. At the same time, however, the review signalled the importance of continued study to improve understanding of the risks and benefits of beginning complementary feeding between four and six months of age. In 1993 an informal consultation was held to determine research priorities in complementary feeding.[4]

STRENGTHENING OF EDUCATION, TRAINING AND INFORMATION ON INFANT AND YOUNG CHILD FEEDING

Training activities linked to the Baby-friendly Hospital Initiative

49. WHO considers training health workers and administrators to be one of the most effective means of meeting the Innocenti Declaration's second operational target (see paragraph 26). Building on the foundations of the Initiative, WHO is striving to develop an overall training strategy for both breast-feeding and lactation management, in close collaboration with UNICEF and other interested agencies and organizations. The aim is to contribute to the creation of a critical mass of trained trainers and staff, by focusing on support, in countries and regions, to major maternity hospitals and institutions responsible for maternal and child health.

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[1] For information on estimated total dietary intakes during the 1980s of pesticides, PCBs, lead, cadmium and mercury, see Assessment of dietary intake of chemical contaminants (document WHO/HPP/FOS/92.6, English only).

[2] The potential of traditional technologies for increasing the energy density of weaning foods: a critical review of existing knowledge with particular reference to malting and fermentation (document WHO/CDD/EDP/92.4).

[3] Recommended length of exclusive breast-feeding, age of introduction of complementary foods and the weanling dilemma (document WHO/CDD/EDP/92.5).

[4] Report on the joint CDD/NUT informal consultation: improving complementary feeding practices for the prevention of diarrhoea (unpublished document).

50. Since 1991 WHO, in cooperation with UNICEF, has been preparing a 40-hour course in breast-feeding counselling for health workers who are responsible for the care of mothers and young children in health centres, maternity facilities and hospitals.[1] The focus is on the clinical and interpersonal skills needed to support mothers to breast-feed successfully. Lectures and clinical practice alternate with demonstrations, small-group sessions and role-play. The course is based on experience showing that 40 hours is the minimum time required to make significant changes in health workers' attitudes and improve their practices. The course was pre-tested first in the Philippines, and then in Jamaica and Bangladesh, preceded by a five-day preparatory session for four or five local trainers, who then conducted the course under supervision. The first formal course in a country was held in the Islamic Republic of Iran in December 1993. In addition to furthering the Baby-friendly Hospital Initiative, the course provides a more specialized cadre of health workers with skills that will enable them to help mothers throughout the two years or more of the recommended period of breast-feeding.

51. WHO and UNICEF, in collaboration with Wellstart International (a WHO collaborating centre) and the World Alliance for Breastfeeding Action (see paragraph 29), organized a workshop on lactation management and the Baby-friendly Hospital Initiative for participants from eastern and central European countries (Saint Petersburg, Russian Federation, August-September 1993). Policy-makers, health professionals, researchers, experts in lactation management and members of mother-support groups - 60 persons from 24 countries - took part in three consecutive sessions: one to train a cadre to assist other countries; one to identify and fill gaps in knowledge of lactation management; and one to introduce the Initiative. The workshop also provided an opportunity to prepare Russian-language editions of two popular WHO publications, the joint WHO/UNICEF statement on breast-feeding and the role of maternity services (paragraph 58) and *Infant feeding: the physiological basis* (paragraph 59), the latter with funds from USAID provided through Wellstart International. To ensure sustained momentum after the Saint Petersburg workshop, immediate follow-up included the consideration of hospitals in Belarus, the Russian Federation and the Ukraine as demonstration sites for implementation of the Initiative. Two UNICEF/WHO workshops for staff from these institutions on lactation management and the Initiative are scheduled to be given in early 1994 by a Polish nongovernmental organization, EKO OKO, at the Institute for Mother and Child in Warsaw, a WHO collaborating centre.

52. Thirty-five doctors, nurses, midwives and nutritionists in **Lebanon** also received training in lactation management and the Baby-friendly Hospital Initiative, with support from UNICEF and WHO, during an 80-hour course. The course curriculum was established by the International Baby Food Action Network (IBFAN)[2] and UNICEF. Much relevant information and educational material is now available in Arabic, including a video film produced by UNICEF Beirut. Another WHO/UNICEF-supported training session took place in **China** in 1992 in preparation for the first round of hospital assessments (see paragraph 27), in support of the Government's goal of a national rate of 80% for exclusive breast-feeding during the first four to six months of life by the year 2000. In 1992-1993 WHO also provided technical support for training on the Initiative in **Egypt**, **Jordan** and the **Philippines**, and helped to establish a regional lactation management training centre in the **Philippines** for the Western Pacific; centres are being set up for French-speaking Africa and the Eastern Mediterranean. In 1993 WHO sponsored several participants at the four-week advanced breast-feeding and lactation management course at the Institute of Child Health in London (a WHO collaborating centre) and a WHO staff member served on the faculty.

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[1] Breastfeeding counselling: a training course (documents WHO/CDR/93.3-93.6; French and Spanish in preparation).

[2] IBFAN is a worldwide coalition of citizen groups working for better infant health through the promotion of breast-feeding and elimination of inappropriate marketing and distribution of breast-milk substitutes, bottles and teats. Founded in 1979, it now counts more than 140 member organizations in 70 countries.

Information for decision-making

Monitoring trends in the prevalence and duration of breast-feeding

53. As part of its global nutrition surveillance activities, WHO gathers and periodically publishes information on the worldwide prevalence and duration of breast-feeding. These data are used to review global, regional and national breast-feeding trends, their implications for fertility and child-spacing (see also paragraph 34), and their relation to child morbidity and mortality. WHO's breast-feeding data bank, with information from over 2000 surveys, studies and review articles covering 156 countries and territories, was until recently structured according to the following indicators: prevalence of breast-feeding (once or more), median duration of breast-feeding, and proportion of children breast-fed at 3, 6, 12, 18 and 24 months of age.

54. A major obstacle to collecting data on the prevalence and duration of breast-feeding has been the lack of uniformity in nomenclature and indicators used to define and describe infant-feeding modes. Significant progress in removing this primary methodological stumbling-block has been achieved since 1990 with the development of standard breast-feeding indicators and methods for using them to collect accurate data from households[1] and in health care facilities[2] (see box below). The indicators are being field-tested while the methodology for their measurement is further refined. Meanwhile, the partners in their development - WHO, UNICEF, SIDA, and USAID - are promoting their worldwide adoption to facilitate comparison of data from different periods in a given country and to increase confidence among programme managers about success achieved in altering attitudes and practices.

55. In June 1993 Wellstart International's Expanded Program on Breastfeeding hosted, on WHO's behalf, a meeting to assess monitoring of breast-feeding trends and to decide on future action.[3] On the basis of a consensus in favour of WHO retaining and reinforcing its responsibility for monitoring breast-feeding trends, a thorough review and restructuring of its data bank are now under way thanks in part to funds provided by USAID. In addition to introducing the new indicators, this reform includes redefining and expanding the system's scope, list of products and users, and preparing appropriate user documentation for wide dissemination in English, French and Spanish. A four-year period has been set to facilitate full transition from the old to the new data banks.

56. WHO is also operating data banks in anthropometry (paragraph 43), iodine deficiency, nutritional anaemia in women, vitamin A deficiency, and low birth weight.

Formulating infant-feeding policy

57. WHO's cooperation with UNICEF in the field of infant and young child feeding, with support from bilateral development agencies such as SIDA and USAID, led to the convening of a technical meeting (Geneva, June 1990) to review the scientific basis of breast-feeding strategies and experience with them. Topics included breast-feeding prevalence and trends, health care systems and practices, lactation management training, mother support groups, information, education and training, and women, work and breast-feeding (see paragraphs 63 to 67). A summary of the meeting's discussions and relevant recommendations is now available in a single volume.[4]

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[1] Indicators for assessing breast-feeding practices: report of an informal meeting, 11-12 June 1991, Geneva, Switzerland (document WHO/CDD/SER/91.14, English and French).

[2] Indicators for assessing health facility practices that affect breastfeeding: report of the Joint WHO/UNICEF Informal Interagency Meeting, 9-10 June 1992, WHO, Geneva (document WHO/CDR/93.1, English; French in preparation).

[3] Participants included representatives of UNICEF, Demographic and Health Surveys, International Science and Technology Institute, La Leche League International, American Public Health Association, Institute for Reproductive Health, and USAID.

[4] Breast-feeding: the technical basis and recommendations for action (document WHO/NUT/MCH/93.1).

STANDARD BREAST-FEEDING INDICATORS

Breast-feeding indicators derived from households	Indicators for assessing health facility practices that affect breast-feeding
Exclusive breast-feeding rate Proportion of infants less than 4 months of age who are exclusively breast-fed Infants <4 months (<120 days) of age who were exclusively breast-fed in the last 24 hours Infants <4 months (<120 days) of age	**Exclusively breast-fed by natural mother rate** Number of infants exclusively breast-fed by their natural mothers from birth to discharge no. of infants discharged
Predominant breast-feeding rate Proportion of infants less than 4 months of age who are predominantly breast-fed Infants <4 months (<120 days) of age who were predominantly breast-fed in the last 24 hours Infants <4 months (<120 days) of age	**Breast-milk substitutes and supplies receipt rate** Number of mothers who received breast-milk substitutes, infant-feeding bottles, or teats at any time prior to discharge or during a prenatal visit to this facility no. of mothers discharged
Timely complementary feeding rate Proportion of infants 6-9 months of age who are receiving breast milk and complementary foods Infants 6-9 months (180-299 days) of age who received complementary foods in addition to breast milk in the last 24 hours Infants 6-9 months of age (180-299 days) of age	**Bottle-fed rate** Number of infants who received any food or drink from a bottle in 24 hours prior to discharge no. of infants discharged
Continued breast-feeding rate (1 year) Proportion of children 12-15 months of age who are breast-feeding Children 12-15 months of age who were breast-fed in the last 24 hours Children 12-15 months of age	**Rooming-in rate** Number of infants rooming-in 24 hours a day, beginning within 1 hr of birth, not separated from mother for more than 1 hr at any time no. of infants discharged
Continued breast-feeding rate (2 years) Proportion of children 20-23 months of age who are breast-feeding Children 20-23 months of age who were breast-fed in the last 24 hours Children 20-23 months of age	**Breast-fed rate** Number of infants breast-feeding in 24 hours prior to discharge no. of infants discharged
Bottle-feeding rate Proportion of infants less than 12 months of age who are receiving any food or drink from a bottle Infants <12 months (<366 days) of age who were bottle-fed in the last 24 hours Infants <12 months (<366 days) of age	**Timely first-suckling rate** Number of infants who first suckled within 1 hour of birth no. of infants discharged
	Exclusively breast-milk fed rate Number of infants exclusively breast-milk fed from birth to discharge no. of infants discharged
	Pacifier use rate Number of infants who received pacifiers at any time prior to discharge no. of infants discharged

58. Just four years after the appearance of the joint WHO/UNICEF statement on breast-feeding and maternity services,[1] which is the centrepiece for the Baby-friendly Hospital Initiative, it is available, or in preparation, in more than 40 language editions. Nearly half a million copies are in print, including 100 000 in English, 40 000 each in French and Spanish, and 12 000 in Russian. Particularly satisfying is the large number of local language editions, for example from central and eastern Europe and developing countries, including eight from the Indian sub-continent, that are being distributed and used in connection with promotion and training activities for the Initiative.

59. In July 1990 WHO published a review of the scientific evidence for dealing with the many questions concerning the appropriate feeding of infants during the first year of life that includes more than 500 references to the literature. The review is now available, or in preparation, in 13 language editions.[2] It is on the list of standard reference works of several organizations, including the Indonesian Society for Perinatology, the Australian Lactation Consultant Association, the International Lactation Consultant Association (paragraph 32), and the International Board of Lactation Consultant Examiners (paragraph 33). The University of Belgrade Medical School is using it as a paediatric textbook.

60. Advances in understanding the importance of vitamin A (see paragraphs 9 to 11) in the broader realm of child health and survival, and renewed commitment by national health authorities and international organizations and bodies provided the impetus for preparing a third revised and expanded edition of WHO's best-selling field manual for assessing vitamin A deficiency.[3]

Review of the breast-feeding content of medical textbooks

61. Together with IBFAN and the Institute for Reproductive Health, WHO has undertaken a desk review of the breast-feeding content of the main medical textbooks in use around the world. Information on breast-feeding from 23 of them was analysed in the light of the latest scientific information and actual clinical experience. Preliminary results show an alarming gap between the two and thus a pressing need to revise and update textbooks accordingly. A final report is expected by mid-1994; on this basis, publishers, editors and authors of selected textbooks will be approached to inform them of the study's findings and recommendations, and to enlist their support in making appropriate changes in future editions. In order to help ensure the success of this exercise, the International Federation of Gynecology and Obstetrics, the International Pediatric Association, and the International Confederation of Midwives (paragraph 31) - all organizations in official relations with WHO - are being asked for support during the next phase.

DEVELOPMENT OF SUPPORT FOR IMPROVED HEALTH AND SOCIAL STATUS OF WOMEN IN RELATION TO INFANT AND YOUNG CHILD FEEDING

Incorporating women's health and related issues into WHO programmes

62. Within WHO, as outside, interest is growing in the links between women's health, the health of families and communities, and the social and economic development of societies. Neglect of women's health stems from a failure to recognize, or to take into account, specific needs, whether determined by the physiological differences between men and women or cultural norms that may contribute to social and economic inequalities between the sexes. These questions are being taken up by WHO in many of its programmes, individually or collectively, in response to the policy decisions of its governing bodies.

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[1] *Protecting, promoting and supporting breast-feeding: the special role of maternity services.* A joint WHO/UNICEF statement. Geneva, World Health Organization, 1989.

[2] Akré, J. (ed.). *Infant feeding: the physiological basis.* (Supplement to Vol. 67 of the *Bulletin of the World Health Organization*), Geneva 1990.

[3] Sommer, A. *Field guide to the detection and control of xerophthalmia*, 2nd ed. Geneva, World Health Organization, 1982. Third edition in preparation in English, French and Spanish under the title "Vitamin A deficiency and its consequences: a field guide to their detection and control".

Institutional mechanisms have been put in place to strengthen the Organization's contribution to improving the status of women, including designation of focal points on "Women, health and development" at headquarters and in each of the six regional offices. The headquarters focal point serves as moderator of an interdivisional steering committee, which strives to maximize the impact of eleven global programmes in meeting the health needs of women. Most recently, the Forty-fifth World Health Assembly established a Global Commission on Women's Health. The fruit of these many efforts has important implications for women, and for the health and nutrition of families, particularly infants and children.

Women, work and breast-feeding

63. On a number of occasions since 1948 the Health Assembly has urged the Organization's Member States to enforce existing, or adopt new, measures to promote and facilitate breast-feeding among employed women. In May 1992 the Health Assembly requested the Director-General to consider, in collaboration with ILO, the options available in the health and other interested sectors for reinforcing the protection of women in the workplace in view of their maternal responsibilities (resolution WHA45.34).

64. This was considered a timely request. Once before - in 1952, in collaboration with WHO - ILO reviewed and updated its original 1919 standard dealing with maternity protection by adopting Convention 103 and Recommendation 95. A second review and updating process was under way, and WHO had been invited to contribute to ILO's law-and-practice report that was to launch the tripartite - government, employer and worker - consultation process. However, at its 258th session in November 1993, the Governing Body of the International Labour Office decided not to retain a proposal to include a revision of Convention 103 and Recommendation 95 on the agenda of the 1995 session of the International Labour Conference. This decision notwithstanding, cooperation with ILO continues in an effort to inform all parties concerned about the multiple benefits of breast-feeding for infants and mothers, and the implications for maternity protection in the workplace.

65. In a special message on the occasion of World Breastfeeding Week 1993 (paragraph 29), the theme of which was creating a "mother-friendly" workplace, the Director-General emphasized the importance of alerting the social partners to the advances in scientific knowledge and practical understanding of breast-feeding's function in promoting human health and development, and to the implications for social policy. Maternity protection in the workplace - and specifically the promotion of breast-feeding - assume greater significance than the relatively limited functions of nutrition and child care originally appeared to suggest. As employers strive to contain costs, they should be careful to take into account the "value added" by social measures on behalf of women workers, such as adequate maternity leave, flexible working schedules, job-sharing, and child-care facilities at or near the workplace. These measures increase satisfaction and productivity, reduce turnover, absenteeism and tardiness, and improve loyalty and morale. And to the extent that they enhance opportunities for employed women to continue breast-feeding, there is a real opportunity for employers to reduce their health costs (see paragraphs 35 to 39). Working outside the home and breast-feeding are compatible when a mother has the support of her family and her employer.[1]

66. On 19 October 1992 the Council of the European Communities adopted Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breast-feeding. According to the Directive such workers "must be considered a specific risk group in many respects, and measures must be taken with regard to their safety and health". Their protection should nevertheless not "work to the detriment of directives concerning equal treatment for men and women". Operative articles cover *inter alia* protection of pregnant and breast-feeding workers from performing duties for which an assessment has revealed a risk of exposure that would jeopardize safety or health, to agents and working conditions listed in an annex; exemption from performing night work during pregnancy and for a period after childbirth; measures to ensure that workers "are entitled to a continuous period of maternity leave of at least 14 weeks allocated before and/or after confinement in accordance with national legislation and/or practice"; and

[1] See chapter 6, "Women, work and breast-feeding", in Breast-feeding: the technical basis and recommendations for action (document WHO/NUT/MCH/93.1, pp. 93-112).

time off, with no loss of pay, for antenatal examinations; prohibition of dismissal; and protection of employment rights. Compliance with the Directive is required no later than October 1994.

67. The Breastfeeding Promotion Committee of the Healthy Mothers, Healthy Babies Coalition in the United States produced in 1993 an information folder[1] providing practical examples of what a number of large private corporations and government agencies are doing to create a work environment that is supportive of breast-feeding. Emphasizing the benefits both to employers and to mothers and their children, the folder provides practical tips about helping breast-feeding employees and a list of resources for breast-feeding education, management and support. As reported earlier, the 1992 amendment to the Child Nutrition Act in the United States may include providing funds to employers to assist in the distribution of breast pumps to breast-feeding women (paragraph 22).

APPROPRIATE MARKETING AND DISTRIBUTION OF BREAST-MILK SUBSTITUTES

68. The Thirty-fourth World Health Assembly in May 1981 adopted the International Code of Marketing of Breast-milk Substitutes[2] in the form of a recommendation and urged all Member States *inter alia* to translate it into national legislation, regulations or other suitable measures; to involve all concerned parties in its implementation; and to monitor compliance with it.

69. The International Code provides for regular reporting to the Director-General (Article 11, paragraph 6) and by the Director-General to the Health Assembly (Article 11, paragraph 7) on the status of its implementation. In addition, the Thirty-fourth World Health Assembly requested the Director-General to report to the Health Assembly in May 1983 on the status of compliance with the Code at country, regional and global levels, and to make proposals for action, if necessary. Accordingly, the Director-General reported to the Thirty-fifth, Thirty-seventh, Thirty-ninth, Forty-first, Forty-third and Forty-fifth World Health Assemblies (in 1982, 1984, 1986, 1988, 1990 and 1992)[3] on steps taken by Member States to give effect to the Code, and to the Thirty-sixth World Health Assembly (1983)[4] on the status of compliance with it. The information given below thus makes up the eighth report on the subject, and the seventh consecutive biennial report, since the Code's adoption 13 years ago.

70. As in previous reports, most of the information has been provided by Member States, either in direct communications to the Director-General, via the regional offices and regional committees, or in statements made by their representatives. Information presented in each report is cumulative; an overall picture may thus be obtained by referring to previous reports, which provide a detailed account of the steps taken by more than 160 countries and territories - individually, and in some cases collectively, through regional and interregional forums. Relevant information from progress reports between 1982 and 1990 has been combined into a single document.[5] Complementing this synthesis is a second paper[6] that focuses on the Code's individual articles and describes how each has been given expression through national legislation and other suitable measures.

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[1] What gives these companies a competitive edge? National Healthy Mothers, Healthy Babies Coalition, Washington, D.C., 1993.

[2] Resolution WHA34.22 and document WHA34/1981/REC/1, Annex 3.

[3] Respectively, documents WHA35/1982/REC/1, Annex 5; WHA37/1984/REC/1, Annex 5, part II; WHA39/1986/REC/1, Annex 6, part 1; EB81/1988/REC/1, Annex 10, part II; WHA43/1990/REC/1, Annex 1, part II; and WHA45/1992/REC/1, Annex 9.

[4] Document A36/7.

[5] The International Code of Marketing of Breast-milk Substitutes: synthesis of reports on action taken (1981-1990) (document WHO/MCH/NUT/90.1, English, French and Spanish).

[6] The International Code of Marketing of Breast-milk Substitutes: survey of national legislation and other measures adopted (1981-1991) (document WHO/HLE/NUT/92.1, English and French).

African Region

71. In **Burkina Faso** the importation and sale of feeding bottles and teats has been governed by legal provisions since 1970, and regulations concerning the packaging and labelling of breast-milk substitutes were promulgated in 1987. In 1991-1992 a multisectoral committee, including representatives of authorities for health, justice, trade, information, and finance, examined steps to be taken to give effect to the International Code in the light of evolving circumstances. With support from the IBFAN Code Documentation Centre (see paragraph 125), a draft national code governing the sale, distribution, promotion, labelling, availability and quality of breast-milk substitutes was prepared, and approved by the Council of Ministers on 28 July 1993.

72. As one of a number of measures it is taking to protect breast-feeding, the Government of **Cape Verde** has prepared draft regulations in response to what it qualifies as "an invasion of breast-milk substitutes owing to recent trade liberalization policy". The regulations, for which WHO's technical contribution was requested, include complementary foods in their scope in an effort to ensure that these products are not used for feeding infants under six months of age.

73. In January 1992 the Government of **Côte d'Ivoire**, with the support of WHO and UNICEF, organized a meeting with local distributors of companies affiliated with the International Association of Infant Food Manufacturers (see also paragraph 147). After this meeting, the Government decided to prohibit donations of breast-milk substitutes in both public and private health services as from 1 February 1992.

74. In 1991 the Ministry of Public Health and Population in **Gabon**, as part of a national plan to protect and promote sound infant-feeding practices in accordance with the commitments made by heads of State at the World Summit for Children (paragraph 2), ordered all infant-food companies to refrain from distributing free or low-priced infant formula or other foods for infants to any public or private health care institution; established a coordinating committee, with the participation of WHO and UNICEF and in association with manufacturers' and distributors' local representatives, to oversee the strict application of the order; prohibited any promotion of milks or other foods for infants; and began a campaign to increase awareness among mothers, families, health workers and national authorities about the benefits of breast-feeding.

75. Although a national code of marketing had been drafted in **Sierra Leone** in the 1980s, the Government reports there was no meaningful follow-up until 1992, with the establishment of a national committee for the Baby-friendly Hospital Initiative. It consists of representatives from the Department of Health, nongovernmental groups including the Sierra Leone Infant Feeding Action Group (an IBFAN affiliate), and UNICEF and WHO. The committee's subgroup responsible for advocacy of the International Code has begun work on a new national draft code, which is expected to receive formal approval from the departments concerned by the end of 1993. There are no national laws dealing with food in general or with imported infant formula in particular. Steps are being taken to stop advertising of infant formula to the general public, and radio talks and discussions on breast-feeding in the major local languages are increasing.

76. A press release issued in July 1993 by the Department of National Health and Population Development in **South Africa** called attention to Article 7.4 of the 1986 South African Code of Ethics for the Marketing of Breast-milk Substitutes, which stipulates that no samples of breast-milk substitutes may be supplied to health workers except for purposes of professional evaluation. Noting that this article concerned physicians and paediatricians as well, the Department decided that providing samples to this category of health worker would cease. Issuing samples of breast-milk substitutes to hospitals and clinics had already been phased out by the end of 1992, after the request by WHO and UNICEF to this effect (paragraph 25).

77. Officials from the **United Republic of Tanzania**, after participating in a course organized by the IBFAN Code Documentation Centre in February 1992, prepared relevant draft regulations for adoption under the Food (Control of Quality) Act, 1978. These texts were reviewed and amended during a workshop organized by the Tanzania Food and Nutrition Centre, with support from WHO and UNICEF, for 40 persons representing health, food and related sectors, and representatives of the media, trade unions

and community development. The draft regulations await formal approval of the National Food Control Commission before being submitted to Parliament for adoption.

Region of the Americas

78. No advertising of infant formula is permitted in the **Bahamas**, where an informal agreement between Government and representatives of infant-formula manufacturers has been reached. Marketing activities, including distribution of product samples, are not permitted in hospitals and maternity clinics, although manufacturers' booklets are available advocating breast-feeding and promoting use of their products for those women who cannot breast-feed. Among the health-care practices described as adversely affecting breast-feeding are routine feeding of dextrose water and formula during the immediate postpartum period. Paediatricians are preparing a policy to discontinue these practices and encourage, unless contraindicated, immediate postpartum breast-feeding of all babies. A "breast-feeding club" initiative was launched in 1992-1993 to reinforce breast-feeding promotion in maternity wards. A newly established national nutrition committee is updating a statement on breast-feeding.

79. The National Program for the Promotion of Breastfeeding in **Belize** advocates exclusive breast-feeding during the first four to six months of life through pre- and post-partum parenting classes. A summary of the International Code, concerning which no legislation has been adopted, has been distributed to health workers. Most of its provisions are reportedly not applied, however, and the health structure has not been modified to facilitate its implementation. Distribution of formula samples in hospitals and maternity clinics continues as part of routine marketing practices.

80. The Department of Health in **Bermuda** describes as a "gentleman's agreement" with infant-formula distributors the approach used to ensure that the International Code is not contravened. However, it also reports that one company provides free formula and gift packs in hospitals for bottle-fed babies.

81. Ministry of Health Resolution 0067/1984 gives effect to the International Code in **Bolivia**. Interinstitutional agreements for applying these standards exist but are not yet fully implemented. Distribution of samples or other marketing activities by formula manufacturers are not allowed in hospitals.

82. The International Code has been distributed in the **Cayman Islands** although no legislation has been adopted in this connection. Promotional posters, contact with marketing personnel, and sponsorship of professional services by commercial interests are not permitted in the health services. Distribution of samples of breast-milk substitutes continues, however.

83. The Government of **Chile** reports that, in addition to voluntary observation of the International Code by local marketers and distributors of infant foods, legislation was adopted in December 1992 to regulate the Code's application within the national health structure. Additional legislation concerning its monitoring is under consideration. Distribution of samples of breast-milk substitutes or other promotional activities are not allowed in the country. The main activities of the national breast-feeding commission are implementation of the Baby-friendly Hospital Initiative, dissemination of the Code and preparation of related educational materials.

84. Ten years after the adoption of stringent standards[1] in **Colombia** to control the marketing of breast-milk substitutes, the promotion of these products was said to be still carried out in almost all maternity institutions. To remedy the situation the Government adopted Decree No. 1397[2] in August 1992, concluded new agreements with infant-formula manufacturers to put an end to free product distribution, and conducted workshops to familiarize health workers with the International Code. At the same time, Decree No. 1396[2] established the National Council for the Promotion of Breast-feeding, under the Ministry of Health; its functions include guidance and encouragement for breast-feeding policy, dissemination of

[1] *International Digest of Health Legislation*, 1981, 32(3): 468-471.

[2] *International Digest of Health Legislation*, 1993, 44(4): 637.

information and education of the general public, and advice on establishing committees to promote breast-feeding.

85. Draft legislation is under consideration in **Costa Rica** to update and strengthen national action giving effect to the International Code, including a special regulation on whole-milk formulas in view of their widespread use in infant feeding. The Ministry of Health has prepared a statement supporting compliance with the Code in health institutions. A member of the National Breast-feeding Committee sits on the panel responsible for evaluating advertising for foods for infants. No samples of breast-milk substitutes may be distributed in hospitals or clinics.

86. The Ministry of Public Health in **Cuba** has sole responsibility for disseminating information relating to infant feeding. The aim of the International Code has been adopted as part of national health policy for ensuring adequate infant nutrition. The Government manufactures the country's only bona fide breast-milk substitute, which is available only by prescription for infants who cannot be breast-fed. Application of the Code in its entirety is reinforced through supervision. International donations of modified milks for paediatric hospitals are used exclusively for feeding infants who are not younger than four months of age.

87. New legislation in **Ecuador** intended specifically to protect breast-feeding is being approved. In 1993 the country's First Lady signed a "code of behaviour", which disallows free distribution of products, with representatives of companies that market infant formula domestically. Health workers are informed of relevant new laws and agreements through special training sessions. However, it is reported that the Code is not applied completely and that loopholes exist owing to lack of specific regulations.

88. In July 1992 the Ministry of Health in **Guatemala** organized a training course on the International Code for its legal advisers, physicians and nutritionists. A WHO legal officer was involved in technical aspects of this exercise, which concentrated on solving problems encountered in implementing various provisions of the Code through existing national legislation, Decree-Law No. 66-83 of 6 June 1983[1] and Government Order No. 841-87 of 30 September 1987.[2] The latter deals *inter alia* with the use and consumption of breast-milk substitutes and complementary foods for infants, dissemination of related information, and responsibilities of marketing personnel and public or private health care providers.

89. In **Jamaica** a ban has been imposed on the advertising of infant formula for children less than one year old, and on the use of infant formula in hospitals, where 80% of deliveries occur. A national infant-feeding policy and code of marketing have been drafted; they are being widely circulated to health workers and used in training.

90. The agreement between the Government of **Mexico** and infant-formula manufacturers restricting their activities in accordance with the International Code has been extended to private clinics and doctors' offices. The Code is displayed openly so that both health personnel and the general public are aware of it. Monitoring ensures the Code is applied fully (paragraph 17), and no product sampling or other form of promotion by formula companies is permitted.

91. Draft measures governing the marketing of breast-milk substitutes in **Panama** were expected to be submitted for adoption into law by the end of 1993. It is reported that no distribution of product samples in maternity wards and hospitals has taken place in the past two years. In recognition of the Innocenti Declaration (paragraph 26), the Ministry of Health signed a new agreement in August 1993 to support and protect breast-feeding.

92. In 1993 the Ministry of Health in **Paraguay** modified a 1991 resolution on appropriate steps to be taken in the health services in accordance with presidential decree No. 16525 of 22 February 1993 regulating marketing of breast-milk substitutes. The decree and the International Code have been distributed to all

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[1] *International Digest of Health Legislation*, 1984, **35**(3): 630.

[2] *International Digest of Health Legislation*, 1992, **43**(1): 96-97.

maternity wards; however, distribution of samples of breast-milk substitutes and other marketing techniques are still permitted there.

93. The Government of **Peru** reports that it is adopting new legislation to give effect to the International Code. Committees have been organized and agreements signed in hospitals. Early mother/child contact is promoted in government institutions to advance implementation of the Code.

94. Under the Anti-Drug Abuse Act of 1986[1] in the **United States** the definition of "adulterated" infant formula has been amended to mean infant formula that does not provide required nutrients, does not meet prescribed quality requirements, or the processing of which is not in compliance with prescribed good manufacturing practices and quality control procedures. Good manufacturing practices and quality control measures are established under the Act, including requirements for the keeping of records. Such requirements relating *inter alia* to microbiological and nutrient testing, manufacturers' audits, and consumer complaints are covered in a December 1991 amendment[2] to the Federal Food, Drug and Cosmetic Act, to "ensure a safe, wholesome, and sanitary source of nutrition for infants".

95. Draft regulations in **Uruguay**, which include only minimal aspects of the International Code, are currently under review. Distribution of infant-formula samples and other promotional activities are not permitted in maternity wards or private clinics, where there are otherwise no specific breast-feeding promotion activities.

South-East Asia Region

96. The **Bangladesh** campaign for the protection and promotion of breast-feeding, which began in November 1992, seeks to achieve universal exclusive breast-feeding for the first five months of life for all babies, and to improve weaning practices and the nutritional status of pregnant and lactating women. Of the campaign's six subcommittees, that dealing with the marketing of breast-milk substitutes closely monitors implementation of the International Code based on national legislation adopted in 1984[3] and amended in 1990. Additional legislation is planned to ensure that national requirements are at least as rigorous as the International Code.

97. In **India**, where 25 million infants are born every year, the Infant Milk Substitutes, Feeding Bottles and Infant Foods (Regulation of Production, Supply and Distribution) Act, 1992,[4] was gazetted on 29 December 1992; it came into force on 1 August 1993 as a "salute to the Innocenti Declaration and on the eve of World Breastfeeding Week". For the purposes of the Act, "infant milk substitute" means "any food being marketed or otherwise represented as a partial or total replacement for mother's milk, whether or not it is suitable for such replacement", whereas "infant food" is defined as "any food ... being marketed or otherwise represented as a complement to mother's milk to meet the growing nutritional needs of the infant after the age of four months". The Act proscribes the donation or distribution of infant milk substitutes or feeding bottles except to orphanages, which may also purchase substitutes or feeding bottles at a price lower than their sale price for the purpose of utilizing them in the institution, although this should not amount to an inducement for the use or sale of the products. The Prevention of Food Adulteration (Fifth Amendment) Rules, 1991,[5] had already prohibited pictures of infants or mothers on labels of breast-milk substitutes, or other pictures which may idealize the use of the product, and the use of such terms as "humanized" or "maternalized", in conformity with the labelling provisions (Article 9) of the International Code. Other labelling requirements include a notice about the superiority of breast milk and a warning about careful and hygienic preparation.

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[1] *International Digest of Health Legislation*, 1992, 43(3): 552-556.

[2] Ibid., p. 556.

[3] *International Digest of Health Legislation*, 1985, 36(2): 425-427.

[4] *International Digest of Health Legislation*, 1993, 44(4): 638-641.

[5] *International Digest of Health Legislation*, 1993, 44(1): 62-63.

98. The Regulations[1] adopted in 1985 in **Indonesia** concerning the manufacture, importation, quality, labelling and marketing of breast-milk substitutes were supplemented in 1991 with guidelines on the marketing and distribution of breast-milk substitutes drawn up by the Ministry of Health for manufacturers and importers, and with corresponding guidelines for health staff and institutions, which emphasize the importance of breast-feeding.

99. The Government of **Nepal** adopted the Breast-milk Substitution Substances (Sale, Distribution and Control) Act, 2049 (1992),[2] calling for the constitution of a Committee for the Promotion and Protection of Breastfeeding. It includes provisions governing monitoring, retail purchase of products, awarding of fellowships and research grants, gifts of equipment and materials to health care facilities, product certification and inspection. Regulations to enforce the Act are under consideration.

100. The Government of **Sri Lanka** reports that recent developments to implement the International Code, in close collaboration with WHO and UNICEF, include formulation of a breast-feeding policy and the signing, in January 1993, of an agreement between the Ministry of Health, manufacturers, distributors and other parties. The agreement ends the practice of accepting, using and distributing free or below-wholesale-price supplies of breast-milk substitutes, feeding bottles and teats in maternity hospitals, hospitals and other health facilities. A monitoring committee has been established to ensure its implementation.

European Region

101. After participating in an IBFAN seminar in the Czech Republic (paragraph 126), representatives of the health and law sectors in **Albania** translated the International Code into Albanian. The Code has been distributed to Government departments and drafting has begun of national legislation to give effect to it.

102. The Government of **Denmark** made Order No. 588 on 8 July 1993[3] to implement, *inter alia*, recent European directives (see paragraph 105). The Order repeals certain provisions dating from 1971 on the marketing, composition and labelling of breast-milk substitutes. Annexes concern composition of infant formulae and follow-on formulae when reconstituted as instructed by the manufacturer.

103. An Order of 9 March 1992[4] in **France** established the characteristics of dietetic milk foods for infants and dietary foods for infants (under four months of age) that may be sold by retail and supplied in any way to the public only by pharmacists.

104. Some delays have occurred in **Poland** in drafting new legislation on marketing breast-milk substitutes, but it is expected that a new law on food and nutrition will authorize the Minister of Health to implement the International Code.

European Community

105. As reported in 1992, the Commission of the European Communities adopted Commission Directive of 14 May 1991 on infant formulae and follow-on formulae (91/321/EEC), which concerns the internal Community market.[5] Council Directive 92/52/EEC[6] of 18 June 1992 deals with the export of these same commodities to third countries. Products are required to be labelled in an appropriate language and in such a way as to avoid any risk of confusion between infant formulae and follow-on formulae. A number of the

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[1] *International Digest of Health Legislation*, 1985, **36**(4): 1005-1007.

[2] *International Digest of Health Legislation*, 1993, **44**(4): 642.

[3] Ibid., p. 638.

[4] *International Digest of Health Legislation*, 1992, **43**(3): 551-552.

[5] *International Digest of Health Legislation*, 1991, **42**(4): 675-688.

[6] *International Digest of Health Legislation*, 1992, **43**(3): 550-551.

stipulations, prohibitions and restrictions laid down in Directive 91/321/EEC also apply to products when exported to third countries.

106. In this connection, the Council of Ministers also adopted a resolution (92/C 172/01) in which it stated that the Commission "will instruct its delegations in third countries to serve as contact points for the competent authorities. Any complaints or criticisms with respect to the marketing practices of a manufacturer based in the Community could be notified to them". Furthermore, "The Commission will be ready to examine such cases and assist in the search for a satisfactory solution for all parties concerned", which the Commission will communicate to the countries in question through official channels. Lastly, "The Commission will forward to the European Parliament and to the Council every two years a report on the results of the application of this resolution".

107. Commission Directive 93/11/EEC of 15 March 1993[1] concerns the release of N-nitrosamines and of substances capable of being converted into N-nitrosamines, from teats and soothers made of elastomer or rubber. These articles must not pass on to release-test liquid under specified conditions any N-nitrosamine and N-nitrosatable substance detectable by a validated method which can detect 0.01 mg in total of N-nitrosamines released/kg and 0.1 mg in total of N-nitrosatable substances/kg. Member States are expected to comply with the Directive no later than 1 April 1994.

Eastern Mediterranean Region

108. The Government of **Bahrain** considers that the number of mothers breast-feeding their children has increased, after reaching an all-time low in 1981, thanks to a ban on all advertising of breast-milk substitutes in the media; a ban on the distribution of breast-milk substitutes in hospitals and clinics, by ministerial decree in January 1993; and the establishment of a national committee responsible for promoting infant and young child nutrition. The Ministry of Health is preparing national legislation to implement the International Code.

109. Complementing other past and current action, the Government of **Egypt** has issued regulations to all concerned government personnel prohibiting the distribution of free or low-cost supplies of infant formula; describing the medical reasons for which infants have to be fed on breast-milk substitutes; and preventing promotion of breast-milk substitutes through the media and direct contact between manufacturers' representatives and mothers. The National Breast-feeding Committee's five-year work plan includes implementation and monitoring of the International Code.

110. To promote the health of infants and young children in **Iraq**, which had suffered considerably from the Gulf war and ensuing trade embargo, the Government has strengthened its breast-feeding programme under a scientific committee. The committee has discussed implementation of the International Code, and draft legislation for this purpose was prepared in 1992 with technical support from WHO.

111. Early in 1993 the Ministry of Health in **Morocco** received on request technical guidance from WHO in drafting a national code of marketing and a corresponding strategy for its implementation, which is now being reviewed in the light of the country's overall breast-feeding promotion strategy.

112. By circular dated 20 October 1992 the Directorate-General of Health Affairs in **Oman** reminded the directors of all public and private health facilities of the Government's commitment to breast-feeding. Under no circumstances are infant-food company agents permitted to distribute their products in hospitals, health centres and private clinics, nor may advertising or promotional materials for these products be displayed in these institutions.

113. Efforts in **Pakistan** to implement the International Code include a notification by the Ministry of Health prohibiting or controlling advertising and distribution of free or low-cost supplies of formula. A

[1] *International Digest of Health Legislation*, 1993, 44(3): 462.

national code of marketing, for adoption as law, is being prepared by the Pakistan Paediatric Association, in consultation with industry and other parties.

114. The Government of **Saudi Arabia** has accepted as national policy the Declaration on Breast-feeding that was adopted in Muscat in January 1993 by the Thirty-fourth Conference of the Ministries of Health Committees of the Gulf Cooperation Council. Recalling the Koranic injunction that "mothers should breast-feed their offspring for two full years", the Declaration stressed the importance of encouraging breast-feeding; it instructed all government and private hospitals, health centres and clinics not to permit free distribution of formula or promotion by hospitals or health centres of any infant formula or other processed food for children, and to raise awareness among mothers and pregnant women of the importance of breast-feeding.

115. The import of milk products, including infant formula, into **Sudan** has been banned since 1981, although refugee populations receive targeted supplies. A national committee for promoting and protecting breast-feeding, established in 1992, seeks to reach community and religious leaders, women's and youth groups, and health workers' professional organizations through training, media campaigns and curricula revision.

116. Subsequent to a request by the Government of the **Syrian Arab Republic** for technical support in implementing the International Code, a WHO team met with national counterparts in October 1993 to discuss regulatory and programme measures to be taken in accordance with national nutrition policy. This included preparation of relevant draft legislation, for consideration by the competent national authorities.

Western Pacific Region

117. In May 1992 manufacturers and importers of infant formula in **Australia** signed an agreement[1] setting out their obligations, which the Government describes as being "substantially in line with the WHO Code". A voluntary agreement describing the responsibilities of manufacturers and importers of infant formula with regard to the Code had already been signed in 1983 and updated in 1986. The 1992 agreement, unlike its predecessors, includes provisions for an independent panel to monitor its implementation. For the purposes of the agreement, the term "infant formula" refers to all formula intended for infants aged less than 12 months, whether "standard formula" for infants aged less than six months or "follow-on formula" for infants aged 6-12 months. Agreements with retailers and bottle and teat manufacturers and importers are expected to follow shortly, as are guidelines for health workers and arrangements for ending free or low-price supplies of infant formula in maternity wards and hospitals.

118. Although a marketing code based on the WHO model has been drafted in **China**, introducing the code as legislation is reported to have become increasingly difficult. However, the Ministry of Public Health is preparing a ministerial order, which could be adopted by other ministries as well, that will be stronger than the regulation issued in April 1992 urging all health facilities not to accept free or low-price supplies of infant formula. Meanwhile, it has been reported that in the **Province of Taiwan**, where fewer than 10% of mothers breast-feed their babies, television advertisements for infant formula were banned as from April 1993. Radio and print advertisements will be discouraged, although the health authorities have no legal means to punish violators.

119. **Malaysia**'s code of ethics for infant formula, dating from 1979, aims at supporting provision of proper nutrition for infants by protecting and promoting breast-feeding and by ensuring adequate standards for infant formula when its use is required. The code is recognized as having a number of weaknesses, which the Ministry of Health is striving to eliminate.

120. In December 1992 the Secretary of Health of **Papua New Guinea** addressed a circular to health authorities to remind them that the country had been one of the first to enact legislation aimed at

[1] *International Digest of Health Legislation*, 1994, **45**(1): 102.

protecting its young population from the risks of bottle-feeding.[1] The Secretary pointed out that free or subsidized supplies of breast-milk substitutes may not be offered to, nor accepted by, health services or health workers at any level, whether private or government; that no bottles, artificial teats or dummies may be used in any maternity care facility or paediatric unit; and that distribution of samples of breast-milk substitutes, or any other infant foods, to health workers or to health institutions, public or private, should be immediately discontinued.

121. In April 1987 the Department of Health in the **Philippines** issued guidelines[2] for implementing its national code of marketing, which had been adopted the previous year.[3] In May 1987 the Department published rules and regulations[4] covering the advertising, promotion and marketing of breast-milk substitutes, breast-milk supplements and related products. The rules and regulations deal, *inter alia*, with the functions and working procedures of the interagency committee responsible for implementing the national code and provisions concerning penalties imposed for violations.

122. The Code of Ethics on the Sale of Infant Formula Products in **Singapore**, which was adopted in 1979, is reported to be under revision.

123. The Ministry of Health and the **Viet Nam** Breast-feeding Programme, with technical and financial support from WHO, organized workshops on implementing the International Code for 80 participants in Ho Chi Minh City and Hue in April 1993. A decree giving effect to the Code is being prepared and a plan of action for breast-feeding promotion drawn up for implementation in 70% of the country's provinces and cities by 1995. WHO had already participated in 1992 in the planning of these and related activities at a national workshop on the International Code; a WHO legal officer collaborated in the drafting of regulations to give effect to the Code, and a consultant advised on lactation management. The International Code was translated into Vietnamese in 1992.

Responding to requests from Member States for technical support

124. Funds provided by the Government of the Netherlands and SIDA continue to enable WHO to respond to requests from Member States for technical support in translating the International Code into appropriate national measures, e.g. in Guatemala, Iraq, Morocco, Syrian Arab Republic, United Republic of Tanzania, and Viet Nam. In addition to sending its own staff, WHO has identified suitable consultants with backgrounds in health, law, standard-setting, and relevant supervisory and inspection activities that would enable them to advise national authorities, on request. A dozen such persons[5] are "on call" for this purpose as part of a professional intersectoral advisory team. Funds from the Netherlands have also enabled WHO to organize a workshop (Cairo, September 1993) on Code implementation for participants from 14 countries[6] of the Eastern Mediterranean Region, with support from UNICEF and participation of the legal adviser of the IBFAN Code Documentation Centre. Also, an interregional seminar for countries of the South-East Asia and Western Pacific regions and another for the Region of the Americas were held in March 1994.

125. As part of a regional strategy that includes training in breast-feeding, lactation management, and effective implementation of the International Code, staff from the IBFAN Code Documentation Centre

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[1] The 1977 Baby Feed Supplies (Control) Act requires that baby feeding bottles, teats and dummies be sold at registered pharmacies and obtained only through medical prescription. See *International Digest of Health Legislation*, 1977, **28**(4): 1038-1039.

[2] *International Digest of Health Legislation*, 1992, **43**(2): 316.

[3] *International Digest of Health Legislation*, 1987, **38**(4): 805-809.

[4] *International Digest of Health Legislation*, 1992, **43**(2): 316-317.

[5] The potential WHO consultants are nationals of Australia, Canada, Chile, Denmark, Egypt, India, Pakistan, Philippines, Poland, Sierra Leone, Thailand, and United Republic of Tanzania.

[6] Bahrain, Cyprus, Egypt, Iraq, Jordan, Lebanon, Morocco, Oman, Pakistan, Qatar, Saudi Arabia, Sudan, Syrian Arab Republic, and United Arab Emirates.

periodically hold training courses on the International Code for participants financed from government or private funds. Course content includes policy development, socioeconomic and legal dimensions of the Code, and analysis of selected national laws and other measures intended to give effect to it. Guidance is provided in legal drafting, and participants have access to the Centre's extensive range of related reference materials. WHO coordinates its own Code-related training activities with those of IBFAN: the two organizations participate in each other's sessions and efforts are made to ensure regional complementarity.

126. In 1992 IBFAN conducted training courses in Malaysia for physicians, lawyers, nutritionists and administrators from 19 Asian and African countries, with technical contributions by a WHO legal officer, and in Guatemala for 15 Latin American and Caribbean countries. In January 1993, in collaboration with WHO and UNICEF, it organized a training workshop in Ouagadougou on the Code for 26 French-speaking participants from the fields of health and law from 16 mainly African countries. In May 1993 IBFAN organized a seminar in Nymburk, Czech Republic, for 30 participants from central and eastern Europe in cooperation with a local voluntary organization and IBFAN affiliate, ANIMA, and with support from the Czech Ministry of Health, UNICEF and WHO. The purpose was to acquaint national officials - paediatricians, child-care specialists and lawyers - with what were, for them, new marketing techniques that contribute to a decline in breast-feeding, and how to deal with evolving market conditions (see paragraphs 152 to 156) by implementing the International Code. IBFAN organized a second African workshop in Malawi, in February 1994, for English-speaking participants.

Giving effect to the International Code: lessons from experience

127. More than a decade of the combined experience of Member States in giving effect to the International Code calls for a number of observations with regard to the Code's aim and legislative and non-legislative means to achieve it; infant formula and related trade issues; and donations or low-price sale of infant formula, whether to maternity wards and hospitals or through supplementary feeding programmes.

The aim of the International Code

128. The aim of the International Code is stated in its Article 1: to contribute to the provision of safe and adequate nutrition for infants. The aim is to be achieved in two ways: first, by protecting and promoting breast-feeding, and, secondly, by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution. In this connection, care should be taken not to confuse the aim of the International Code, the measures adopted to achieve the aim, and the impact of the measures in a given context. Thus, for example, even if the aim of the Code *per se* is not to reduce infant formula consumption, generally speaking this would be the expected outcome if its aim were successfully achieved.

129. By the same token, in exceptional circumstances, it is possible that efforts to ensure safe and adequate nutrition for infants can result, at least temporarily, in an **increase** in the consumption of infant formula. For example, as noted in the last report[1] to the Health Assembly, in March 1991, after the cessation of hostilities in the Gulf, WHO drew the attention of the Chairman of the Sanctions Committee of the United Nations Security Council "to the ... acute need [in **Iraq**] among infants and children for infant formula and suitable energy-dense complementary foods" (paragraph 110 of the present report concerns Government action to improve the situation). **French Polynesia** is another case in point. The health authorities reported in 1989 that, in view of its disastrous impact on infant nutrition and health, first priority had initially been accorded to combating the long-standing and widespread practice peculiar to the territory of using sweetened condensed milk to feed infants. Subsequently the authorities concluded, on the basis of rising imports and use of bona fide breast-milk substitutes and effects observed in health clinics, that a shift in policy, giving first priority to breast-feeding promotion and reduction of the use of breast-milk substitutes to cases of strict necessity, was both warranted and feasible.[2]

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[1] Document WHA45/1992/REC/1, Annex 9, paragraphs 33-34.

[2] Document WHA43/1990/REC/1, Annex 1, paragraph 184.

A combination of legislative and other suitable measures

130. According to Article 11, paragraph 1 of the Code, governments should take action to give effect to the Code, "as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures". Most governments have given effect to at least portions of the International Code through legally enforceable means. However, as shown in this and past reports by the Director-General, the "other suitable measures" category offers considerable latitude for action, sometimes in addition to, at other times in place of, legislation. Through an inventive blend of approaches Member States are giving effect, in whole or in part, to their collective decisions as expressed in the resolutions of the Health Assembly and in the International Code. They are consistently doing this not in isolation, but as part of their wider efforts to address the health, nutritional problems, and related social status of women and families.

131. The wealth of information provided by more than 160 countries and territories, which has been summarized in this and past reports to the Health Assembly, represents a compilation of experiences for countries to draw on in assessing their own actions for giving effect to the Code. It covers the wide range of approaches that countries are using, in their health care systems and society as a whole, for this purpose. In general, the overall trend during the past 13 years has been the tailoring of approaches to fit country-specific situations. The patterns may be summarized as follows:

- review, amendment and updating of existing legislation;
- adoption of new legislation;
- preparation and updating of guidelines;
- establishment of permanent or ad hoc governmental/nongovernmental bodies responsible for implementing and monitoring the Code;
- negotiation and updating of voluntary agreements with the infant-food industry, and occasionally with health workers' organizations;
- review and updating of administrative arrangements;
- improvement of the breast-feeding content of initial and in-service training for health workers;
- monitoring infant-formula manufacturers' export activities;
- control by State authority of licensing and marketing arrangements for infant formula;
- administrative or legal measures requiring prior obtainment of the advice of a health worker before breast-milk substitutes can be made available;
- administrative, legislative or voluntary means either permitting donations or low-price sale of relevant supplies through official channels only, or disallowing the practice entirely.

132. In-depth country reports[1] show that it can be difficult to decide which portions of national measures can and should be adopted into law. In some countries - **Canada, Germany** and **United States**, for example - restrictions on advertising have implications for constitutional provisions relating to free speech. In such cases countries have tended to reach voluntary agreements with the infant-food industry, even if this has not always worked to the satisfaction of all parties. For example, the United States Government reports that in mid-1989 first one, then another, of the five major infant-formula companies began to advertise its product directly to consumers. The American Academy of Pediatrics has announced its opposition to such advertising and has adopted a policy terminating support it receives from any company which promotes its product directly to the public. (See in this connection paragraphs 133 to 139.) In the **Philippines**, despite adopting legislation to give effect to Article 5 (advertising and promotion to the general public), the Government has been unable to prohibit direct advertising of products within the scope of the Code owing to policy relating to freedom of commercial speech. Instead, such advertisements are referred for approval to a vetting committee. In **Sweden**, where relevant changes in the constitution were estimated to require at least six years, part of the national measures adopted were issued as guidelines; part as regulations for the health sector; part as a voluntary agreement with the infant-food industry; part as an agreement with the Consumer Board and the Business Delegation on Marketing Law that any future entrants would conform to the voluntary agreement; and part as a unilateral pledge by industry regarding non-commercial informational and educational materials to the public. Swedish companies agreed to abide by these agreements in both domestic and foreign markets. **Australia** (see paragraph 117) has proceeded, simultaneously or successively, on a number of fronts: specific legislation directed at some of the special concerns expressed in the Code; general legislation controlling misleading and deceptive conduct, thus facilitating compliance with other provisions of the Code; compliance with the Code by infant formula manufacturers through a voluntary agreement; promotion and monitoring of compliance by voluntary groups; and adoption of relevant health care policies by health authorities. Many other examples of an inventive combination of legislative and non-legislative means to give effect to the International Code are featured in the synthesis and global-survey documents (see paragraph 70). In contrast, a number of developing countries, for example **Chile, Ecuador, India, Mexico, Peru, Philippines, Tunisia, United Republic of Tanzania,** and **Zimbabwe** have drafted relatively comprehensive legislation among the various measures they have taken to give effect to the Code.

Infant formula and related trade issues

133. **Health implications of direct advertising of infant formula.** The last report to the Health Assembly briefly considered the health implications of direct advertising of infant formula to the general public.[2] It pointed out that, because of the hazards associated with using breast-milk substitutes, infant formula was no ordinary consumer product, but that, up to the age of four to six months, it should be treated more as a nutritional medicine that should be used with the advice and under the supervision of health workers. The report also noted that, even viewed from the viewpoint of fostering competition, direct advertising to mothers with infants in the first four to six months of life was singularly inappropriate because advertising infant formula as a substitute for breast milk competes unfairly with normal, healthy breast-feeding, which is not subject to advertising, yet which is the safest and lowest-cost method of nourishing an infant; and advertising infant formula as a substitute for breast milk favours uninformed decision-making, bypassing the necessary advice and supervision of the mother's physician or health worker. In this respect, the report concluded, it can be considered that advertising of infant formula fails to achieve the objectives of ensuring

[1] Review and evaluation of national action taken to give effect to the International Code of Marketing of Breast-milk Substitutes: report of a technical meeting, The Hague, 30 September - 3 October 1991 (document WHO/MCH/NUT/91.2, English and French). Participating countries were: Brazil, Egypt, Finland, Guatemala, Islamic Republic of Iran, Kenya, Netherlands, Nigeria, Papua New Guinea, Philippines, Poland, Sweden, United Kingdom of Great Britain and Northern Ireland, and Yemen. Also present at the meeting were representatives of the International Federation of Gynecology and Obstetrics, the International Pediatric Association, the International Confederation of Midwives, the International Organization of Consumers Unions, and the International Association of Infant Food Manufacturers. The conclusions and recommendations of the technical meeting are reproduced in the report by the Director-General on infant and young child nutrition to the Forty-fifth World Health Assembly (document WHA45/1992/REC/1, Annex 9, paragraphs 124-132).

[2] Document WHA45/1992/REC/1, Annex 9, paragraphs 120-123.

best quality at the lowest cost and creating an informed public, which are among the benefits assumed to be a result of direct advertising.

134. The debate continues about the extent to which direct advertising of infant formula to the general public influences the prevalence and duration of breast-feeding. Choice of infant-feeding mode is a highly complex process that is affected by multiple factors including cultural traditions, educational opportunities, accessibility of objective and consistent information, time available and perceived options. WHO has consistently stated that appropriate marketing and distribution of breast-milk substitutes is only **one** of several important factors where protecting healthy practices in respect of infant and young child feeding is concerned.

135. Reviewing the basic principles common to **all** advertising and promotion is instructive in this context. Generally speaking, all producers competing in the marketplace do so for two reasons: to expand the market for a given class of product, whatever its type; and to expand their share of the market - present and future - over that of their competitors. To achieve these ends, simultaneously or consecutively, the marketing of infant formula presupposes a market increasing in size as more infants are fed artificially. Moreover, the advertising of infant formula is not passive, nor is it without consequences. Trying to prove the precise effect of advertising, however, misses the point that there are inherent dangers in encouraging uninformed decision-making and the bypassing of the mother's physician or other health worker. Those who suggest that direct advertising has no negative effect on breast-feeding should be asked to demonstrate that such advertising **fails** to influence a mother's decision about how to feed her infant.

136. **The perception of infant formula as "just another processed food".** The perception of infant formula as a processed food like any other is having similar consequences in quite different environments. Thus, for example, in some countries with established market economies the authority responsible for overseeing trade insists that manufacturers and distributors of infant formula compete with each other, as do those of any food commodity, by engaging in usual marketing practices including direct advertising and promotion to the general public. At the same time, in many countries that are moving from centrally planned to market economies, there is considerable resistance to placing limits on commercial behaviour after years of centralized decision-making.

137. WHO has concluded that a decision on whether to use infant formula and, if so, which product and how, should not depend upon the effectiveness of commercial advertising. Proper use of infant formula should rather be the result of informed decision-making based on objective and consistent advice, and appropriate supervision. This message is implicit in the final paragraph of the preamble to the International Code, which states:

> *Believing that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products.*

138. No breast-milk substitute, not even the most sophisticated and nutritionally balanced formula, can begin to offer the numerous unique health advantages that breast milk provides for babies. Nor can artificial feeding do more than approximate the act of breast-feeding, in physiological and emotional significance, for babies and mothers alike. And no matter how appropriate infant formula may be from a nutritional standpoint, when infants are not breast-fed or are breast-fed only partially, feeding with formula remains a deviation from the biological norm for virtually all infants. Therefore, infant formula should not be marketed or distributed in **any** environment in ways that may interfere with the protection and promotion of breast-feeding.

139. It is true that in some environments feeding infants artificially is particularly dangerous, even life-threatening, because of the high cost of infant formula, lack of clean water, difficulties associated with reading or following mixing instructions, and poor hygiene. However, even where these conditions generally do not prevail, artificial feeding still carries with it increased risks to the health of both infants and mothers. The perception of infant formula as "just another processed food", and therefore one that should be subject

to "usual marketing practices", is unlikely to change until the health community at large has managed to communicate clearly the message that the marketing and distribution of breast-milk substitutes is not only, or even primarily, a trade issue. Indeed, it is a matter of promoting good health and safe nutrition for **all** infants, irrespective of the environment.

140. **Purported impact of the General Agreement on Tariffs and Trade (GATT).** On a number of occasions in recent years, including the Forty-fifth World Health Assembly,[1] certain nongovernmental groups have expressed concern about the purported impact on implementation of the International Code of the conclusions reached during negotiations in the context of GATT. With the drawing to a close on 15 December 1993 of the "Uruguay Round" of debate on global trade liberalization, it is useful to recall an important principle underlying all deliberations of GATT since 1969. Article XX of the Text of the General Agreement,[2] which concerns general exceptions, states:

> *Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade,* ***nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures ... necessary to protect human ... health [or] necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement*** ... (emphasis added).

141. On this basis, and in the absence of even anecdotal evidence suggesting the contrary, it appears reasonable to assume that the conclusion of the "Uruguay Round" of GATT negotiations will not weaken the capacity of Member States to adopt and enforce national measures, including laws and regulations, to give effect to the principles and aim of the International Code. Where possible impact on international trade in products within the scope of the Code is concerned, it should be recalled that, in keeping with the Code's Article 11, paragraph 1, relevant measures adopted to give effect to it "should apply on the same basis to all those involved in the manufacture and marketing of products within [its] scope".

Donations or low-price sales of infant formula

142. In the light of the discussion of the agenda item "infant and young child nutrition" during the ninety-third session of the Executive Board in January 1994, it is important to recall that the Director-General, in his report[3] to the Forty-third World Health Assembly in May 1990, provided clarification concerning donations or low-price sales of infant formula:

> *213. In accordance with Article 6, paragraph 6, of the International Code, donations or low-price sales of infant formula may be made to institutions or organizations. However, such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes, and should not be used by manufacturers or distributors as a sales inducement. Furthermore, paragraph 7 of the same Article recalls that, where donated supplies of infant formula are distributed outside an institution or organization, it should take steps to ensure that they can be continued for as long as the infants concerned need them. Article 3 of the Code defines supplies as "quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need".*
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> *214. On the other hand, the Code states that manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within its scope (Article 5, paragraph 2); that there should be no giving of samples to induce sales directly to the consumer at the retail level (Article 5, paragraph 3); that samples of infant formula should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level; and that health workers, in turn, should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families (Article 7,*

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[1] See document WHA45/1992/REC/3, summary record of the ninth meeting of Committee B, pp. 221-227.

[2] Basic instruments and selected documents, Volume IV, Text of the General Agreement, 1969, pp. 37-38.

[3] Document WHA43/1990/REC/1, Annex 1, p. 76.

paragraph 4). Article 3 of the Code defines samples as "single or small quantities of a product provided without cost".

215. At the Thirty-eighth World Health Assembly, in May 1985, a number of delegates requested that the Director-General provide clarification regarding the phrase "infants who have to be fed on breast-milk substitutes" in Article 6, paragraph 6, of the Code. Accordingly, following a joint WHO/UNICEF consultation on the subject, guidelines[1] were prepared concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes; these were presented to the Thirty-ninth World Health Assembly in May 1986. Member States were invited to use these guidelines in determining for themselves, on the basis of their particular health and socioeconomic circumstances, how to protect infants and mothers against inappropriate feeding practices, which infants have to be fed on breast-milk substitutes, and how best to ensure that these infants receive an appropriate substitute for as long as they need it. The Health Assembly adopted resolution WHA39.28 urging Member States inter alia "to ensure that the small amounts of breast-milk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies". This recommendation notwithstanding, the Director-General considers that the International Code has not been modified by this or any other resolution.

143. Based on anecdotal evidence, what appears to be occurring in some cases is that quantities of infant formula are being provided free or at low price to some institutions, including hospital paediatric wards and health centres, for use in feeding many infants, each for a short period. This would of course be equivalent to providing samples, which is expressly disallowed by the Code.

144. In their joint letter to heads of State (see paragraph 25), the Director-General of WHO and the Executive Director of UNICEF requested a commitment to ending free and low-cost supplies of infant formula in maternity wards and hospitals. More recently, the Forty-fifth World Health Assembly (1992) urged Member States "to take measures appropriate to national circumstances aimed at ending the donation or low-priced sale of breast-milk substitutes to health facilities providing maternity services" (resolution WHA45.34).

145. As reported to the twenty-ninth session (1-2 February 1993) of the UNICEF/WHO Joint Committee on Health Policy (JCHP),[2] in consultation with the International Association of Infant Food Manufacturers (IFM), a member of the International Special Dietary Foods Industries (admitted into official relations with WHO in 1987), the target for December 1992 had been set for ending free or low-cost supplies of infant formula to maternity wards and hospitals in developing countries. According to information available to UNICEF and WHO, as of February 1993 this practice either did not exist, or governments had taken action to end it, in 122 countries; in only eight developing countries had no such action been initiated. The Committee noted further that progress had also been made in industrialized countries, particularly in Europe.

146. In explanation of the different deadlines recommended for developing and industrialized countries to end distribution of free or low-cost supplies of infant formula, it was stated that progress was such that actual cessation of supplies could be expected in most countries by mid-1993. However, the conformity date for industrialized countries had been set to coincide with the entry into force of the European Directive on Infant Formulae and Follow-on Formulae scheduled for June 1994 (paragraph 105). JCHP recommended that UNICEF and WHO should urge full compliance, by June 1993, with government action prohibiting the distribution of free or low-cost supplies of infant formula, and that the target date of June 1994 should be set for ending distribution of free or low-cost supplies of infant formula in both developing and industrialized countries. By September 1993 more than 70 developing countries had taken specific action to this end (see also individual country reports above).

[1] Document WHA39/1986/REC/1, Annex 6, part 2.

[2] See document EB92/1993/REC/1, Part I, Annex 2, paragraph 74.

147. As noted in the last report to the Health Assembly,[1] IFM had agreed to work with WHO and UNICEF in a country-by-country process aimed at the establishment, by governments, of regulatory or other official measures putting an end to donations or low-price supplies of infant formula to maternity wards and hospitals in developing countries. In September 1992, the Association's policy in this regard was extended to cover the newly independent States of the former USSR and countries of eastern Europe. At the same time, its President reiterated his membership's view that it was essential that the measures taken by governments be clear and unambiguous, and that they engage the responsibility not only of all manufacturers but also of all concerned in the health care system.

148. WHO and UNICEF are encouraged by positive action where developing countries are concerned. However, they agree that the next step will be to end free and low-cost supplies of infant formula that contribute to routine bottle-feeding in health care facilities in all industrialized countries. This practice is reported to have already ceased, through voluntary agreement by the infant-food industry, in Denmark, Germany, Ireland, Netherlands, and United Kingdom, while similar steps are expected in Australia (paragraph 117) in 1994.

Proposed definitions by the International Association of Infant Food Manufacturers and monitoring mechanisms in respect of donations or low-price sales of infant formula

149. In November 1992 WHO and UNICEF reviewed informally with the Association the situation with regard to cessation of donations and low-price supplies of infant formula in maternity wards and hospitals in developing countries. In recalling his membership's commitment to cooperating with governments to achieve this goal, the President of the Association stressed the need for governments to formulate definitions and criteria for monitoring mechanisms that would apply to **all** concerned - manufacturers and distributors and the health care system alike - and that would be "impartial, objective and enforceable". WHO requested the Association to put forward suggestions in this regard.

150. In January 1993 the President of the Association communicated such suggestions to WHO and UNICEF. The Association considers that key definitions include the meaning of "low price"; for example, whether this means a price below the lowest price offered within the context of normal procurement, a price below ex-factory or landed duty-paid cost, or a price below recommended retail price. It also believes that governments should decide whether it is appropriate to provide donations or low-price supplies of infant formula to health facilities where maternity services are **not** provided. In cases where such supplies are deemed appropriate, governments may wish to consider adopting mechanisms to ensure that the needs of infants who have to be fed on breast-milk substitutes are adequately and appropriately covered, for example by channelling supplies through national health authorities or another approved agency. In cases where no donations or low-price supplies are permitted, alternative procurement channels could be established, whether by governments, relief agencies or other charitable organizations for bona fide purposes.

151. WHO appreciates the suggestions put forward by the Association and, to the extent that resources permit, intends to consider them, together with various other proposals that have been made for relevant guidelines. It is considered that the underlying principles governing relevant national measures should include clear definitions, which are communicated to and understood by all parties; transparent monitoring and reporting procedures to determine whether alleged violations contravene national measures; and a monitoring authority established under government responsibility. It is hoped that the long-standing and unusually contentious matter of donations or low-price supplies of infant formula will be resolved rapidly, and that **all** parties have grasped the central lesson from this experience: that only through proper dialogue, entered into in good faith, can disputes of this magnitude and duration be satisfactorily resolved so that resources can continue to be used to good effect.

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[1] Document WHA45/1992/REC/1, Annex 9, paragraph 137.

Charitable distribution of breast-milk substitutes through ad hoc or long-term feeding programmes

152. As noted in the last report by the Director-General, the results of a thorough review and evaluation of experience in giving effect to the International Code undertaken by 14 Member States[1] were discussed by representatives of the countries concerned at a technical meeting hosted by the Government of the Netherlands in The Hague in September-October 1991. Among the difficulties cited in preparing and implementing national measures to give effect to the International Code was a failure to respect the Code's principles and aim in newly evolving market conditions, e.g. countries moving from centrally planned to market economies, or population groups beginning to participate for the first time in a cash economy. In this connection, participants recommended that:

> *Charitable and other donor agencies should exert great care in initiating, or responding to, requests for free supplies of infant foods. These agencies should review, and adapt as appropriate, the policies relating to the distribution and use of milk products for infant feeding that have been adopted by such bodies as the Office of the United Nations High Commissioner for Refugees, the World Food Programme, and the International Committee of the Red Cross. In order to avoid interfering with breast-feeding, no more than the required minimum amount of infant foods should be provided for distribution under appropriate supervision and follow-up.*[2]

153. More recently, participants from eastern and central European countries at the 1993 workshop on the Baby-friendly Hospital Initiative (see paragraph 51) unanimously recommended that donors should be urged **not** to send breast-milk substitutes indiscriminately to countries in central and eastern Europe. In emergency situations, they concluded, governments should request that donors make funds available for breast-feeding promotion.

154. There have been a number of reports of large sums from public and private sources being spent, in well-meant solidarity, to provide breast-milk substitutes for distribution through supplementary feeding programmes in countries of central and eastern Europe, including the republics of the former USSR. There are also examples of infant-formula distribution taking place in maternity wards, including distribution to mothers who have already successfully initiated breast-feeding, "in case of lactation failure". In contrast, resources to protect and promote breast-feeding in these same environments are sorely lacking. (A noteworthy exception is Bosnia and Herzegovina where, in 1993, breast-feeding rates in Sarajevo were reported to have increased from 16% to 60% owing to a policy that emphasizes satisfaction of the nutritional needs of mothers to enable them to meet those of their infants.)

155. Donations and requests for infant formula as a high-priority food-aid commodity are frequently the result of ignorance on several levels: in the health care system, where human milk, lactation management, and the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes may be poorly understood; in the community, where accurate information about actual infant-feeding practices may be lacking; and among policy-makers and administrators who, in struggling to meet the immediate nutrition needs of their populations, may not be fully aware of the importance of protecting and promoting breast-feeding.

156. As noted above (paragraph 142), the Thirty-ninth World Health Assembly reviewed guidelines concerning the circumstances in which infants have to be fed on breast-milk substitutes. Though not entirely up to date - for example as regards breast-feeding and risk of HIV infection (see paragraphs 40 to 41) - the guidelines remain useful when examining the main concerns. The principles laid down as part of the policy of organizations and bodies of the United Nations system (e.g. UNHCR, WFP) on distribution and use of milk products for infant feeding, to which WHO contributed on technical aspects, are likewise relevant. Nevertheless, neither the guidelines nor United Nations system policy deal directly with specific

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[1] Brazil, Egypt, Finland, Guatemala, Islamic Republic of Iran, Kenya, Netherlands, Nigeria, Papua New Guinea, Philippines, Poland, Sweden, United Kingdom, and Yemen.

[2] Document WHA45/1992/REC/1, Annex 9, paragraphs 128.

situations that have arisen more recently, including those described by participants in the technical meeting in The Hague and in the workshop in Saint Petersburg (Russian Federation). Clear and practical policy guidance is called for in this connection, for uniform application by all governmental, intergovernmental and nongovernmental authorities concerned.

CONCLUSION

157. One of the tangible results of the ICN - the World Declaration on Nutrition - offers a challenging vision of a world transformed. Meanwhile, its Plan of Action for Nutrition charts a credible course for achieving this transformation. The ability of the international community to move from the potential to the actual, from the world we know to the world we would inhabit, turns, as before, on whether the political will can be mustered in pursuit of this objective.

158. What is different today, however - and this is perhaps ICN's most immediate contribution - is the pivotal position that nutrition now occupies in the collective consciousness. The international community, with one voice, unabashedly declares hunger and malnutrition to be unacceptable in a world that has both the knowledge and the resources to end this human catastrophe.[1] Building on this global consensus means moving with all deliberate speed to effect the changes called for so that the ambitious goals so solemnly set can be achieved within the agreed time frame.

159. Where the focus of this report is concerned, there is much encouraging evidence from around the world that Member States are taking seriously their collective commitments as they relate to protecting and promoting the nutritional well-being of infants, young children, and pregnant and lactating women. Nevertheless, the world is not standing still. As impressive as the progress achieved clearly is, much more is required if the challenges dominating nutrition's present and near-future are to be met. It would be difficult to overestimate either the number or complexity of these challenges just seven years from the start of the third millennium AD, when fully 51% of the world's estimated 6228 million people will be living in urban agglomerations.

160. What contributions at this stage is it reasonable to expect from a number of the main actors? With ICN fresh in their memory it is perhaps easiest for **governments** to use the opportunity to determine their own role, which is spelled out in the World Declaration and Plan of Action for Nutrition, and paragraph 2 of resolution WHA46.7.

161. **Professional and other technical bodies** should enjoin their membership, whether doctors, nurses, midwives, lactation consultants, or other members of the health team, to re-dedicate themselves to protecting and promoting safe and adequate nutrition for **all** children. They should of course continue to educate their members in accordance with the latest scientific information; but to multiply the effects of their action they also need to strengthen old, and forge new, alliances, whether with other professional associations or other key groups espousing similar values.

162. **Nongovernmental organizations**, to which WHO and its Member States owe so much for their tireless efforts over the years, should understand how highly the Organization values their contribution and their continued close collaboration. It would not be an exaggeration to say that, were they to cease playing the role frequently requested of them by the Health Assembly, WHO would be hampered in carrying out its own "good offices" function through the dialogue in which it continually engages with all concerned parties. Bearing in mind the breadth of WHO's responsibilities, however - as well as the inherent limitations of an international intergovernmental organization - they should also appreciate that identity of interests does not necessarily translate into identical forms of action. The key to collaboration between WHO and nongovernmental organizations remains complementarity.

[1] World Declaration on Nutrition, paragraph 1.

163. Where **commercial enterprises** are concerned, manufacturers and distributors of processed foods intended for infants and young children continue to play an important and constructive role; their contribution is in fact growing in the light of world demographic trends, particularly increasing urbanization. In this connection, however, they remain responsible for monitoring their marketing practices according to the principles and aim of the International Code. **All** manufacturers and distributors of products within its scope[1] - whether operating domestically or internationally, in developing or industrialized countries - are invited once again to ensure that these products are not marketed or distributed in ways that may interfere with breast-feeding.

164. The special burden placed on all concerned parties for the nutritional well-being of infants and young children is defined simultaneously from the perspective of hard science and ethical principles. The early months of life are a precious, precarious moment; they cannot be recaptured. Adequate diet is more crucial in infancy than at any other time of life because of the infant's high nutritional requirements in relation to body weight and the influence of proper or faulty nutrition during the first months on future health and development. If the nutritional well-being of people is a pre-condition for the development of societies, it is all the more so where their most vulnerable members - infants and young children - are concerned. Governments will be unsuccessful in their efforts to accelerate economic development in any significant long-term sense until optimal child growth and development are ensured for the majority. As a result of ICN, the technical basis for continued action is clear. So, too, is the moral basis in terms of social equity and the right of everyone to adequate nutrition.

MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

165. This paragraph invited the Health Assembly to consider the resolution on infant and young child nutrition recommended in resolution EB93.R9. The recommended resolution was adopted as resolution WHA47.5

166. In resolution EB93.R9, the Executive Board had requested the Director-General, "in transmitting the report to the Forty-seventh World Health Assembly, to draw specific attention to the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes ...". In response to this request, the Health Assembly was referred to document WHA39/1986/REC/1, Annex 6, part 2, and to the Consensus Statement from the WHO/UNICEF Consultation on HIV Transmission and Breast-feeding (Geneva, 30 April - 1 May 1992).[2]

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[1] The scope of the International Code (Article 2) includes feeding bottles and teats.

[2] *Weekly Epidemiological Record*, 1992, **67**(24): 177-179.

ANNEX 2

Global change and budgetary reform[1]

1. WHO response to global change

Progress report by the Director-General

[A47/16 - 29 March 1994]

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I. INTRODUCTION

1. The Working Group on the WHO Response to Global Change, formed by the Executive Board at its ninetieth session in May 1992, presented its report to the Board at its ninety-second session in May 1993. The Board, by resolution EB92.R2, adopted the conclusions and the 47 recommendations[2] of the report. In May 1993 the Forty-sixth World Health Assembly, informed that this report had been prepared and circulated to members of the Board, adopted resolution WHA46.16, requesting the Director-General to make a full report to the Forty-seventh World Health Assembly on progress in responding to the Working Group's report.

2. To study more specific ways and means of implementing the recommendations, the Programme Committee of the Executive Board at its eighteenth session (July 1993) reviewed the report and classified

[1] See resolutions WHA47.6, WHA47.7 and WHA47.8.

[2] A list of the 47 recommendations in numerical order appears in document EB93/1994/REC/1, Annex 1, Part 1, Appendix.

the various recommendations into three categories according to the practical feasibility and urgency of their implementation:

- the first category comprised recommendations already implemented (recommendations 17-18, 43 and 45);

- the second included recommendations on which a report would be presented to the Executive Board in January 1994 (recommendations 1-14, 19, 23-24, 27-28 and 46-47);

- the third category contained recommendations which might take longer to implement (recommendations 15-16, 20-22, 25-26 and 29-44).

3. The Programme Committee of the Executive Board at its nineteenth session (November 1993) endorsed preliminary plans for the implementation of the last two categories.

4. The Executive Board at its ninety-third session (January 1994) reviewed in depth the implementation of the recommendations (see section III).[1] It confirmed that a number of recommendations had already been carried out, and reviewed the mechanisms (internal and related to governing bodies) proposed by the Director-General to guide and facilitate further implementation. In resolution EB93.R13 it decided to change its Programme Committee into a Programme Development Committee, *inter alia* to follow the process and effects of reforms initiated to carry out the recommendations of the Executive Board Working Group on the WHO Response to Global Change (see section II).

II. IMPLEMENTATION OF RECOMMENDATIONS: INTERNAL AND EXTERNAL MECHANISMS

5. In studying provisions for carrying out the recommendations and in starting to execute them, it became apparent that for more cost-effective implementation at all levels of the Organization a number of these recommendations could be grouped and dealt with together, since:

- they had a common purpose, namely to rationalize the work of the governing bodies and their subcommittees, or to improve certain managerial aspects of the work of WHO;

- they applied to the same parts of the Organization, and grouping them would facilitate implementation and follow-up; and

- grouping them would make implementation more efficient and possibly produce savings.

6. While implementing the recommendations related to global change WHO is carrying out a general process of reorganization of its programmes in order to improve execution of the Ninth General Programme of Work: the programme structure and the whole managerial process, together with the necessary administrative support, are being adjusted. The requirements of resolution WHA46.35 on budgetary reform are also being taken into account. As part of the process, the Director-General in August 1993 decided to establish mechanisms linking programme management in headquarters and the regions, namely the Management Development Committee (MDC) and the Global Policy Council (GPC). In turn, GPC created a series of time-limited "development teams", which will cease to exist upon completion of their mandate; these teams, multidisciplinary groups of WHO staff, will develop policy concepts, elements, and management tools to implement rapidly and effectively the various recommendations of the Executive Board Working Group within the context of the WHO managerial process. Specific functions of MDC, GPC and development teams are described in Appendix 1.

[1] Reports presented to the ninety-third session of the Executive Board appear in document EB93/1994/REC/1, Annex 1; summary records are contained in document EB93/1994/REC/2.

7. The Executive Board at its ninety-third session (January 1994) decided to set up a mechanism whereby the Board divided into three subgroups to carry out thorough programme reviews; in resolution EB93.R13 it further established a Programme Development Committee and an Administration, Budget and Finance Committee in order to support the reform process. Regional committees were called on to follow reforms and assist in programme development. The mechanisms related to the Executive Board for the monitoring of the implementation of recommendations on global change are described in Appendix 2.

III. IMPLEMENTATION OF RECOMMENDATIONS: PROGRESS REPORT

A. General considerations

8. As of May 1994 18 recommendations have been implemented and plans made for the implementation of the remaining 29. It is intended to move as fast as possible and it is expected that all recommendations will be implemented within two to three years depending on the funding available. Although a number of recommendations, some of which have already been implemented, imply relatively small additional costs (e.g. recommendations 10, 11 and 12) and may even result in savings (e.g. recommendations 7, 8 and 9), others will require more time and resources, because either implementation is complex, or the structural changes in the management of the Organization will need additional financing.

9. This is the case, for example, of recommendations 2, 3 and 4 on updating WHO policy, which will imply further direct consultations with Member States; and of recommendations 19 and 20 on the development of the WHO Management Information System, which may encounter not only technical but also financial constraints. These matters were touched upon during the Programme Committee in November 1993 and during the Executive Board in January 1994.

10. Although it is intended to implement most of the recommendations of the Working Group on the WHO Response to Global Change within the next two to three years, some of the reforms called for will imply fundamental changes in the programmes of the Organization and its administration. It has therefore been decided to incorporate these changes into the current management and development process of WHO programmes. The work of the development teams and subsequent reporting to the Global Policy Council and the Programme Development Committee will be instrumental to the reform process.

B. Stages of implementation

11. The status of implementation of recommendations is given below for each of the three categories.

(i) **Recommendations already implemented or in final planning stage (18)**	**Implementation status**
1. Make an annual assessment of world health status and needs, and recommend relevant WHO priorities for international health action to meet those needs.	Linked to recommendation 46; document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section I; proposal endorsed by decision EB93(6)

5. *Submit to the 1994 World Health Assembly a proposed resolution authorizing the Executive Board, in coordination with the Director-General, to establish a routine procedure for prior review of all resolutions proposed to the World Health Assembly that have potential impact on the objectives, policy and orientations of WHO, or that have implications in terms of staffing, costs, budgetary resources and/or administrative support. The Executive Board and the Director-General will ensure that resolutions proposed to the World Health Assembly are accompanied by the necessary background information, and that the text of the proposed resolutions includes provision for time limit, evaluation and reporting, as appropriate.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section III; proposal endorsed by resolution EB93.R1 and submitted to the Forty-seventh World Health Assembly; implementation started in January 1994
6. *Consider and submit to the Board in January 1994 further proposals for improvements in the method of work of the World Health Assembly, to focus discussions on major policy, strategy and programme issues, make better use of audiovisual methods, and realize further economies in the duration and cost of the Health Assembly.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section IV; follow-up in two to four years
7. *Identify clearly in Executive Board documents, in an appropriate form, the issues that require the advice, guidance or decision of the Board, confirmed by vote when necessary.* 8. *Ensure that Executive Board discussions genuinely focus on, and reach clear conclusions and decisions with respect to, all issues concerning health policy, technical, budgetary and financial aspects or other overall supervisory or advisory functions.* 9. *Prepare summary records that are more succinct, with less reporting of various statements made during discussions, and more focus on conclusions and decisions reached, in addition to the resolutions and decisions formally adopted by the Executive Board.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section V; new document format introduced in January 1994 and approved by decision EB93(9) which also approved shortening of the summary records
10. *Establish subgroups or committees to meet during, and as part of, the Executive Board sessions each year, to review and evaluate a number of specific programmes, giving attention to interrelated elements of programme policy, priority, targets, plans, budgets, and other available resources including technology. Past performance, outputs and expected outcomes would be evaluated. The temporary subgroups should recommend actions to be taken, including tradeoffs within available resources, and report back to the plenary Executive Board which alone can take the final decision.* 11. *Use the subgroups mentioned above, or establish dedicated subgroups as appropriate, to advise the Executive Board on "cross-programme" issues such as administration and finance.*	Trial run in January 1994 of programme reviews through Executive Board subgroups; methods for reviews in document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VI, endorsed by decision EB93(8); see also resolution EB93.R13 which established the Administration, Budget and Finance Committee

12. *Reconsider the need for, and the terms of reference of, the Programme Committee of the Executive Board; consider a change in the timing of post-Assembly sessions of the Board, and the plan of work of the Programme Committee to better match the work of the Board and its subgroups.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VI; resolution EB93.R13 changed the Programme Committee to the Programme Development Committee; its plan of work will be established by the Executive Board
13. *Form a special ad-hoc subcommittee of the Executive Board to consider options for nomination and terms of office of the Director-General and Regional Directors, including the use of search committees and report thereon to the Executive Board in January 1994.*	Views of Member States and regional committees to be solicited and reported to the Executive Board in January 1995 (see document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VII)
14. *Establish a small working group to recommend how to: improve ways in which the Board members are designated; improve the selection procedures for the officers of the Board; and achieve more active involvement of all members throughout the year in the work of the Organization. Specifically, the working group should consider the possibility of designating a chairman-elect from among the officers of the Board, one year in advance of formal election under Rule 12, and the continued involvement of the outgoing chairman the following year, to permit a team approach at each session of the Board. The working group should also consider ways and means to improve communication and participation among the Chairman, Board members and the Director-General throughout the year, and to keep all Board members informed of the involvement of individual Board members in the work of WHO. The Working Group should report to the Board by January 1994.*	Report of Programme Committee, document EB93/1994/REC/1, Annex 1, Part 1; Executive Board consensus reflected in decision EB93(12)
17. *Consider the establishment of a policy development team, utilizing current staff to orient the long-term vision, policy direction and programme priorities for the health sector and WHO.*	Global Policy Council and development teams[1] established (see section II above)
18. *Strengthen and develop, with the Regional Directors, an improved policy planning and analysis capability/system to recommend clear priorities for programme objectives, targets and budgets. These priorities should be coordinated at all levels of the Organization and reported to the Executive Board (or the Programme Committee if it is retained) on an annual basis.*	Management Development Committee and Global Policy Council established (see section II above); see resolution EB93.R13 with regard to the role of the Programme Development Committee

[1] For titles and respective responsibilities of development teams, see Appendix 1.

23. *Review the current delegation of authority between headquarters and regional offices and introduce appropriate changes in the light of experience and current needs, and report on progress to the Executive Board by January 1994.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section IX; the Global Policy Council is following up and will report at a later stage with the conclusions of the development team[1] (see section II above)
24. *Include as part of the Executive Board's working agenda, on a regular basis, meetings with Regional Directors to review strategies and progress on key operational and management issues.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VI; proposal endorsed by decision EB93(10)
28. *Review, update and standardize the delegations of authority, the country office administrative/management and operating procedures, and the basic operating resources for WHO Representative offices throughout the Organization and report to the January 1994 session of the Executive Board on the results.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section IX (see recommendation 23)
46. *Issue an annual publication which reports on the Organization's efforts and programmes for improving the world health situation. The report should be similar to UNICEF's* The State of the World's Children *in target audience and promotional context.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section I; proposal endorsed by decision EB93(6); resource mobilization beginning in 1994; publication to start in 1995
47. *Devise means for the Executive Board to monitor the work and continue activities, including the potential contribution from the current members of its Working Group on the WHO Response to Global Change.*	See paragraph 3 of resolution EB93.R13, document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VI, and section II above
(ii) Recommendations to be implemented for January 1995 (5)	
16. *Request the regional committees to study their own method of work with a view to harmonizing their actions with the work of the regional office, other regions, the Executive Board and the World Health Assembly and report thereon to the Executive Board in January 1995.*	Implementation to be completed in autumn 1994; report to be made to the ninety-fifth session of the Executive Board (January 1995)
20. *Provide a detailed analysis of the current status, capability, compatibility, plans and programmes of existing management information systems throughout the Organization (headquarters, regional and country levels). The Director-General should develop alternate plans for a WHO worldwide system which could be implemented within variable time frames, e.g. within 3, 5 and/or 10 years.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VIII; proposal endorsed by decision EB93(11); creation of a development team;[1] report to be presented to the ninety-fourth session of the Executive Board (May 1994); plans for implementation to be completed in mid-1995

[1] For titles and respective responsibilities of development teams, see Appendix 1.

35. *Assign an Executive Board member to sit on the management committee of each major extrabudgetary funded programme (generally consisting only of donors), to facilitate coordination and compatibility of policies, decisions and priorities with those of the World Health Assembly/Executive Board.*	Information to be presented to the ninety-fifth session of the Executive Board (January 1995)
38. *Noting that the regional and country allocations are based mainly on allocations for previous years, establish budgeting systems/mechanisms to derive the greatest benefit from the process of budgeting by objectives/targets and to facilitate the achievement of priorities and to provide for periodic adjustments of these priorities in accordance with changing health needs.*	Implementation from 1994 onwards through new programme budget guidance and implementation of resolution WHA46.35 on budgetary reform
45. *Develop WHO's capability to make greater use of modern communication techniques and methods, particularly mass media tools, to introduce health promotion and disease prevention concepts.*	Creation of a development team;[1] report to be presented to the ninety-fifth session of the Executive Board (January 1995)
(iii) Recommendations to be implemented progressively in 1994, 1995 and 1996 (24)	
2. *Analyse and define for the year 2000 the specific objectives and operational targets, measured through precise indicators, and mobilize appropriate resources to ensure their attainment. This should make full use of resources and expertise in regions and countries.*	) Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section II; proposal endorsed by decision EB93(7); further reporting to the ninety-fifth, ninety-sixth and ninety-seventh sessions of the Executive Board (January and May 1995 and January 1996)
3. *To the extent that targets will not be met by the year 2000, to propose alternative strategies and plans for intensified health programmes, with budgetary resources required to attain minimum goals, objectives and targets for the year 2005, 2010 or as appropriate.*	
4. *Study the feasibility of organizing international workshops or other forums to develop consensus for any adjustments or new directions in the strategy for health for all; stress health promotion and disease prevention and their implications for extending lifespan or disability-free years (e.g. through individual and community responsibility).*	
15. *Conduct from time to time surveys of Member States' opinions and perceptions of the relevance, functioning, efficiency and effectiveness of the work of WHO at all organizational levels.*	Implementation to start in 1995 together with recommendations 2 and 3

[1] For titles and respective responsibilities of development teams, see Appendix 1.

19. *Propose and implement appropriate management and communication systems, particularly with the Regional Directors, to achieve the designated objectives and targets according to the priorities identified. Such management and communications systems should be served by the management information systems for effective and efficient policy implementation.*	Management Development Committee, Global Policy Council and development team[1] created; document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section VIII; proposal endorsed by decision EB93(11); regular reporting to Programme Development Committee; linked with recommendation 20
21. *Review the effectiveness of current WHO procedures and criteria utilized at headquarters, regional office and country levels for the development of appropriate staffing patterns and the selection and recruitment of staff.*	) Development team[1] created and progressive implementation from 1995 onwards
22. *Review the practices of providing technical consultation for the Organization and identify changes needed in the provision and utilization of technical experts.*	)
25. *Evaluate current and planned country health programmes and determine the profile of skills and qualifications required to select highly qualified WHO Representatives.*	) Studies to be undertaken by development team as proposed in document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section IX
26. *Develop appropriate procedures for ensuring career development of the WHO Representatives through initial and periodic training and by rotation of WHO Representatives (between regions and headquarters) in the light of the Organization's current needs.*	)
27. *Direct the Regional Directors and the WHO Representatives to provide leadership in intersectoral coordination among the United Nations agencies and between major donors, and report to the January 1994 session of the Executive Board on the results.*	Document EB93/1994/REC/1, Annex 1, Parts 1 and 2, section X; studies to be reported to the ninety-fifth session of the Executive Board (January 1995)
29. *Review the role of the WHO Representative and recommend appropriate measures to strengthen the integration of the work of the WHO Representative into the policy and strategy development of the Organization. In addition, the Director-General should take advantage of low-cost improvements in communication technologies, such as CD ROMS and integration with electronically keyed national libraries (of medicine and others), to improve access to information for the WHO Representative.*	Planning by development team and progressive implementation from 1995 onwards
30. *Inquire among Member States their interest in having alternate forms of WHO representation within their countries.*	Progressive implementation in conjunction with recommendations 25, 26 and 27

[1] For the titles and respective responsibilities of development teams, see Appendix 1.

31.	*Ensure that the Organization be active in its response to the structural and operating reforms taking place in the United Nations and its programmes. WHO should develop concept papers or action papers to facilitate the adoption of procedures, within the United Nations system, which further interagency cooperation and collaboration in the resolution of health and development problems.*	Being studied by the respective development teams[1] for progressive implementation from 1995 onwards
32.	*Engage in discussions with appropriate elements of United Nations leadership to ensure optimal use of United Nations "unified offices" with United Nations specialized agency coordinators (not only UNDP coordinators). The newly-designed system, under the overall coordination of UNDP, could provide clear leadership of the "UN country-team" by the specialized United Nations agencies in their areas of expertise, e.g. WHO on health matters.*	
33.	*Take appropriate measures to present appropriate information and recommendations to the United Nations/donor agencies responsible for development projects to include disease surveillance, prevention, and control as an integral component of each development project, programme intervention or targeted service for specific geographical areas.*	Implementation progressing; to be reported on at the ninety-fifth session of the Executive Board (January 1995)
34.	*Engage in dialogue with the United Nations secretariat to study means for reducing differences in regions and operating procedures among United Nations agencies.*	For later implementation when planning for recommendations 29-33 is more advanced
36.	*Seek approval from the World Health Assembly to have the authority to assess appropriate overhead rates, up to 35% for extrabudgetary programmes.*	Being studied; will be reported to the ninety-fifth session of the Executive Board (January 1995)
37.	*Establish a pledging system to secure additional funds for priority regular budget programmes including those dealing with normative functions.*	To be implemented in 1995/1996 in conjunction with recommendation 33
39.	*Improve the personnel procedures to ensure: technical competence as the primary basis for the selection and recruitment of long- and short-term staff; the design and implementation of appropriate career development and continuing education programmes; and the development of a staff rotation system between headquarters and regions. The Director-General should assess the impact of the geographic distribution of posts on the quality of staff.*	To be implemented in relation to recommendation 21
40.	*Draw to the attention of the World Health Assembly the impact on the quality of staff and on the ability of the Organization to perform its mandated functions due to politically motivated appointments made by the Secretariat as a result of pressures by Member States.*	The Programme Committee at its eighteenth session noted that this subject needed further discussion; linked to recommendation 39

[1] For titles and respective responsibilities of development teams, see Appendix 1.

41. *With a view to ensuring the best possible use of all resources available to the health sector, review and update existing guidelines and procedures related to WHO collaborating centres and their participation in research initiatives for the Organization. In particular, the review should focus on ways to facilitate, in a cumulative manner, the coordination of research efforts by the worldwide network of collaborating centres to achieve health-for-all targets and other priority health initiatives.*	Implementation under way after review of WHO's role in research by the Executive Board and in close relation with recommendations 19 and 20
42. *Require every programme to include a budgetary item for conducting basic science or operational research activities as part of its institutional development process to achieve technical excellence.*	Progressive implementation as of 1995 after the review of WHO's role in research by the Executive Board
43. *Establish a small group to determine with the Director-General ways to expand the use of WHO collaborating centres. A special focus should be given to the implementation of priority health research and of primary health care/health-for-all initiatives.*	) Development team created;[1] progressive implementation as of 1995 after the review of WHO's role in research by the Executive Board
44. *Develop annual plans with each collaborating centre to facilitate the implementation of appropriate international health work, and the evaluation of the capability of the centre to maintain its special designation.*	)

IV. MATTERS FOR CONSIDERATION BY THE HEALTH ASSEMBLY

12. The Health Assembly may wish to note that the provisions of resolution WHA46.16 have been met. However, difficulties have been encountered in relation to paragraph 1(3) ("to mobilize the necessary resources to ensure the systematic implementation of the priorities established") as only two Member States have provided financial support for the implementation of the recommendations on global change.

13. The Health Assembly may wish to request the Executive Board and its Programme Development Committee to follow up implementation of the recommendations and to report to the Health Assembly until the recommendations have been fully implemented.

[1] For titles and respective responsibilities of development teams, see Appendix 1.

Appendix 1

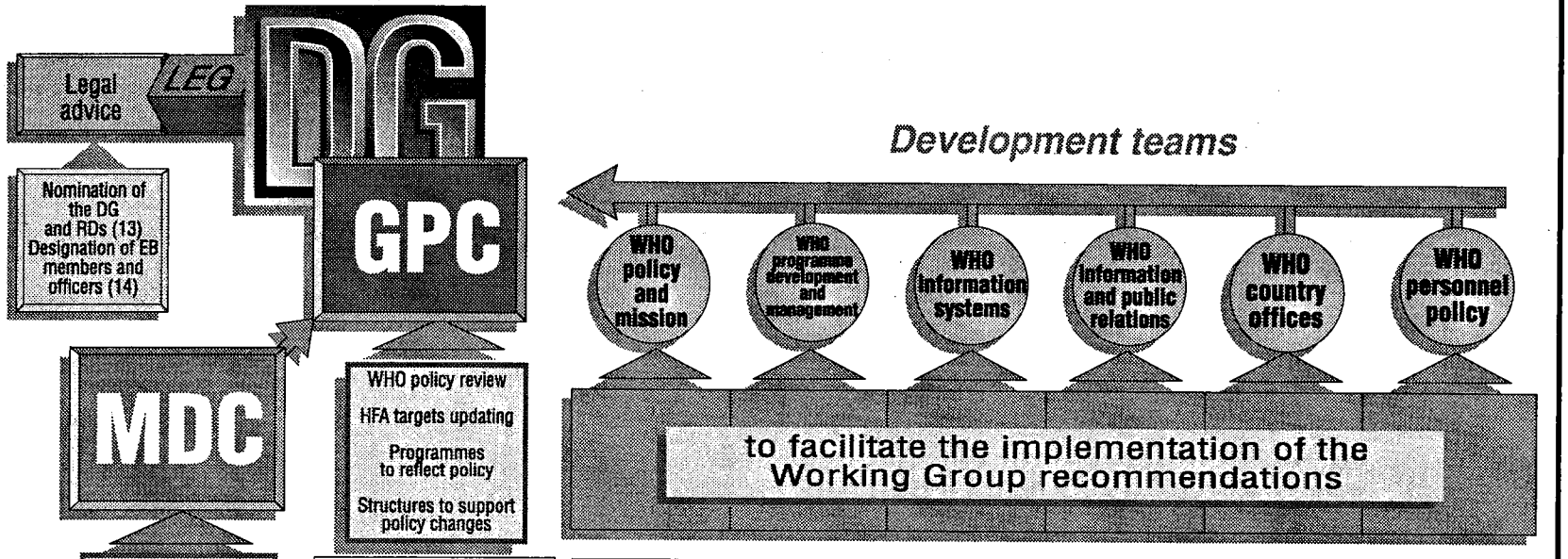
INTERNAL MECHANISMS FOR IMPLEMENTATION OF RECOMMENDATIONS ON GLOBAL CHANGE

TITLE	*FUNCTIONS*	RECOMMENDATIONS
A. POLICY AND MANAGERIAL GROUPS		
Global Policy Council (GPC)	- *Restate the mission of WHO in the light of world changes;* - *review the WHO health-for-all policy and its regional variations; monitor the development of the related targets at all levels; and ensure periodic updating;* - *ensure, through a coordinated approach to programming, budgeting, monitoring and evaluation, that programme implementation at headquarters and at regional and country levels follows the global policy while giving due respect to national priorities;* - *adjust the managerial structure of the Organization in line with the reforms emanating from the study on WHO response to global change.*	Health-for-all policy update (2, 3, 4); delegation of authority (23) and steering of the work of the development teams
Management Development Committee (MDC)	- *Application of the managerial process at all levels of the Organization, including programming, implementation, monitoring and evaluation;* - *coherence and complementarity of programme activities, their technical content and approach, and the programme budget, in accordance with the Organization's agreed policies, strategies and priorities;* - *follow up development of the general programmes of work and the related biennial programme budgets.*	Methods of work of governing bodies (16, 24); financial resources management (36, 37, 38); collaborating centres (41, 42, 43, 44)

TITLE	*FUNCTIONS*	RECOMMENDATIONS
Development teams	- *Make proposals for and facilitate the fulfilment of the major recommendations of the Executive Board Working Group on the WHO Response to Global Change, including proposals for staff training to enable the staff to understand, accept and perform those changes.*	
- WHO policy and mission		World health status and WHO activity report (1, 46); health-for-all policy update (2, 3, 4); collaboration within the United Nations system (31)
- WHO programme development and management		Programme development and management (10, 11, 18, 19, 20, 22); Member States' views on WHO performance (15); collaboration within the United Nations system (32, 33, 34); collaborating centres (41, 42, 43, 44)
- The management of WHO information systems		Information resources (1, 19, 20, 29, 45, 46)
- WHO's information and public relations policy		Information policy (45)
- The role of WHO country offices		Role of WHO country offices (23, 25, 26, 27, 28, 30)
- WHO's personnel policy		Personnel policy (21, 39, 40)
Task force on health and development policies	- *Provide external scientific and political advice on the most promising policy orientations in the light of continuing and emerging health problems and on policy for health and socioeconomic development.*	Health-for-all policy update (2, 3, 4)
B. LEGAL COUNSEL		
Legal Counsel	- *Provide legal advice on constitutional and legal questions; administrative and personnel matters; legal aspects of human rights.*	Nomination of the Director-General and the Regional Directors (13); designation of Executive Board members and officers (14)

Implementation of recommendations on global change

WHO internal mechanisms



World health status and WHO activity report (1, 46) HFA policy update (2, 3, 4, 15, 17) Collaboration within UN system (31)	Programme development and management (10, 11, 18, 19, 20, 22) Member States' views on WHO performance (15) Collaboration within UN system (33, 34) Collaborating centres (41, 42, 43, 44)	Information resources (1, 19, 20, 29, 45, 46)	Information policy (45)	Role of country offices (23, 25, 26, 27, 28, 29, 30)	Personnel policy (21, 39, 40)

LYT94009

LEG= Legal Counsel - GPC= Global Policy Council - MDC= Management Development Committee - HFA= Health for all

Appendix 2

MECHANISMS RELATED TO THE EXECUTIVE BOARD FOR MONITORING THE IMPLEMENTATION OF RECOMMENDATIONS ON GLOBAL CHANGE

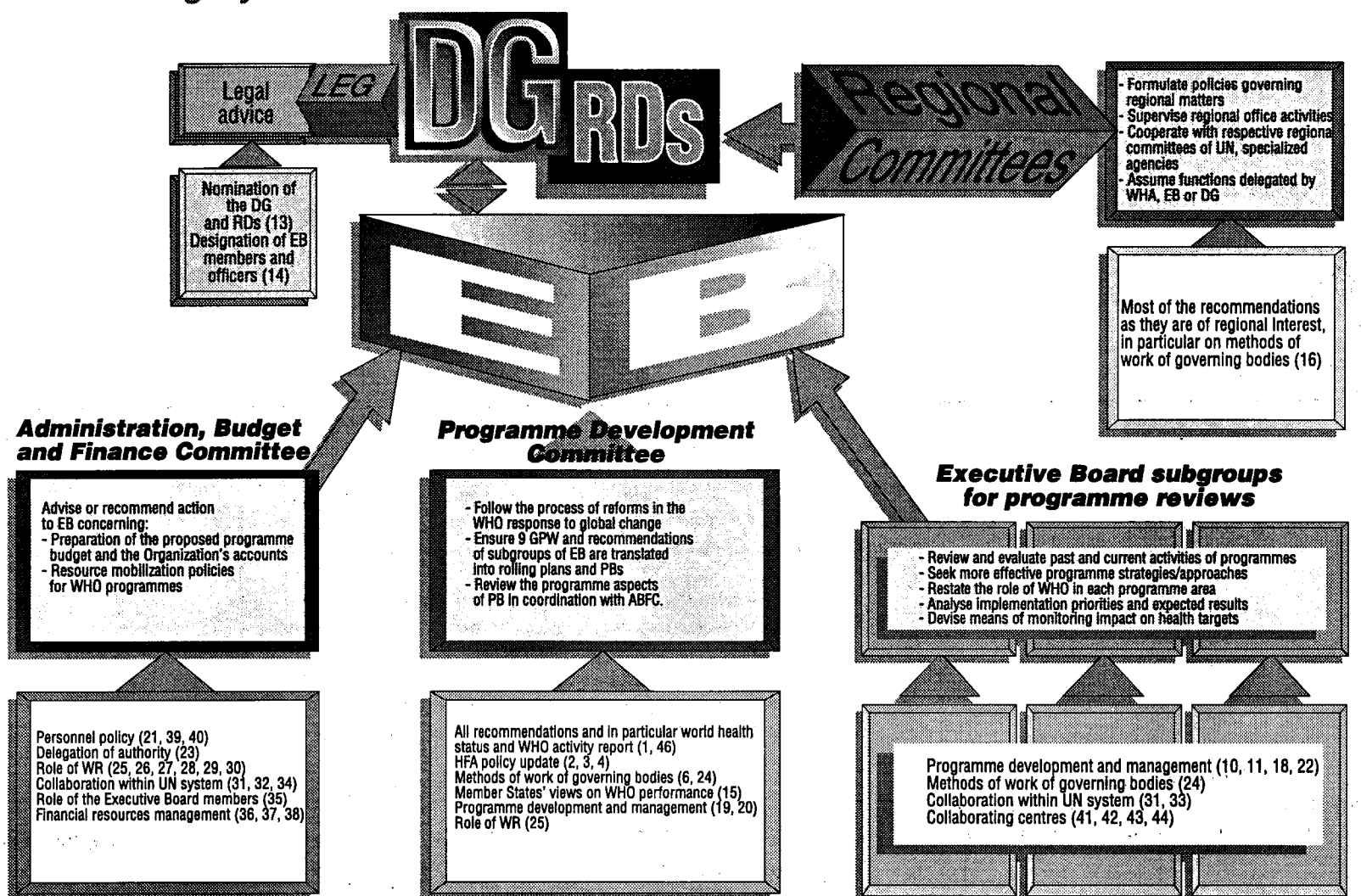
TITLE	*FUNCTIONS*	RECOMMENDATIONS
Executive Board	- *Advise on questions referred by the Health Assembly and on matters assigned to the Organization by conventions, agreements and regulations;* - *submit advice or proposals on its own initiative to the Health Assembly;* - *prepare the Health Assembly agenda;* - *submit a general programme of work to the Health Assembly for consideration/approval;* - *take emergency measures; may authorize the Director-General to take steps to combat epidemics, participate in/organize health relief for victims of a calamity and undertake urgent studies.*	Oversight, direction and monitoring of the process of global change (Report of the Executive Board Working Group on the WHO Response to Global Change, document EB92/1993/REC/1, Annex 1)
Executive Board subgroups for programme reviews	- *Review and evaluate past and current activities of the programme, concentrating on outputs and potential impact on: (i) specific health situations in countries; (ii) the world health situation as a whole;* - *seek new, more effective programme strategies/approaches for the future;* - *investigate what resources would and/or should be available;* - *review the role of WHO in each programme area;* - *analyse priorities for implementation of programme activities;* - *specify expected results;* - *devise ways and means of monitoring progress of activities and impact on health targets and other programmes.*	Programme development and management (10, 11, 18, 22); methods of work of governing bodies (24); collaboration within the United Nations system (31, 33); collaborating centres (41, 42, 43, 44)

TITLE	*FUNCTIONS*	RECOMMENDATIONS
Programme Development Committee	- *Follow the process of reforms initiated, implement the recommendations of the Executive Board Working Group on the WHO Response to Global Change, and assist more generally in the process of programme development in WHO;* - *ensure that the Ninth General Programme of Work is translated into rolling plans and biennial programme budgets for implementation, and that recommendations of the three subgroups of the Executive Board established for programme reviews are reflected therein;* - *review the programme aspects of the programme budget in coordination with the Administration, Budget and Finance Committee;* - *ensure that regional committees use similar approaches.*	All recommendations and, in particular, world health status and WHO activity report (1, 46); health-for-all policy update (2, 3, 4); methods of work of governing bodies (6, 24); Member States' views on WHO performance (15); programme development and management (19, 20); role of WHO country offices (25); basic or operational research (42)
Administration, Budget and Finance Committee	*Give comments to the Executive Board on:* - *the proposed programme budget;* - *resource mobilization policies for WHO programmes, including funds raised for special and cosponsored programmes;* - *the Organization's accounts;* - *any other matters in the administrative, personnel or financial fields on the Executive Board's session agenda or otherwise delegated by the Executive Board.*	Personnel policy (21); delegation of authority (23); role of WHO Representatives (25, 26, 27, 28, 29, 30); collaboration within the United Nations system (31, 32, 34); role of Executive Board members (35); financial resources management (36, 37, 38); personnel policy (39, 40)

TITLE	*FUNCTIONS*	RECOMMENDATIONS
Regional committees	(taken from the Constitution of WHO, Article 50) - *Formulate policies governing exclusively regional matters;* - *supervise regional office activities;* - *cooperate with respective regional committees of the United Nations, other specialized agencies and regional international organizations having common interests;* - *advise the Organization, through the Director-General, on health matters which have wider than regional significance;* - *recommend additional regional appropriations by governments of the respective regions if the proportion allotted to that region from the Organization's central budget is insufficient;* - *assume functions delegated by the Health Assembly, the Board or the Director-General.*	Most of the recommendations, as they are of regional interest and, in particular, methods of work of governing bodies (16)

Implementation of recommendations on global change

Monitoring by Executive Board



LYT94010

LEG= Legal Counsel - 9 GPW= Ninth General Programme of Work - PBs= Programme budgets - ABFC= Administrative Budget and Finance Committee - WR= WHO Representative - HFA= Health for all

2. Budgetary reform

Report by the Director-General

[A47/17 - 24 March 1994]

I. INTRODUCTION

1. The Forty-sixth World Health Assembly in May 1993 adopted resolution WHA46.35 on budgetary reform. Operative paragraph 5 of the resolution requested the Director-General to report to the ninety-third session of the Executive Board in January 1994 and to the Forty-seventh World Health Assembly on progress achieved in implementing all aspects of the resolution.

II. IMPLEMENTATION OF RESOLUTION WHA46.35

2. The Director-General has acted over the past year to implement all aspects of the resolution. He also sought the views and advice of the Executive Board and its Programme Committee on the proposed steps to be taken. Detailed reports by the Director-General to the Executive Board are contained in document EB93/1994/REC/1, Annex 2. The following table gives the appropriate cross-reference under the eight broad issues referred to in the resolution, together with a brief commentary on current implementation status.

Issues raised in resolution WHA46.35	Action taken and reported to Executive Board
1. Introduction of a simpler, more user-friendly budget (operative paragraphs 1 and 2(a)).	Substantially revised budget format, presented in document CDG/93.1, reproduced in document EB93/1994/REC/1, Annex 2, part 3, Appendix 2.
2. Reduction in the lead time between the initiation of the budget preparation and its eventual approval (operative paragraph 2(b)).	New measures taken, outlined in document EB93/1994/REC/1, Annex 2, part 1, paragraph 3 and Appendix, and part 3, Appendix 1, paragraphs 13 to 15.
3. Establishment of strategic and financial priorities within general global objectives (operative paragraph 2(c)).	Priority-setting, covered in Ninth General Programme of Work and in document EB93/1994/REC/1, Annex 2, part 3, Appendix 2, paragraphs 5 to 7.
4. Target-setting, resource allocation and evaluation (operative paragraphs 2(d) to 2(f)).	New approaches, given in document EB93/1994/REC/1, Annex 2, part 3, Appendix 2 and its Attachment 2.
5. Information on actual cost increases during the last financial period to be compared with forecasts (operative paragraph 2(g)).	Will be done, as noted in document EB93/1994/REC/1, Annex 2, part 1, paragraph 7.
6. Use of the United Nations common accounting standards (operative paragraph 2(h)).	Has been implemented as appropriate for 1992-1993 accounts, as noted in document EB93/1994/REC/1, Annex 2, part 1, paragraph 8.

Issues raised in resolution WHA46.35	Action taken and reported to Executive Board
7. Measures to achieve a more appropriate ratio of staff costs to all other programme costs (operative paragraph 3).	Issue being studied in connection with 1996-1997 budget and covered in document EB93/1994/REC/1, Annex 2, part 1, paragraphs 9 and 10.
8. Establishment of an Administration Budget and Finance Committee of the Executive Board (operative paragraph 4).	Established by ninety-third session of the Executive Board; membership, terms of reference and other information given in resolution EB93.R13. (See also document EB93/1994/REC/1, Annex 1, Part 2, section VI.)

3. The Executive Board, at its ninety-third session in January 1994, noted with satisfaction the progress made in responding to the issue of budgetary reform.

4. Work is now proceeding towards the preparation of the Director-General's programme budget proposals for 1996-1997, incorporating the recommendations made in resolution WHA46.35. It is intended that the proposals, in the new format, will be issued in 1994, as usual in early December.

III. MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

5. The Health Assembly may wish to discuss in detail the progress made in response to the issues raised in resolution WHA46.35 in the light of the reports contained in document EB93/1994/REC/1, Annex 2, and to comment or give further guidance as it deems necessary.

3. Implementation of the special report of the External Auditor

Report by the Director-General

[A47/33 - 25 March 1994]

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I. INTRODUCTION

1. The Forty-sixth World Health Assembly, in May 1993, considered a special report of the External Auditor[1] and adopted resolution WHA46.21. The resolution requested the Director-General to report on actions taken to implement it to the Executive Board in January 1994 and to the Forty-seventh World Health Assembly.

2. In all, some 15 recommendations were made by the External Auditor. They may be conveniently divided into those relating to contracts with Executive Board members, those on other contractual matters, and a miscellaneous group.

II. RECOMMENDATIONS RELATING TO CONTRACTS WITH EXECUTIVE BOARD MEMBERS

3. The External Auditor recommended as follows:

> *WHO's legal advice of 1984 not to employ members of the Executive Board, and to exercise caution over their use as temporary advisers, is not set out in the WHO Manual, was not disseminated and has*

[1] Documents A46/33 and A46/33 Corr.1.

not generally been applied. There has therefore been a continuing risk of conflict of interests arising from the award of contracts to these individuals. I welcome WHO's plan to embody the legal advice of 1984 in the regulations. I recommend, however, that this policy be extended to include Executive Board members, alternates and advisers. I also recommend that all contracts placed with members of the Executive Board should be submitted for approval at Assistant Director-General level; that all members of the Executive Board be asked to register a declaration of financial interests with bodies having, or likely to have, a contractual relationship with WHO; and that payments made to individual members of the Executive Board be so noted in WHO's published accounts.

4. The Health Assembly requested the Director-General to establish, in full consultation with the Executive Board, a policy relating to employment of Board members, alternates and advisers, with due regard to the recommendations of the External Auditor. In order to ensure that certain measures were in place as soon as possible, the Director-General issued provisional guidelines on 28 September 1993 on a number of the matters referred to by the External Auditor, noting that the final overall policy would be determined after consultation with the Executive Board.

5. The provisional guidelines were reviewed by the Executive Board at its ninety-third session in January 1994.[1] In the light of the views of the Board, the provisional guidelines were amended in one area and the revised version is now attached for the information of the Assembly as Appendix 1.

6. It will be noted that there are two areas where the guidelines are somewhat different from the recommendations of the External Auditor. First, information about contracts with Executive Board members, alternates or advisers will be issued, not in the annual accounts, but as an information paper to the Executive Board's January sessions. Secondly, the idea of a register of financial interests was not supported and is not referred to in the guidelines.

III. RECOMMENDATIONS RELATING TO OTHER CONTRACTUAL MATTERS

7. An information circular informing staff of new procedures to be followed was issued in December 1993 and is attached as Appendix 2.

IV. RECOMMENDATIONS ON OTHER MATTERS

8. The final group of recommendations of the External Auditor related to media services, the accountability of programme managers to Assistant Directors-General, a security policy for computer operations, the travel budget for the Office of the Director-General, and the policy on class of travel of Executive Board members.

9. The External Auditor recommended that WHO should establish a policy to guide its future media services needs. Planning is now under way for this, including the establishment of a special development team within the Secretariat. The Global Policy Council reviewed the matter at its first session, and will continue to monitor progress in the development of a public information/public relations policy for the Organization during the course of the next year. It is the intention to submit this to the Executive Board in January 1995.

10. An internal computer security committee has now been introduced to improve existing procedures in this area and to ensure regular monitoring of these procedures.

11. The main means for senior management to monitor operations more closely (in particular, as the External Auditor stated, "in comparing expenditure against technical achievement") will be the proposed new management information system, the detailed planning for which will be reviewed by the Executive Board at its ninety-fourth session in May 1994. The completion of this system is regarded as a high priority

[1] See summary records of the seventh and the thirteenth meetings of the ninety-third session of the Executive Board (document EB93/1994/REC/2).

by the Director-General. Other measures will be considered in the context of the restructuring exercise now under way.

12. The External Auditor recommended that the Director-General's Office should budget more realistically for travel. This had in fact already been done in respect of the proposals for the 1994-1995 budget which were later adopted by the Health Assembly. Lastly, the Health Assembly resolution[1] relating to reimbursement for travel of Executive Board members at no more than the normal economy fare has been followed.

V. OTHER ASPECTS OF RESOLUTION WHA46.21

13. Health Assembly resolution WHA46.21 also referred to the need to make appropriate adjustments to WHO structures and staff. The process of reform of the WHO structure which the Director-General is currently effecting has throughout given consideration to ensuring maximum transparency, accountability and efficient use of WHO resources.

VI. PROCEDURES FOR SPECIAL AUDITS

14. During the debate in Committee B at the Forty-sixth World Health Assembly in May 1993, the delegate of Zimbabwe raised the issue of the procedures to follow when special audits were requested. He suggested that the Executive Board might wish to consider the question in view of concerns he had about the procedures relating to this particular special audit.[2] The Health Assembly agreed that a paragraph on the issue raised by Zimbabwe should be included in the report of the Director-General to the Board in January 1994.[3] The issue was referred to by certain members of the Board in their interventions, some being in favour of a review but others suggesting this might not be necessary. No decision for change was taken by the Board on this matter.

VII. MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

15. The Assembly is invited to take note of the progress made in implementing the recommendations of the special report of the External Auditor.

Appendix 1

GUIDELINES REGARDING CONTRACTUAL RELATIONS AND EMPLOYMENT OF EXECUTIVE BOARD MEMBERS, ALTERNATES AND ADVISERS AT THE WORLD HEALTH ORGANIZATION

EMPLOYMENT

1. No Board member, alternate or adviser should be employed as a staff member (fixed-term or short-term professional/short-term consultant).

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[1] Resolution WHA30.10.

[2] See summary record of the fifth meeting of Committee B (document WHA46/1993/REC/3, pp. 222 and 223).

[3] Document EB93/12.

TEMPORARY ADVISERS

2. All letters inviting persons to become temporary advisers* must be cleared through headquarters or regional personnel officers, who will have the responsibility for ensuring that the attention of the Regional Director or Assistant Director-General is drawn to the fact that the appointment involves a Board member, alternate or adviser.

3. Caution should be exercised when considering the appointment of Board members, alternates and advisers as temporary advisers. Particular attention should be paid to the potential for conflict of interest. A clear statement should be on file as to the purpose of the temporary advisership.

4. Except in the case of attendance at formal WHO meetings, all such appointments should be approved by the responsible Regional Director or Assistant Director-General.

OTHER TYPES OF CONTRACTS WITH INDIVIDUALS

5. No other type of contract (such as contractual service agreements, special service agreements, exchange of letters, agreement for performance of work) should be established with a Board member, alternate or adviser that involves payment of monies by WHO to a Board member, alternate or adviser.

CONTRACTS WITH INSTITUTIONS

6. Caution should be exercised if it is known that a contract is about to be entered into with an institution in which a Board member, alternate or adviser has an interest. The question as to whether there is any potential conflict of interest should be considered. Where the interest is known to be in a private capacity, all such contracts should have final approval by a Regional Director or Assistant Director-General, and shall be reported to the Director of Personnel at headquarters.

RECORD-KEEPING

7. The Cabinet of the Director-General will inform Regional Directors, Assistant Directors-General, the Director of Personnel and the Director of Budget and Finance at headquarters of the names of Board members, their alternates or advisers, and keep them up to date on any changes in this list.

8. Personnel offices (at headquarters and in the regions) should keep a record of instances of Board members, alternates or advisers being appointed as temporary advisers. Quarterly reports of this information should be made to the Director of Personnel at headquarters.

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* See WHO Manual paragraphs 590-710. Paragraphs 590 and 600 give the basic definition as follows:

590: The term "temporary adviser" applies to persons invited for short periods of not more than sixty consecutive days to give advice or assistance to the Organization. It does not normally apply to persons engaged to give advice or assistance to a Member State. Temporary advisers are not considered as staff members in any sense and receive neither appointments nor salary.

600: Temporary advisers are paid a daily allowance consisting of the standard United States dollar per diem rate for the country or countries in which they are serving and may be paid an additional amount up to US$ 50 per day. Such amount should be recommended by the technical unit concerned at the time of formulation of proposals for the activity in which the temporary adviser is to be engaged. In determining the level of the supplement, circumstances such as the degree of responsibility of the individual and/or the significance of the activity should be considered in each case. In some instances (e.g. temporary advisers who are invited to participate in meetings) no supplement may be paid, while in other situations a lower amount than US$ 50, in multiples of US$ 10, may be justified.

REPORTING ARRANGEMENTS

9. An information paper will be prepared every year for the January session of the Executive Board listing appointments of Board members, alternates and advisers as temporary advisers, and contracts with any institutions in which Board members, alternates or advisers are known to have any interest in a private capacity.

Appendix 2

WORLD HEALTH ORGANIZATION

INFORMATION CIRCULAR
CIRCULAR No. 94

IC/93/94
9 December 1993

Distribution: HQ + RO

ORIGINAL: ENGLISH

WHO ACTION ON THE RECOMMENDATIONS OF THE EXTERNAL AUDITOR IN HIS REPORT OF 2 APRIL 1993

(Documents A46/33 and A46/33 Corr.1)

In the above report, the External Auditor made a series of recommendations following a special audit. The guidelines below summarize the action to be taken with respect to those of his recommendations which are relevant for organization-wide implementation. They are intended to introduce additional safeguards while trying to avoid excessive bureaucracy. Experience with them should be carefully monitored for purposes of an evaluation in six months. Detailed Manual changes will follow in due course.

CONTRACT AND PROJECT JUSTIFICATION

1. Audit Recommendation - **WHO should establish more rigorous procedures for scrutinising and challenging all contract proposals, especially those initiated outside the Secretariat, to ensure that they are consistent with WHO's needs and aims.**

Audit Recommendation - **WHO should review and record the justification for all projects.**

WHO Action to be taken - Programme managers should ensure that there is a written justification on file of why a project contract is being entered into. When a pre-printed form does not give sufficient space for justification, a separate memorandum should be written. At all stages of processing, the question of whether the expenditure is consistent with WHO's needs and aims should be considered. In cases where this is not completely apparent, specific reference should be made to the advantages for WHO of the activity and resultant expenditure. At all stages, consideration should be given as to whether to refer a proposal to a supervisor because of any uncertainties, or because, for the type of contract in question, expenditure levels are higher than those normally dealt with by a programme manager.

CONTRACTS AND CONTRACT REVIEW COMMITTEE

2. Audit Recommendation - **WHO should review the various types of contract currently used with the aim of simplifying those available.**

Audit Recommendation - **WHO should strengthen the arrangements for the review and approval of contracts.**

Audit Recommendation - **All contracts for research and contracts where a pre-determined contractor is used should be subject to the Contract Review Committee arrangements which already apply under the supplies and equipment provisions of the WHO Manual and wherever appropriate, should be subject to tender.**

WHO Action to be taken - All contracts (except those for research where an established Steering, or similar, Committee review exists, for fixed-term and short-term staff, for consultants and temporary advisers or for special services agreements) shall be subject both to the Contract Review Committee scrutiny and to the tendering arrangements which apply under Section VI.1 of the WHO Manual (Supplies and Equipment). Membership of the Contract Review Committee shall also be as laid down in Manual Section VI.1, except where otherwise stated in the Manual. In the case of contracts for research where an established Steering (or similar) Committee review exists, this Committee should ensure that any administrative, financial and legal issues have been considered by the appropriate responsible offices and divisions and may request referral in particular cases to the Contract Review Committee.

Simplification of types of contract will be dealt with in the forthcoming amendments to the Manual.

CONTRIBUTIONS TO CONFERENCES NOT ORGANIZED BY WHO

3. Audit Recommendation - **Before agreeing to contribute to conferences, WHO should review the conference budget. After the event, WHO should require a statement of the full conference income and expenditure in order to be better placed to gauge the value of its contribution to the event.**

WHO Action to be taken - Any agreement for a WHO contribution to a conference not organized by WHO should be entered into only on the following conditions:

(a) A conference budget has been received from the organizers and reviewed by the Programme Manager inter alia for the purpose of ensuring that the WHO contribution is reasonable in the context of the total budget.

(b) The conference organizer has agreed to provide a financial statement of conference income and expenditure on completion of the activity.

CONSULTANTS AND TEMPORARY ADVISERS

4. Audit Recommendation - **WHO should establish tight controls over temporary adviser contracts; WHO should ensure, prior to approval, that projects proposed are fully justified as worthy of WHO support, and should require participants to submit a report on the outcome of the project.**

Audit Recommendation - **On the recruitment of consultants and temporary advisers, WHO should make full use of its Personnel Division to broaden the scope of contractor choice; WHO should also consistently and vigorously evaluate the performance of consultants and temporary advisers to help inform the choice of future contractors.**

WHO Action to be taken - Proposals to use temporary advisers, other than those attending inter-governmental and WHO sponsored meetings, should include a written record of the reason for the proposed contract and its benefit to WHO's programme. Such temporary advisers should be requested to complete a report on their work at the end of their period with the Organization. All proposals to recruit such temporary advisers must be cleared by the Division of Personnel or the equivalent at regional level.

Consultants are to be evaluated according to Manual provisions. Procedures for evaluating temporary advisers will be included in forthcoming Manual changes.

EXECUTIVE BOARD MEMBERS

5. Audit Recommendation - **WHO's legal advice of 1984 not to employ Members of the Executive Board and to exercise caution over their use as temporary advisers should be embodied in the regulations. This policy should be extended to include Executive Board members' alternates and advisers.**

Audit Recommendation - **All contracts placed with Members of the Executive Board should be submitted for approval at Assistant Director-General level; all Members of the Executive Board should be asked to register a declaration of financial interests with bodies having, or likely to have, a contractual relationship with WHO; payments made to individual Members of the Executive Board should be noted in WHO's published accounts.**

WHO Action to be taken - Provisional guidance (see appendix)* in response to the above recommendations was issued to Regional Directors and Assistant Directors-General on 28 September 1993. As requested by the World Health Assembly, final decisions will be established in full consultation with the Executive Board.

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* See Appendix 1 above; guidance now issued in final form.

ANNEX 3

Implementation of WHO's revised drug strategy[1]

Report by the Director-General

[A47/8 - 5 April 1994]

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[1] See resolutions WHA47.11, WHA47.12, WHA47.13 and WHA47.17.

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PART A. REGULATORY AND NORMATIVE ASPECTS

I. REGULATORY ISSUES

1. Quality assurance is no longer exclusively directed to ensuring that registered pharmaceutical products, including biological products and herbal medicines, are manufactured and stored in accordance with defined norms of good manufacturing practice and that they conform with pharmacopoeial or other officially recognized specifications. In recent years its scope has widened; it is now also concerned with detecting and preventing the distribution of counterfeit, spurious and substandard pharmaceutical products. Both administrative and technical activities are involved that fall within the professional domain of the pharmacist.

2. Concern about the prevalence of illicit products and active ingredients was first expressed at the Health Assembly in 1988.[1] Since then, a large body of narrative evidence has confirmed the widespread existence of illegal manufacturing practices ranging from sophisticated production of counterfeit branded products to fabrication of poor-quality substitutes of authentic generic products.[2] Insofar as these products escape every form of control, their existence is a threat to public health.

3. No administration can regard itself as immune to the criminal activity involved. Indeed, in some countries, infiltration of these illicit products into the legitimate distribution chain has occurred on a scale that threatens to undermine public confidence in health-care delivery. Particularly vulnerable are countries that are rapidly developing an industrial infrastructure and in which large numbers of newly established

[1] See resolution WHA41.16.

[2] Counterfeit drugs. Report of a WHO/IFPMA workshop, 1-3 April 1992 (document WHO/DMP/CFD/92).

small companies have gained a foothold in the domestic market.[1,2] This diversification of the manufacturing base and the concomitant increase in the number of products on national markets have strained the capacity of regulatory authorities in many countries to assure the quality even of legitimately manufactured products. This frailty of control has been objectively documented within the past few years in many developing countries, and particularly those that are industrializing fast.[3,4,5]

4. The possibility of increasing national regulatory capacity through greater governmental allocation or subvention is strictly limited in the prevailing economic climate. As a consequence, regulatory authorities in industrialized countries are looking to pharmaceutical companies to meet the costs of product registration through "user fees".[6] These costs are ultimately passed on to consumers of pharmaceutical products not only in developed, but also in developing countries. Most developing countries, because of their relatively small drug markets, do not possess the leverage to impose significant charges on the industry. It is nonetheless vital that the staff in small regulatory authorities is adequate for both the administrative and the technical elements of an effective system of quality assurance.

Guiding principles for small national drug regulatory authorities

5. The legal and administrative framework needed to define and control the legitimate drug market must also be devised and equipped to frustrate trade in illicit products.[7] WHO's Guiding principles for small national drug regulatory authorities have been prepared to meet this objective.[8] They place emphasis on the need to define the legitimate domestic market by compiling a comprehensive inventory of finished

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[1] See, for example, *Scrip: World Pharmaceutical News*, No. 1785, 12 January 1993, p. 16 "The trade associations claim that small companies make up 50% of [one important exporting country's] pharmaceutical industry and account for the bulk of its exports".

[2] See, for example, *Scrip: World Pharmaceutical News*, No. 1791, 2 February 1993, p. 21, in which the director general of an important exporting country's State Pharmaceutical Administration is quoted as saying that many aspects of the department's work had not kept pace with the establishment of a market economy. The article also notes that "the availability and use of spurious and counterfeit products is reported to be increasing, causing possibly hundreds of fatalities over the past few years. ... spurious drugs worth more than $ 53 million have been seized nationwide since 1991 ... The spurious medicines are said to be manufactured mainly in small village factories ...".

[3] Counterfeit medicines. *International Pharmacy Journal*, 1993, 7(2): 65-70. A questionnaire directed to 72 national pharmaceutical bodies elicited 44 replies. Counterfeit medicines were known to exist in 14 of these countries. The analysis of replies noted that in the developing countries, with one exception, prescribed medicines were involved as well as over-the-counter products. In only two countries was the incidence described as "insignificant". Three countries were reported as having "significant" counterfeit problems, while two others had a "substantial" problem. In two countries, branded and generic counterfeit medicines were involved.

[4] *WHO Drug Information*, 1992, 6(4): 169. Within the past three years WHO has been notified of three apparently dissociated events in which many children are reported to have died after having taken locally formulated medicinal syrups in which the toxic industrial solvent diethylene glycol was substituted for propylene glycol.

[5] The CVI Asia Initiative Working Group reported that "Of the 10 vaccine producing countries in the [Asia-Pacific] region ... only 3 countries ... were assessed to have internationally acceptable standards for vaccine production and quality control and effective national regulatory mechanisms." It noted that in some countries national regulatory requirements were rarely effectively enforced. CVI Working Group Meeting on Asia Initiative, Rockefeller Archives Center, New York, July 28-30 1993: report.

[6] See, for example, *Scrip: World Pharmaceutical News*, No. 1798, 26 February 1993, p. 4, which reports that the European Commission suggested in a discussion paper on the financing of the future European Medicines Agency that "The standard fee for a full product approval application under the proposed [European Communities] centralized procedure should initially be set at ECU 200 000 (about $ 240 000)".

See also, *FDA Backgrounder*, 3 August 1993, on user fees. The United States has begun to levy charges on submissions for new prescription drugs. These raised a total of US$ 36 million in 1993, and the charges will rise incrementally over five years to reach US$ 84 million in 1997.

[7] Document WHO/DMP/CFD/92.

[8] In, *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first Report.* Geneva, World Health Organization, 1990 (WHO Technical Report Series, No. 790, Annex 6).

pharmaceutical and biological products, manufacturers, wholesale dealers and distributors, including import agencies, in both the public and the private sector. The inventory serves as the basis for creating a formal system of registration (or licensing) - a necessary prerequisite for effective enforcement.

6. A critical examination of the legal basis of regulatory control in both developed and developing countries is now being undertaken within WHO to identify the loopholes which allow pharmaceutical products to be manufactured, imported, exported or distributed in such a way that they escape the controls of WHO's Good Manufacturing Practices for Pharmaceutical Products, product licensing and other regulatory requirements.

7. The basic objective is to provide an operational basis for effective enforcement of regulatory decisions. This is dependent, in turn, upon the existence of:

- a capacity to organize, store, retrieve and analyse technical and administrative data held by the central licensing authority;
- a channel for information on products to be imported through the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce;
- an inspectorate that includes qualified pharmacists to assure compliance with good manufacturing practices and regulations concerning storage and distribution; and
- an efficient national drug quality control laboratory.

Computerized databases for regulatory authorities

8. Effective administration of a registration system requires the development of a computerized data storage and retrieval system. WHO has developed a model software package specifically for this purpose, which is intended to run on a desk-top computer. It is designed to support the licensing of both products and manufacturers, and it is offered without charge in a form that can be readily adapted to accommodate specific national needs. It is oriented particularly to the pharmaceutical aspects of regulation and the assurance of quality. It provides an administrative tool for pharmacists engaged in drug regulation and it contains several databases, including a full transcript of the pharmaceuticals section of the United Nations *Consolidated list of products whose consumption and/or sale have been banned, severely restricted or not approved by governments*, and a worldwide listing of 76 000 generic names and synonyms that facilitates their translation into the internationally recognized *International nonproprietary names (INN) for pharmaceutical substances*.[1]

The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce

9. A comprehensive registration system must embrace imported as well as domestically manufactured products. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[2] provides a channel for exchange of information between competent authorities in importing and exporting countries on drug products proposed for export. Guidelines for implementing the Scheme were provisionally endorsed in resolution WHA45.29, and further evaluations are in progress.

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[1] *International nonproprietary names (INN) for pharmaceutical substances, Cumulative List No. 8.* Geneva, World Health Organization, 1992.

[2] WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first Report.* Geneva, World Health Organization, 1990 (WHO Technical Report Series, No. 790, Annex 5).

Good manufacturing practices

10. The implementation of the Certification Scheme is dependent upon timely revision of WHO's Good practices in the manufacture and quality control of drugs.[1] Frequent updating of these practices is now required as a result of the rapid evolution of approaches to chemical and biological syntheses of active ingredients. By resolution WHA47.11 the Health Assembly intends to accelerate the adoption of proposed revisions and amendments by conferring upon the Executive Board the authority to endorse proposals contained in forthcoming reports of competent WHO expert committees, instead of submitting them to the Health Assembly for formal adoption, as at present.[2] In other respects the consultative mechanisms will remain unchanged. Proposed technical amendments to the manufacturing practices are invariably drawn up in consultation with national drug regulatory authorities and bodies representative of the pharmaceutical industries. They are subsequently discussed within the biennial International Conference of Drug Regulatory Authorities (see paragraph 15) before they are submitted, for formalization, to the competent WHO expert committee.

Training needs

11. WHO continues to sponsor and support training programmes at national, regional and interregional levels for drug regulators, including staff responsible for the registration process, pharmaceutical inspectors, and the staff of national drug quality control laboratories. Long-standing collaboration is maintained with the International Federation of Pharmaceutical Manufacturers Associations in organizing training of individual inspectors in in-process quality control.

12. WHO now also arranges, at the invitation of the national authority and with the active participation of local inspectors, informal assessments of the manufacture and regulatory oversight of specific products. These assessments, which were first made to assure the quality of vaccines distributed by UNICEF,[3] are now also undertaken under the aegis of the Children's Vaccine Initiative.[4] Assessments are also being undertaken of the manufacture of oral contraceptive products in collaboration with the Special Programme of Research, Development and Research Training in Human Reproduction. As an important step in assuring the quality of the products in question, these missions not only enhance standards of quality control, but also contribute to the training of national inspectors and promote international harmonization of standards of inspection.

Quality assurance as a professional responsibility

13. Quality assurance of pharmaceutical products is part of the professional training of the pharmacist. However, the potential contribution of pharmacists to the health team has yet to be fully recognized in many countries, and in some the profession remains virtually unrepresented. In an effort to define the scope and potential of pharmaceutical services, WHO organized two meetings on the role of the pharmacist (New Delhi, 1988 and Tokyo, 1993).[5] Without an adequate cadre of qualified pharmacists working in regulatory authorities, in pharmaceutical manufacturing companies and in the community, concern about

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[1] Subsequently named "Good Manufacturing Practices for Pharmaceutical Products". See *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-second Report.* Geneva, World Health Organization, 1992 (WHO Technical Report Series, No. 823, p. 2).

[2] See also document EB93/1994/REC/1, Annex 4.

[3] Procedure for evaluating the acceptability in principle of vaccines proposed to United Nations agencies for use in immunization programmes (revised 1988), *WHO Expert Committee on Biological Standardization. Thirty-ninth Report.* Geneva, World Health Organization, 1989 (WHO Technical Report Series, No. 786, Annex 1).

[4] Children's Vaccine Initiative, Annual report of Task Force on Quality Control: assessment of regulatory procedures. Fifth meeting of the Management Advisory Committee, Cairo, 27-28 May 1993 (document CVI/MAC-5/93.10).

[5] See "The role of the pharmacist in the health care system". Report of a WHO consultative group. New Delhi, 13-16 December 1988 (document WHO/PHARM/DAP/90.1).

falsely labelled, spurious, counterfeited and substandard pharmaceutical products expressed in resolution WHA41.16 is unlikely to be allayed.

14. Resolution WHA47.12 on the role of the pharmacist in support of the WHO revised drug strategy recognizes the part played by the pharmacist in the health care system, particularly in quality assurance and the safe and effective administration of medicines.[1]

II. NORMATIVE ASPECTS

Relationships with national drug regulatory authorities

15. WHO's record of effective collaboration with national drug regulatory authorities is the product of several formal multilateral administrative arrangements:

- nomination of a national information (or liaison) officer within each national authority, who assumes responsibility for receiving and acting upon information from WHO concerning the safety and efficacy of pharmaceutical and biological products, and who arranges for WHO to be kept informed of relevant national decisions concerning the regulation of these products when these decisions are of international relevance and concern;

- institution of the biennial International Conference of Drug Regulatory Authorities, created under the aegis of WHO in 1978 with the objectives of promoting collaboration between national authorities, forging a consensus on matters of mutual interest, facilitating timely and adequate exchange of technical information, and discussing contemporary issues of international relevance;

- liaison with the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, instituted in 1991 as a forum for discussion between representatives of regulatory authorities from the Member States of the European Union, Japan and the United States of America and experts from the pharmaceutical industry within these territories, WHO's objective being consultation on the global applicability of the proposals emanating from the Conference within the broader constituency of WHO's Member States.

Channels for exchange of information

16. A programme in which WHO has normative responsibilities on a global scale cannot operate effectively without efficient channels of communication with competent national authorities and other interested parties.

17. In its normative functions - and particularly when updating the WHO Model List of Essential Drugs and issuing requirements and pharmacopoeial specifications regarding specific pharmaceutical and biological preparations - WHO continues to rely upon endorsement by the three expert committees concerned and publishes their reports in the WHO Technical Report Series.

18. Exchange of information with national authorities on national regulatory decisions, and particularly those of a restrictive nature taken on grounds of public safety, occurs rapidly in the monthly WHO Pharmaceuticals Newsletter and, when urgency demands, in special deliveries of WHO Drug Alert. They are recorded in definitive form in the United Nations *Consolidated list of products whose consumption and/or sale have been banned, severely restricted or not approved by governments*, and the possibility is being explored of producing the section on pharmaceutical products, together with much other material produced by WHO, on CD-ROM for reading and transcription using desktop computers.

[1] See also document EB93/1994/REC/1, Annex 4.

19. Information of relevance to governments and prescribers, as well as commentaries and explanatory articles on normative activities, are issued in the quarterly subscription periodical *WHO Drug Information*. This also serves as the vehicle for lists of International Nonproprietary Names as required by resolution EB15.R7. Much of the information contained in this periodical is subsequently republished in journals issued by nongovernmental organizations and independent drug bulletins. In all, more than 6000 copies of *WHO Drug Information* are circulated in English, French and Spanish, for which 2000 annual subscriptions of Sw.fr. 60 are received for the English-language version alone. Despite the revenue from subscriptions, publication will cease as from 1995 unless US$ 50 000 per annum can be found to support the costs of printing.

Standards and requirements for pharmaceutical and biological products

20. Definition of pharmacopoeial standards and other requirements for pharmaceutical and biological products, which is one of the constitutional functions of WHO, continues. This work, which sets norms for in-process control of biological preparations and for the testing of all finished products within national drug control laboratories, is the basis of *The International Pharmacopoeia* and the annual reports of the WHO Expert Committee on Biological Standardization. It is now complemented by a series of rapid tests that can be performed by pharmacists, outside a sophisticated laboratory setting, in order to verify pharmaceutical substances in both starting materials and finished dosage forms. The objective is to enable pharmacists at all levels to become engaged at first hand in combating, with simple analytical controls, the infiltration of distribution channels by substandard and illicit products.

21. The publication of a pharmacopoeial monograph for a pharmaceutical substance, or the issue of formal requirements for a biological substance, needs to be complemented by the establishment of an international reference substance. Collaborating centres in Denmark, Netherlands, Sweden, United Kingdom, and United States of America have this task. The collective costs far exceed the regular budget allotments for WHO's programme on Drug and vaccine quality, safety and efficacy.

22. There is strong pressure on these international laboratories for biological standards: as the result of the rapid development of biologically assisted synthetic processes they have had to respond to the considerable challenge of establishing new international reference materials for a variety of vaccines, monoclonal antibodies and recombinant DNA products.

New normative instruments

23. With a view to facilitating international movement of finished dosage forms of essential drugs, a guideline has been drafted on marketing authorization requirements applicable to interchangeable multisource (generic) pharmaceutical products. The draft prepared in two consultations convened in 1993 has been circulated for comment to national drug regulatory authorities and interested nongovernmental organizations. A novel aspect of the guidelines is the proposal that a single internationally acknowledged reference product should be designated as a basis for testing bioequivalence or any other criterion of clinical interchangeability, when assurance is required. This is intended, for instance, to meet current concern that the bioavailabililty of generic forms of some fixed combination antituberculosis drugs is unreliable and, in some instances, too low to ensure an adequate clinical response.

24. National regulatory authorities long associated with the development of new drug products now recognize that the data on the basis of which such products are approved for marketing need to be validated through the application of WHO's Good clinical practices and good laboratory practices. Guidelines on the formulation of relevant global standards have recently been issued by WHO with a view to facilitating acceptance by any national regulatory authority of clinical data assembled elsewhere to support an application for product registration.

Essential drugs and model prescribing information

25. The biennial meetings of the WHO Expert Committee on the Use of Essential Drugs continue to provide the mechanism for formal revision and updating of the WHO Model List of Essential Drugs. The

basic format of the list remains unchanged. However, the continued emergence of bacteria and parasites resistant to first-line antimicrobial drugs has resulted in an extension of the concept of strategic "reserve antimicrobials". Previously limited to antibacterial drugs, this connotation has now been extended to some newly introduced antimalarial compounds.

26. Work continues on extending the WHO Model Prescribing Information series to all the drugs contained in the Model List. The task has become more demanding because of the need to update the three booklets initially prepared (on drugs used, respectively, in anaesthesia, for parasitic diseases and for mycobacterial diseases) while creating new material. Booklets on sexually transmitted diseases and diseases of the skin are in final manuscript, and drafts of others are in preparation. The booklet on parasitic diseases has already received international recognition as an authoritative source.

International programme for the monitoring of adverse drug reactions

27. The activities of this programme - in which 41 national drug monitoring centres now participate - continue to be conducted from a collaborating centre in Uppsala, Sweden, which is staffed and funded by the Government of Sweden.

28. Participating centres now submit reports of spontaneously notified and serious suspected adverse drug effects to the collaborating centre, where the international database is used both to signal and to confirm suspicions regarding causal relations between the administration of drugs and the adverse effects. After 25 years of existence, the efficiency with which the collaborating centre can operate and its operating costs continue to be compromised by failure of the other monitoring centres collectively to accept a single system of terminology and classification as a basis for entering data in the system.

29. Increasingly, other WHO programmes are involved in surveillance of the performance of antimicrobials for use against infectious and other communicable diseases endemic in developing countries. Current studies relate to community use of ivermectin to suppress onchocerciasis; bioavailability of rifampicin in fixed-dose antituberculosis combination products; and development of resistance to newly introduced antimalarials including, in particular, artemisinin and its derivatives.

III. MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

30. This paragraph invited the Health Assembly to consider the resolution on implementation of WHO's revised drug strategy: revision and amendment of WHO's Good Manufacturing Practices for Pharmaceutical Products recommended in resolution EB93.R6, and the resolution on the role of the pharmacist in support of the WHO revised drug strategy recommended in resolution EB93.R12. The recommended resolutions were adopted as resolutions WHA47.11 and WHA47.12, respectively.

PART B. THE RATIONAL USE OF DRUGS: THE ACTION PROGRAMME ON ESSENTIAL DRUGS

I. INTRODUCTION

31. In 1984 the Thirty-seventh World Health Assembly adopted resolution WHA37.33 on the rational use of drugs, which expressed concern about the inappropriate prescribing and use of drugs, and awareness of the need for better knowledge of drug consumption and prescription practices, unbiased and complete information for health personnel and the general public about drugs, and adequate training of prescribers. It urged Member States to tackle these needs, to strengthen drug selection and use, and to implement comprehensive and rational drug policies. The Director-General was requested to provide continued

support at national, regional and global levels for this work, and to hold a meeting of experts of all concerned parties on the subject.

32. In accordance with the resolution, WHO convened a Conference of Experts on the Rational Use of Drugs (Nairobi, 1985). The Director-General presented a report of this conference and WHO's revised drug strategy to the Thirty-ninth World Health Assembly (1986); both documents were endorsed by resolution WHA39.27.[1] Highlights of the strategy were to support governments in formulating and implementing national drug policies and action programmes on essential drugs, to expand normative functions, to intensify dissemination of information, to promote better training of health personnel, and to promote collaborative research.

33. In 1988 the Director-General reported to the Executive Board on progress made and problems encountered in implementing the new strategy.[2] Resolution WHA41.16 on the rational use of drugs adopted the same year requested, *inter alia*, the Director-General to implement the remaining components of the revised drug strategy and to seek extrabudgetary resources in addition to those in the regular budget to that end.

34. In 1990 the Director-General reported to the Forty-third World Health Assembly on progress in the Action Programme on Essential Drugs,[3] responsible for implementing the operational aspects of the strategy: the Programme's strategies had had a positive impact on the understanding, acceptance and implementation of the essential drugs concept, but methods of implementation needed to be improved; the priorities and approaches of the Programme differed with each country's socioeconomic situation but the conceptual basis was the same in all; although the generous support initially provided to the Programme was acknowledged, broader support would be needed in future years.

35. In 1992 the Director-General reported to the Forty-fifth World Health Assembly on the implementation of the revised drug strategy through a progress report on the Action Programme on Essential Drugs[4] and a report on the safety and efficacy of pharmaceutical products.[5] Activities had accelerated during the biennium and collaboration with Member States had been strengthened through intensified country support; however, half the population of developing countries still lacked regular access to the most needed essential drugs, and socioeconomic deterioration in the developing world had made progress difficult. The report concluded that the current level of cooperation was not sufficient to counter the socioeconomic decline in developing countries; Member States would need to increase their efforts significantly to make the most of the present political will and momentum in the development of national drug policies and in the implementation of national essential drugs programmes.

II. SITUATION ANALYSIS

A decade of development

36. This report brings up to date the situation in aspects of the WHO revised drug strategy that contribute to the appropriate use of drugs throughout the world. The rational use of drugs is taken in its broad sense to encompass drug selection, procurement, supply and distribution, regulation, quality assurance, production, financing, information and education policies, including human resources development. These aspects of rational use comprise the fundamental elements of a comprehensive national drug policy.

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[1] See also document WHA39/1986/REC/1, Annex 5.

[2] Document EB81/1988/REC/1, Annex 6, Appendix.

[3] Document WHA43/1990/REC/1, Annex 6.

[4] Document WHA45/1992/REC/1, Annex 5.

[5] Document WHA45/1992/REC/1, Annex 6.

37. Although many WHO disease control programmes are involved in rational drug use, this report focuses on the work of WHO's Action Programme on Essential Drugs. It describes the emphasis on direct country support and global WHO advocacy in support of measures for rational use. It also reports on the Programme's "development work" component and operational research undertaken on problems at global and national levels and on technical and policy tools that countries can use to rationalize their pharmaceutical sector and facilitate equity of access to an assured supply of safe and effective drugs.

38. In 1981, when WHO launched its Action Programme on Essential Drugs, the main problem identified was the lack of drugs for the public sector, especially for primary health care. Although countries were spending between 20% and 40% of their scanty health budgets on importing drugs, most people in the rural areas and in urban slums had no access to these drugs. At all levels of the health system - national level, hospital or health centre, patient - many countries lacked drugs in sufficient quantities. At the same time a wide variety of drugs were available in private pharmacies but were out of reach for most of the population. From the earliest days of the WHO Action Programme, rational drug use was a major need; however, the availability of the most essential drugs had to come first. Limited resources alone did not explain the shortage of drugs at all levels; weak government capability to develop and implement policies and programmes, lack of commitment to those goals, absence of management skills, and poor training in the rational use of drugs for pharmacists, physicians and other health workers exacerbated the situation.

39. The main questions were: Which drugs should be purchased with a limited budget? How could drugs be provided to the periphery and to the urban poor? How could a country reduce its expenditure of limited foreign exchange on imported drugs while increasing pharmaceutical coverage? One of WHO's priorities therefore was to assist Member States in finding ways to ensure drug access while strengthening capacity-building.

40. The essential drugs concept was the basic answer to the main difficulties encountered. The strategies developed by WHO through the Action Programme on Essential Drugs focused on this concept, which was advocated as the most appropriate tool to make the best use of resources in selection, procurement, storage, distribution and use of drugs; with the formulation of essential drugs lists and the establishment of national drug policies and management programmes relevant to the health needs of populations, significant savings could be made by rationalizing the purchase, storage, distribution and use of drugs. Attention was initially mainly directed towards the public sector and the development of essential drugs programmes. Emphasis was laid on better use of the limited resources. Few activities focused on the private sector, although the essential drugs concept was largely valid also for this sector.

41. After the Nairobi Conference of Experts and the adoption of the revised drug strategy, the scope of WHO's activities was extended: national drug policies, although always part of the mandate of the Action Programme, became an even more prominent concept. Rational use emerged as a major concern; the nature and the scale of misuse were investigated by WHO and others. Socioeconomic aspects of drug use received increased attention.

42. Throughout the 1980s WHO's work in the pharmaceutical sector continued to cover direct country support: responding to the needs of countries in developing and implementing essential drugs programmes and national drug policies; conducting operational research on subjects of global and national relevance; developing guidelines and training materials; promoting and advocating core concepts of rational drug use at the global and national levels; and providing normative information in support of rational drug use. The emphasis first placed on equity of access to health care at the International Conference on Primary Health Care (Alma-Ata, 1978) has continued to direct WHO's work in this sector ever since.

Progress

43. Today the essential drugs concept is widely accepted as being in the interest of public health. A major accomplishment of WHO's work and leadership has been to make the concept a main item on the "international health agenda" of many organizations around the world and to change the conceptual framework for pharmaceutical policy in developing countries. The scope of the concept has expanded to form a policy and now includes all aspects of a national pharmaceutical system. Multilateral and bilateral

agencies and nongovernmental organizations have adopted the approach promoted by WHO. Efforts to improve the efficiency of the public health system through the application of the essential drugs concept now meet with little criticism.

44. Increasing attention has been paid by governments to establishing mechanisms to improve the availability of drugs, and many have tried to rationalize their drug sector. Most developing countries have drawn up limited lists of drugs under international nonproprietary names for the public sector and many have established national essential drugs programmes, often supported by donors.

45. At the global level, the availability of generic drugs at low cost on the international market, and the services offered by such nonprofit organizations as the International Dispensary Association, Equipment to Charity Hospitals Overseas, and UNICEF's supply centre in Copenhagen have increased competition and contributed to a lowering of drug prices.

46. Governments, often for cost-containment reasons, are now more aware of and have started to tackle the problems linked with irrational prescribing and use of drugs. The academic world has become more conscious of its responsibilities and of the dangers of inadequate training, and there is growing awareness of the need for strategies to combat irrational drug use. The public has also been sensitized to these issues through the important role played by consumer groups in advocating the provision of more and better drug information to the public.

47. Lastly, the concept of comprehensive national drug policies, covering both public and private sectors, has gained ground. Countries widely differing in socioeconomic development, such as Australia, Malawi, Philippines and Syrian Arab Republic, are implementing national drug policies. There is also a movement towards the adoption of subregional policies, as indicated by the current framing of a common drug policy by the Andean countries.

48. Despite these advances, strategies designed in the 1980s have not been successful in solving some of the problems, including the provision of financing mechanisms for drugs.

Constraints and problems

49. Access to essential drugs remains limited and inequitable in many countries, despite much effort. Structural weaknesses of the public drug sector continue to handicap the functioning of the health system. Although procurement and distribution have improved in a number of countries, progress has been challenged by the economic crisis and the structural adjustment process. Ministry-of-health budgets for drugs have often decreased in real terms while alternative financing methods, including cost sharing and fiscal policies favouring essential drugs, are still not fully implemented and evaluated. Equity of access to drugs for the indigent and needy, particularly in societies where cash income is highly restricted, has not always been adequately assured.

50. Planning, programming and budgeting capacities are still limited in many of the least-developed countries, and trained staff to establish and implement national drug policies, including the regulatory aspects, are scarce.

51. Some essential drugs programmes and disease control programmes with a drug supply component are insufficiently institutionalized and are not fully coordinated with and integrated into national health policies. They continue to be fully dependent on donors, and strategies designed in the 1980s to ensure their long-term sustainability have to be reviewed.

52. Inappropriate use of drugs is a cause of great concern, leading not only to waste of resources but also to the possibility - as in the case of the misuse of antibiotics - of serious long-term public health consequences. In many countries, prescribers and the public have no access to objective information about the appropriate use of medicines, and commercial marketing practices remain a cause for concern.

53. Cooperation and coordination for a common policy framework need to be strengthened between all parties in and outside WHO.

54. Improvements in regulation through the strengthening of the drug regulatory and quality assurance mechanisms, are a priority. Consequences of current poor regulation include an increase in retail drug prices, a concentration of the distribution network in the main towns, a shift to less essential drugs with a higher profit margin, and an irrational use of drugs and resources in general. These factors all impede access to needed drugs.

55. Many of these failures are linked to slow development and to new problems and challenges. The pharmaceutical sector is part of a wider context, and structural constraints in other sectors within countries contribute to the failure of many programmes and projects. Moreover, there is a global imbalance in the pharmaceutical sector: a strong "supply side" influences consumption in the wrong way when the "demand side" consists of often poorly informed prescribers and public. This is particularly true in developing countries, where the administration often has limited resources and negotiating power. Such an imbalance contributes greatly to the difficulty of implementing rational drug policies.

56. In conclusion, many countries face the critical problem of how to make the best use of limited available resources to improve access to high-priority drugs and how to use the drugs themselves rationally. This calls for the establishment of new priorities and strategies at country and global levels by all parties. It also necessitates an integrated approach: a national drug policy must be conceived within the overall framework of national health policy. WHO's support to countries in designing new strategies within the framework of such a coordinated approach is discussed below.

III. RATIONAL DRUG USE WITHIN A POLICY FRAMEWORK

Why countries need a national drug policy

57. The present lack of adequate supplies of drugs appropriate for health needs, the problems of drug financing and the widespread irrational use of drugs not only result from financial constraints but also reflect the priorities and attitudes of governments, prescribers, dispensers, consumers and the pharmaceutical industry.

58. A national drug policy that covers both the public and the private sectors is an expression of goals for improving the supply and use of drugs, the priorities among those goals and the main directions for attaining them. It forms an integral part of a national health policy and provides a framework for action.

59. Government regulation of the pharmaceutical market is necessary for appropriate drug use; drugs are different from other goods and their commerce differs from other markets. First, they are a basic necessity to maintain life and to relieve suffering. In these conditions they should be available to all, regardless of ability to pay. Secondly, the need for drugs is as unpredictable as major illness and cannot be planned within an individual's budget. This deduction has led in developed countries to the creation of health insurance systems. Thirdly, a major factor where drugs are concerned is the consumer's relative lack of knowledge; prescription drugs are complex chemical entities, and most consumers cannot judge the appropriateness and the quality of the medicines, even after use. The very nature of the pharmaceutical market contributes to this uncertainty. Lastly, drugs are manufactured by a competitive pharmaceutical industry within a system that favours the proliferation of products.

60. With such conflicting interests and powerful social and economic forces at work, and because of the distinctive characteristics of drugs, it is essential that the State should define the objectives of rational use and develop a policy for the benefit of public health and the patient. It should avoid total reliance on free choice and the exchange between consumers and providers, which fails to ensure universal coverage or equal access to even the most essential drugs, or their rational use. Only through a clear definition of the objectives, coordination of the different components of the system, and cooperation among the different sectors involved - mainly health, finance, trade and industry - can improvements be made.

WHO's support to national drug policy development

61. Each nation, of course, has to establish its own drug policy according to its own political and economic realities and in the light of its own problems and possibilities. The choice made reflects its social values and culture. Whatever the process, each country has to specify its goals and priorities according to the description and analysis of its drug problems. However, some core objectives have been defined which can be summarized as follows:

- to make available effective, safe, low-cost drugs of good quality to meet the needs of the entire population (essential drugs);
- to ensure that all drugs are used rationally; and
- to develop, where economically and technically feasible, national pharmaceutical production that supports economic growth and the overall development strategy of the country.

62. To reach these objectives, any policy should address all aspects of drug development, manufacture, financing, distribution and use in the public and the private sectors. Such a policy would include:

- legislation to ensure drug safety, efficacy and quality, and to regulate production, marketing and dispensing;
- national procurement on the basis of an essential drugs list in the public sector;
- strategies to enhance the affordability of drugs in the public and private sectors;
- provision of independent drug information, and measures to improve the education of both prescribers and consumers in rational drug use.

63. To frame a comprehensive national drug policy and to bring about the reforms essential to realizing goals are measures that require the **unequivocal political will and commitment of governments**. But good policy-making implies also that alternative goals have been considered; that the objectives decided upon are clear; that means for achieving them are known, feasible and agreed on by all parties; and that the progress and cost of implementation are measured, as well as the effects. WHO can and does cooperate extensively with countries in this process.

64. The implications of the various strategies should be discussed with all the interested parties, including professional groups, health workers, consumers, teaching staff in the health field, and pharmaceutical manufacturers. Full consideration should be given to all their views and advice in order to ensure that the policy takes into account the needs expressed by the interested parties and encourages their participation in its implementation. Once decided, a written statement of the national drug policy is important, not only because it provides a comprehensive and detailed framework for all pharmaceutical development but also because it explicitly demonstrates the full commitment of the ministry of health and the government.

65. In accordance with this approach, WHO's Action Programme on Essential Drugs in the past decade has provided operational support to Benin, Bhutan, Colombia, Guinea, Kenya, Malawi, Mongolia, Myanmar, Syrian Arab Republic and other countries in the design of comprehensive national drug policies. WHO is currently cooperating with over 50 countries in one or more aspects of the pharmaceutical sector. In some countries support has focused on or started with a particular technical aspect, but it increasingly encompasses an integrated approach to the entire pharmaceutical sector within the framework of a national drug policy. Some examples are given under specific subject headings in the following sections.

66. The Organization's extensive involvement in such direct operational support to countries enables it to share experience and information on policy and technical strategies in countries and regions, thus broadening the pool of common knowledge and enabling countries to draw on experience in other parts of the world. This cross-fertilization and networking approach has been systematically promoted and

strengthened in the past two years through a series of regional meetings: for French and Portuguese-speaking countries in the African Region (Cotonou, Benin and Brazzaville, 1993); for Andean countries (Cartagena, Colombia, 1993); for countries in the South-East Asia Region (New Delhi, 1991 and 1993); for French-speaking countries in the European Region (Grenoble, France, 1993); and for countries of the Association of South-East Asian Nations (ASEAN) (Jakarta, 1993).

67. WHO's support to countries includes its normative work, such as that for international nonproprietary names, quality assurance and control norms, model prescribing information and guidelines for developing small regulatory authorities, thus providing an indispensable tool to countries in the long-term development and implementation of comprehensive national drug policies, strategies and plans of action.

IV. KEY ELEMENTS OF A NATIONAL DRUG POLICY

68. The following are key components of a national drug policy on which WHO's operational country support and the Programme's "development work" component has focused. The underlying principles of its structured technical approach, and examples of recent activities, are described below.

Drug selection and procurement

National drug priorities

69. The cornerstone of an efficient pharmaceutical supply system is the selection of drugs. Drug selection and prioritizing have an important influence on a number of important fiscal, legislative, administrative and quality control requirements of the pharmaceutical supply system. In drug procurement, purchasing power is significantly diluted by the existence of large numbers of duplicate and nonessential products. By focusing on a reduced number of drugs the efficiency of the procurement process can be significantly improved, discounts for bulk purchase obtained, and quality control analysis undertaken more easily. Management costs for storage, record-keeping and personnel can be reduced, since these are directly related to the number of different drug products in the inventory. Distribution is greatly facilitated and simplified when the number of products is reduced. When only products which meet real health needs are available, health care personnel can improve the efficiency and appropriateness of drug prescription and dispensing. Education and training are facilitated, particularly in countries where nurses and paramedical staff are often prescribers. The provision of objective prescribing information through formulary publications, therapeutic manuals or standard treatment guides is also greatly facilitated.

70. In developed countries, selected drug lists are commonly to be found as hospital or practice formularies and within State and private reimbursement systems. A new development is the use of such lists as an educational tool. In many developing countries, drug prioritizing lies at the heart of national drug policy and strategies for rational use. Over 120 Member States have now drawn up and regularly update national essential drugs lists - many with WHO support. Most use the lists as a tool primarily for the public sector, but some countries - for example, Malawi, Sudan and Zimbabwe - do so for both the public and the private sector. It seems probable - with the present trend towards expansion of the role of the private sector, rising drug prices, and the proliferation of products marketed globally - that national drug registration criteria will become more stringent in an increasing number of countries, particularly those in which foreign exchange is strictly limited.

71. WHO's Model List of Essential Drugs, first published in 1977 and updated biennially by the Expert Committee on the Use of Essential Drugs,[1] has provided many countries with a useful starting point from which to draw up, adapt and update their own national list to meet their particular therapeutic needs and circumstances.

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[1] The seventh and latest published model list of some 270 pharmaceutical substances appears in *The use of essential drugs. Fifth report of the WHO Expert Committee*. Geneva, World Health Organization, 1992 (WHO Technical Report Series, No. 825).

Rational procurement

72. Many countries with no centralized purchasing system pay prices for drugs that far exceed those on the international market, failing to obtain bulk discounts. At the same time inadequate planning infrastructures prevent them from estimating needs accurately and sufficiently far in advance, and they lack information on the best available market prices. Studies have shown that procurement is the area in which the greatest improvements and savings in drug supply can be made. For example, if drugs are ranked by value it generally appears that about 25 to 30 essential items account for a significant portion of expenditure, so that procurement should concentrate on acquiring the high-value items at the top of the list at the best price possible.

73. In cooperating with countries to strengthen drug procurement WHO gives high priority to the development of human resources through national and regional training seminars, such as the series of workshops on the subject held under the auspices of the African Preferential Trade Area in 1991 and 1992, with WHO support, in Burundi, Kenya, Mozambique, Uganda and United Republic of Tanzania, and attended by 113 participants from 14 countries. WHO also collaborated, supported and participated in a workshop organized by the International Trade Centre, UNCTAD/General Agreement on Tariffs and Trade (Benin, 1992) on drug procurement and trade in the Economic Community of West African States to promote links between neighbouring countries.

74. The International Trade Centre is collaborating with WHO in another approach to procurement. The first issue of a jointly sponsored monthly bulletin, the Pharmaceutical raw materials/essential drugs report, appeared in March 1992. It informs developing countries of purchasing prices of raw materials for the production of essential drugs in order to improve the importers' opportunities for negotiation.

75. The use of the international nonproprietary (generic) name is essential to standardize drug procurement and information. Procurement by generic name can result in significant savings on the cost of more expensive, brand-name drugs. It may also contribute to better drug use, enabling prescribers, dispensers and the public to become familiar with a single common name for a specific active substance. An increasing number of countries have made inclusion of the international nonproprietary name on all advertisements and drug packages obligatory by law.

Supply and logistics

76. In its operational support WHO aims to build up a comprehensive logistics infrastructure and to solve supply problems. Its technical and financial support covers drug quantification, upgrading of local production, technology transfer, development of storage and inventory control systems, and drug management and distribution. In exceptional situations, an essential drugs supply component is included in WHO-supported country programmes.

77. In response to the difficult economic situation in many countries some bilateral donors are providing drugs as aid in kind. During the decade WHO has helped a number of such countries to define and plan their overall needs, including donor financing of the development of human resources, educational and organizational structures, and regulation.

78. Good drug storage and inventory practices at central hospitals and health centres are essential for a health service to function well. In Algeria, Benin, Bhutan, Guinea, Malawi and Myanmar training courses for health officers and supervisors in drug store management and inventory control at all levels were conducted in 1992. The stores management curriculum produced and used in the Bhutan Essential Drugs Programme has benefited other countries in the region, such as Maldives and Myanmar.

79. After compiling reliable consumption data using the WHO Action Programme's methodology of combined morbidity, standard treatment and past consumption statistics, the Governments of Bhutan and Burundi increased their drug budgets in 1992 better to meet their needs.

Quality assurance

80. Ensuring that drugs produced, entering or available in a country are of acceptable quality is a responsibility that can only be taken by the government and exemplifies the role of State policy in both the public and the private sector. Quality assurance encompasses good manufacturing practices, drug registration, effective regulation, quality control facilities and inspection, and supervision of the supply and storage of drugs.

81. WHO is cooperating with countries at both the global development level and the national operational level to ensure that only drugs which are safe, effective and of acceptable quality are marketed. It continues to fulfil the full range of normative functions described in the Director-General's report to the Forty-fifth World Health Assembly.[1]

82. As part of measures for strengthening drug quality assurance systems in developing countries, WHO assessed the effectiveness in both importing and exporting countries of its Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, with technical assistance from the United States Food and Drug Administration and financial assistance from USAID's Office of Health. Field work has covered 15 countries in Africa, the Americas, South-East Asia, the Eastern Mediterranean and the Western Pacific. Data and a full report will be available in 1994.

83. With the increase in liberalization of pharmaceutical markets, drug regulatory control, quality assurance and inspection systems required urgent attention in many developing countries. WHO responded to these needs by supporting human resources development; submitting analyses and recommendations on reorganizations in ministries of health; indicating the application of WHO's technical guidelines; and giving technical, managerial, administrative and financial assistance.

84. As an integral part of the national drug policy framework, and within an agreed master plan for development of the drug sector, drug registration systems are being established or strengthened in many countries, including Benin, Gambia, Guinea, Maldives, Mongolia, Myanmar, Philippines and United Republic of Tanzania. This involves making an initial standardized inventory of marketed products, adopting drug registration criteria, and applying them in preregistration product evaluation. The first module of WHO's software package for drug regulatory authorities is now in use in five countries in the Americas and Eastern Mediterranean. Courses on all aspects of regulatory control are receiving support in the countries in question, and in others where regulation and inspection need to be strengthened.

85. WHO also provides advice to countries on the feasibility of establishing national drug quality control laboratories and on the technical and financial resources necessary, as it did in a 1993 evaluation mission to the United Republic of Tanzania. Ideally, each country should have its own capacity for quality control. However, some countries will not be in a position to establish their own laboratories for some time. To meet their needs, WHO is focusing on the development and strengthening of regional drug quality control laboratories, such as the one in Zimbabwe, and on cooperating with countries in establishing a mechanism whereby drug samples can be tested in a neighbouring country that has quality control facilities. A meeting reviewed the functions and management of four regional laboratories in Africa (Cameroon, Ghana, Niger and Zimbabwe) (Niger, November 1993).

86. Despite the concern expressed at the public health and economic consequences of counterfeiting drugs,[2] very few reliable data on the extent of the problem exist in the public domain. WHO, through its Action Programme on Essential Drugs and in collaboration with the French *Réseau Médicaments et Développement*, is undertaking a study of the quality of drugs on the African pharmaceutical market, focusing specifically on the problem of counterfeit drugs. A report of the first phase of the research,

[1] Document WHA45/1992/REC/1, Annex 5.

[2] Resolution WHA41.16. See also the report of a joint WHO/IFPMA workshop on counterfeit drugs (document WHO/DMP/CFD/92).

covering an analysis of the literature and a questionnaire completed by 25 countries, is now available.[1] One striking finding from the first phase of the research is that no reliable independent or government data concerning the magnitude of the problem could be obtained. The review of the specialized and popular press concluded that, apart from a few known cases which were always cited, published information was vague and few documented studies existed on drug counterfeiting that would permit the nature of the problem, the supply and production routes, or the financial implications to be determined. Field studies under way in five African countries are attempting to elucidate the extent of the problem.

87. Quality assurance of legitimate drugs is also the object of operational research under the Action Programme. A longitudinal study of 10 potentially unstable drugs distributed in Sudan followed them through the supply chain for 12 months in 1991 and 1992. Another study in 1992 investigated the stability of injectable oxytocics in tropical climates.[2] Oxytocics are potentially life-saving drugs used in the treatment and prevention of excessive uterine bleeding following obstetric delivery. Previous research had indicated problems with their stability under tropical conditions. Field-testing in Gambia, Malawi, Sudan and Zimbabwe was followed by laboratory analysis. The research concluded that the stability of oxytocin is better than that of ergometrine and methylergometrine, a finding with significant public health implications. In the case of ergometrine the study produced an easy way to determine visually whether the level of active ingredient was still adequate. Further stability-testing of essential drugs is being undertaken.

88. Quality assurance is a necessity and a government responsibility, but it has to be recognized that many developing countries have not yet been able to establish a comprehensive and enforceable drug regulatory system. A number of reports during the past biennium have indicated that the rigorous safety and information standards imposed in countries with well developed regulatory systems are not always maintained for drugs that are exported. Such countries have a particular responsibility to disallow such double standards.

Financing

89. Faced with the new socioeconomic environment of an open-market economy, many countries are reconsidering their public health and pharmaceutical policies with a view to a more rational use of drugs and the best use of resources. In most countries, and particularly in developing ones, expenditure on drugs is the most critical aspect of the financing of the entire health sector. Such expenditure is not, financially speaking, the major component of a health budget (salaries absorb a higher percentage) but it is the most important and sensitive.

90. Rapid economic, political and social change has occurred in the past two years in many countries. The proper role of government in health care is being redefined. Changes in the structure of drug markets may change the quality and affordability of health care. Clearly there is a need - probably one of the highest priorities today in the health sector - to understand how the objectives of countries in health and pharmaceutical policy may be affected by economic changes.

91. One tool prepared by WHO for governments and policy-makers is a guide to the economic aspects of drug supply and use,[3] which offers a framework for policy-makers and administrators to analyse the economic and financial aspects of pharmaceutical policies based on the essential drugs concept. A companion volume, offering detailed guidance for the development of practical economic strategies in the pharmaceutical sector, is in the final stages of preparation.

92. Another aspect of WHO's support to ministries of health facing the new economic situation was the organization, by PAHO and the Ministry of Health of Venezuela, of a conference to study the economic and public health advantages of the essential drugs concept and the implementation of comprehensive

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[1] Qualité des Médicaments sur le Marché pharmaceutique africain: Le problème de la contrefaçon. Paris, *Réseau Médicaments et Développement*, 1992. (Unpublished document.)

[2] Stability of injectable oxytocics in tropical climates (document WHO/DAP/93.6).

[3] Access to drugs and finance: basic economic and financial analysis (document WHO/DAP/91.5).

national drug policies (Caracas, 1992). It concluded that new approaches to the financing of drugs were needed, always with the ultimate objective of greater accessibility and equitable supply. The new context called for more effective competition and greater market transparency. The conference recommended the adoption of generic drug policies as a central point of the essential drugs strategy in Latin America.

93. In the difficult circumstances created by the devaluation of the CFA franc (approximately 50%) WHO is providing technical support at country level under the Action Programme for governmental measures to mitigate the impact on drug supplies, and at global level to coordinate a range of measures also aimed at safeguarding the availability and affordability of essential drugs.

94. As economic pressures continue to make it difficult for many countries to provide adequate funds for the supply of drugs to health services, increasing reliance is placed on pharmacies and drug outlets in the private sector, but their prices are often beyond the reach of much of the population. Many countries are now experimenting with a variety of ways of providing additional funds for drugs or of determining how available funds are spent, for example, through fiscal policies favouring the production or marketing of essential drugs. Recent discussions on financing of drug supplies have often focused on cost recovery or cost sharing - charging patients for drugs at the time of their illness - yet insufficient attention is being paid to improving the use of existing resources and to reducing waste in the drug supply system.

95. Decisions on drug financing affect the availability of drugs and the way drugs are used. Technical support to countries in this area can be crucial, but more information is still needed on the short- and long-term consequences of various modalities of drug financing. Through the Action Programme WHO is supporting a number of studies in this field; subjects include the contribution of the private sector to drug accessibility in Africa, the impact of modes of payment on drug use, and the expenditure of individuals and families on drugs.

96. WHO is also playing an important role in the development of tools for analysis and research, and "intervention" strategies to enable countries and communities not only to obtain the best value from the money spent on drugs but also to ensure that decisions on financing are consistent with public health goals.

Education and training

97. Inappropriate drug prescribing by physicians and health workers and inappropriate use of medicines by the general public are growing problems in both the public and the private sector of developed and developing countries. In the case of prescribers, contributing factors in education and training include pharmacological instruction that is theoretically rather than practically oriented; outdated information and absence of continuing education programmes; lack of skill in evaluating different sources of prescribing information, or lack of information itself; and the influence on younger personnel of poor prescribing practices by senior staff. In the case of consumers, problems include lack of basic education in schools about the use of medicines - how they work in the body and how they can do harm as well as good; the lack of culturally sensitive education campaigns on appropriate drug use; aggressive and misleading drug promotion; and the often poor communication skills of prescribers and dispensers which inhibit understanding and contribute to failure to follow treatment.

98. WHO striving to improve prescriber and manager education in a number of ways. At national level they include comprehensive training programmes within the framework of the planning and implementation of essential drugs programmes. At the global and regional levels, recent activities have included:

- the preparation, with the University of Gröningen (Netherlands), of a student manual on the principles of rational prescribing[1] which can be used as the basis for an interactive course in practical drug therapeutics (the manual deals with problem-solving skills rather than the rote learning of time-limited information; it was field-tested on groups of students in seven medical schools in Australia, India, Indonesia, Nepal, Netherlands, Nigeria and the United States of

[1] Model guide to good prescribing (document WHO/DAP/91.12).

America in 1993. Standardized tests of student performance made before, immediately after and six months after the course indicate substantial and sustained learning gains compared with control groups; the manual will be available for widespread distribution during 1994);

- collaboration with the International Network for the Rational Use of Drugs in the organization of training courses on rational drug use, which were held in Indonesia in 1990, Nepal in 1992, and Zimbabwe in 1993 (the latter heavily oversubscribed, was attended by 42 participants from 19 countries; a course in Ghana in 1994 was equally successful. The approach is highly participatory and practically oriented, and covers drug use problems, the task of developing and evaluating interventions, and public and prescriber education materials and campaigns. Participants receive an extensive file of lecture and teaching notes and visual material which enables them to reproduce the course in their own countries);

- the development, in collaboration with the School of Pharmacy, Robert Gordon University, Scotland, of a pioneering course in drug management and rational use to meet the needs of middle-level pharmaceutical and other health personnel from developing countries (the curriculum covers drug policy and legislation, and all aspects of pharmaceutical management, including the provision of formularies and information; teaching staff all have extensive experience of drug management in developing countries and guest lecturers include staff of the WHO Action Programme. The response to the first two courses has been very positive and a record number of applications has been received for the 1994 course);

- further collaboration with Robert Gordon University on design of a "distance learning" project on drug supply and management, aimed specifically at developing countries, together with the Commonwealth Pharmaceutical Association and The Commonwealth of Learning;

- familiarization of key staff (professors of clinical pharmacology and internal medicine) of all 90 medical and pharmacy schools in the Eastern Mediterranean with the essential drugs concept in order to promote teaching on the rational use of drugs in the undergraduate curriculum (the three-day workshop consists of discussion of the essential drugs concept; presentation of various methods of teaching pharmacology, therapeutics and rational prescribing; discussion of possible modification of curricula; and preparation of plans of action. Extensive documentation is available and follow-up support is given on request; by the end of 1993 over 80% of the schools had been covered);

- in collaboration with La Trobe University, Australia, development of prototype audiovisual material to guide medical students in determining and evaluating sources of drug information, with special reference to WHO's Ethical Criteria for Medicinal Drug Promotion.

99. The Action Programme's approach to education of the public is to promote the development in countries of carefully tested materials and programmes that are culturally appropriate, taking into account people's knowledge, attitudes and practices in the use of medicines, and the realities of the national drug supply situation. WHO has supported research for the development of such programmes in countries including Kenya, Malawi, Myanmar, Nepal, Sudan, Thailand and Zimbabwe, and further projects are under development in the Syrian Arab Republic and Yemen. Major public education campaigns, using printed materials and the mass media, are under way within the framework of country support to Bolivia, Colombia and Philippines. WHO tries wherever possible to involve a wide range of other organizations and bodies in such work in order to maximize the impact and disseminate the material as widely as possible. The contribution of consumer organizations, in countries where these exist, is particularly significant.

100. Effective education of the public in the rational use of drugs is not easy, particularly in developing countries. There is still resistance on the part of the prescribers to the "empowerment" of the consumer; human and financial resources for research and educational campaigns are scarce; the campaigns are expensive and have to be repeated; and little has been done to determine how such education can be sustainable and how it is to be evaluated and followed up. Yet it is vital. Users' expectations can and do influence prescribing patterns, and an informed dialogue between patient and prescriber is essential if the

purposes of medicines and the manner in which they should be taken are to be properly understood. Furthermore, over 50% of medicines are bought directly from pharmacies or other outlets, including the informal sector. This proportion can be expected to increase if the role of the public sector continues to diminish. It is essential that education of the public should become recognized as fundamental to rational drug use and part of policy. WHO, through its Action Programme, using advocacy material and direct country support, is endeavouring to promote this important aspect.

Information

101. A medicine has been described as "an active substance plus information". Yet in many parts of the world the information is lacking or is inadequate to permit a fully informed decision for rational use. Throughout the world physicians are the target of powerful commercial marketing campaigns, but these are intended to promote a specific product and do not provide the prescriber with the comprehensive information needed for objective comparison and assessment for the best possible prescription. Pharmaceutical marketing is covered in Annex 4 of the present volume. In contrast to the plethora of commercial material, objective and comparative drug information is very limited in many countries. In the developing world, especially, prescribers often have little or no access to the type of relevant and up-to-date drug information that is essential for effective clinical practice.

102. A major focus of WHO's country support is therefore to collaborate in the development of therapeutic guides, formularies, and standard treatment regimes, not only with ministries of health but also with other development and aid agencies. WHO's normative materials, for example the WHO Model Prescribing Information series, and treatment guidelines drawn up in such programme areas as diarrhoeal diseases, acute respiratory infection, AIDS, tuberculosis and sexually transmitted diseases, are invaluable tools in this work. Close collaboration ensures that the essential drugs concept prevails in the selection of proposed drugs and in the production of clinical management guidelines.

103. Other material for providing drug information to countries includes the WHO Pharmaceuticals Newsletter and WHO Drug Alert, containing notifications from Member States on drug regulation and surveillance of marketed products, and *WHO Drug Information*, which reviews topics related to drug development and regulation, embracing socioeconomic as well as technical matters. WHO also collaborates closely with the United Nations in its production of the *Consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments*.

104. Despite the value of WHO's normative functions, global norms have to be adapted to the local level. Experience has shown that if there is to be real commitment to the use of therapeutic guidelines within a country and if they are to relate meaningfully to local circumstances, they must be formulated nationally, albeit drawing on the normative work of WHO. Such undertaking should involve all professional groups, such as pharmacists, physicians, primary health care workers and specialists from different sectors and organizations who would not commonly share experience in their daily work. Material should be field-tested at national level, and a plan prepared to maximize dissemination and impact of the guidelines. WHO promotes and supports this integrated and collaborative approach within the context of a national drug policy. In two workshops (Kenya, 1993), for example, one group, with technical support from WHO, provisionally updated the national essential drugs list, while a parallel group, supported by USAID, formulated clinical treatment guidelines. The two groups then worked together to ensure that the material was compatible and supportive of the draft national drug policy, which has since been adopted.

105. If they are to be effective for prescription, therapeutic guidelines must be enforced by an appropriate training programme. WHO, through its support to national essential drugs programmes, facilitates this integrated approach of combined information and training. Staff from countries that have already prepared material using this approach provide valuable technical support to other countries at a similar stage in the process.

106. In addition to such financial and technical cooperation with WHO, Member States can also draw upon therapeutic guidelines and essential drugs lists already prepared with countries.[1]

107. Drug bulletins are another important source of information. WHO sponsors participants from developing countries in the training workshops organized by the International Society of Drug Bulletins for editors of new or planned publications. It also provides direct technical support for starting up national drug bulletins, of which those in Cameroon and Philippines are the latest examples.

108. Such support is not limited to printed material; in most developed countries national or regional information centres are important sources of data for prescribers and - in some cases - the public; they are equally, if not more necessary in developing countries, where their impact may be even greater. WHO has supported the establishment of drug information centres in the African and Western Pacific regions, and is cooperating with Bolivia, Philippines and Syrian Arab Republic, among others, for similar purposes.

109. Information for consumers is another pressing need, and one which is likely to increase as drug supply in the public sector diminishes and consumers turn to the informal sector or buy medicine over the counter. Self-medication is already estimated to account for over 50% of drugs consumed in many countries, and the indications are that the majority of consumers lack the information needed to purchase and use them appropriately. WHO's country support strategy in education of the public is covered under education and training.

110. The Action Programme's documentation centre continues to act as an invaluable source of reference material and information for Member States, other agencies, national staff, researchers and nongovernmental organizations. It was strengthened in 1993 by the creation of a computerized database, with key documents related to all aspects of drug policies and programmes. It distributes over 20 000 documents per year free of charge, the majority to developing countries. The third edition of the Selected annotated bibliography on essential drugs will be produced in 1994 and is also available on computer diskette.

V. WHO'S ADVOCACY ROLE

111. WHO, through its Action Programme on Essential Drugs and its disease control programmes, plays a leading role in the advocacy of rational drug use, including the essential drugs concept, and of comprehensive national drug policies.

112. The *Essential Drugs Monitor*, published in English, French and Spanish, continues to be the cornerstone of advocacy and information under the Action Programme. The *Monitor*, which has a readership of over 200 000, covers developments in rational use and national drug policy, operational research, product development and evaluation. The editorial policy is to provide a global forum to promote an integrated approach to drug policy and measures for rational use. The *Monitor*'s impact is widened by its common use as a teaching tool by institutions in both developed and developing countries, and by the frequent reproduction of its articles in other publications. A readership survey found that it influenced professional decision-making in the majority of its readers and that it contained information not available elsewhere. The March/April 1992 issue of WHO's magazine *World Health* took essential drugs as its theme for a lay readership, with articles on the benefits of drug policy, common areas of drug misuse, drug donations, and initiatives for consumer education.

113. Audiovisual material is highly effective and increasingly widespread. Under the Action Programme WHO is preparing a series of video films on regional approaches to the essential drugs concept and rational drug use. The first two, covering South-East Asia (in English) and Latin America (in Spanish and English), will be available in 1994. The series is intended to provide an effective tool for advocacy and training and to present key concepts relating to essential drugs and rational use to a lay and a professional audience.

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[1] National, regional and international essential drugs lists, formularies and treatment guides (document WHO/DAP/94.2).

VI. OPERATIONAL RESEARCH

114. Surprisingly little is known about patterns of drug use in different parts of the world or influences on prescribing behaviour, patterns that result in the spending of thousands of millions of dollars and have profound social, health and economic consequences. Comparatively little is invested to learn how the drugs already available are actually used, what is the impact of commercial marketing, procurement and other factors on such use, or how new drugs compare with those they replace in therapeutic efficacy and cost. Despite the pioneering work of a few schools, there has not been much investigation of what medical students and health workers are taught about pharmacotherapy, and whether they acquire the necessary skills for a lifetime of prescribing in an increasingly complex area. The limited information available from both developed and developing countries strongly indicates that drugs are not generally obtained and used in the best conditions; it further suggests that outdated methodology for training and the discrepancies between commercial and noncommercial drug information contribute to misuse, and that some prescribers totally lack objective therapeutic information.

115. Information is needed in key areas to permit change and intervention - to know what measures will work, under what circumstances, and why. WHO's operational research under the Action Programme is aimed precisely at providing such information and solutions to the many challenges faced by countries wishing to improve drug availability and use. The strengthening of such research provides a real means for monitoring changes in the world drug situation, defining problems and testing solutions. Operational research contributes reliable, validated data to the development and country support components of the Programme. Increased attention is being given to operational research at country level, concentrating on the rational use of drugs. Research projects are under way in 21 countries, covering such areas as drug financing, monitoring of pricing levels, prescribing practices, people's perception and use of drugs, pharmacotherapy training for medical students, injections, the effects of training workshops, ration kits for drug supply, and the impact of essential drugs policies.

116. An operational research component has been included in all national essential drugs programmes started since 1992; in that year, support was provided to 15 new projects.

117. The Action Programme has built upon experience with country support in order to establish appropriate and standardized research methodology. Methods include investigation of drug use at the community level and in health facilities, design of indicators to monitor progress in the implementation of national drug policies, and national surveys of the pharmaceutical sector (not only for the Programme but also for policy-makers, managers and other international cooperating agencies). The national drug policy indicators will be used to compile a database for the regular updated editions of WHO's *World Drug Situation*.

118. The Action Programme has strongly promoted the practical application of research results in current projects, promoting increased awareness in ministries of health of the value of operational research in problem-solving and the monitoring of implementation. However, much remains to be done; research at country level still has many constraints, including lack of expertise, slow decision-making at government level, and inadequate use of the research results. In accordance with the recommendations of a consultation on operational research in 1992, the Action Programme has created a system based on modern techniques of data-processing that allows the processing and retrieval of information on all research projects.

119. The Action Programme has strong links with universities and networks such as the International Network for the Rational Use of Drugs and the European and African drug utilization research groups. The African group has been reactivated with WHO's support, and it is expected that its membership will be extended and that it will be able to play a more significant role in strengthening research capabilities in the African Region.

120. Greater priority has been given in the 1990s to the dissemination of research findings, both through peer review of the scientific press and in the new research series of the Action Programme,[1] which is widely distributed and available free of charge.

VII. CONCLUSIONS AND OUTLOOK

121. The difficulties of the health sector in ensuring access to essential drugs and the rational use of drugs are increasingly complex and arise in a rapidly changing environment, calling for innovative solutions, according to region and country. The main issues are described below.

Availability of resources. As a result of the world economic crisis the purchasing power of households has decreased in many countries, especially in Africa. This seems to be a contributory factor in increases in malnutrition and various diseases, such as acute respiratory infections, cholera, tuberculosis, AIDS, and sexually transmitted diseases, which in turn lead to a greater demand for health services and drugs. Demand is further exacerbated by population growth in some regions. The increases come at a time when diminishing revenue has further restricted the ability of households to pay for drugs, and when structural adjustment policies, by increasing the price of imported drugs and reducing public expenditure, have in many countries aggravated drug shortages in health services. Demand is therefore growing while resources, public or private, are decreasing or static. This trend will continue in many countries for the foreseeable future and the challenge will be for WHO to collaborate with countries in making the best use of limited public funds and the private sector.

Technical efficiency. In most developing countries there is a serious lack of adequately trained health personnel, particularly at primary health care level. Since primary health care is not always fully developed, provision of drugs at the periphery remains a major concern. Many countries also suffer from inefficiency and waste of resources at the secondary and tertiary levels. Consequently, the public health services in many poorer countries cannot meet the needs of the population. National training and management capacity is crucial to ensure the best use of existing resources at all levels and the sustainability of national drug policies.

Expansion of the private sector. In most developing countries the private sector is increasingly taking over drug supply, either as a result of deliberate State policy, or because of shortage of financing for the public sector. The profile of the pharmaceutical sector has therefore changed, affecting access and consumption. The State often has little control over the private sector and cannot enforce its policies. The legal framework is often inadequate, outdated and unenforceable with the staff available. Action is needed by Member States to ensure that the private sector complements the public sector in a way that contributes to public health goals and national development, and that laws and regulations are designed and enforced to match these goals.

Drug financing. Although different modalities of drug financing are currently being implemented, most notably "cost recovery" or "cost sharing" systems, little is known about their long-term viability and public health consequences. Such data are urgently required, and caution is needed when considering applying model systems at national level.

Information and education. In most countries the use of prescription drugs and self-medication is far from rational. In many, if not most developing countries, training and information of prescribers is inadequate, education of consumers is non-existent and drug promotion practices continue to give cause for concern. A concerted effort is needed by ministries of health and of education, the academic world, consumer organizations and the pharmaceutical industry, WHO and other health and development agencies in their respective fields of competence to ensure improved drug information and use and related education and training.

[1] DAP Research Series.

International aid. The present world drug situation is characterized by the increased interest of major development agencies in supporting the drug component of health services (the World Bank, regional development banks, UNDP, UNICEF, the European Union, bilateral agencies, etc.). However, weak coordination, the absence of clear strategies, the lack of consistent policy and the absence of specific expertise in these agencies often leads to poor integration of cooperation in national drug policies and to low investment in setting up a framework and structures for their implementation. This reduces the effectiveness of cooperation, even when it relates to an important and growing part of the pharmaceutical market in a country. Donations also continue to cause problems, especially because increasing donations in kind often do not match needs. In certain cases aid may even conflict with overall government drug policies. Agreement is needed between all the agencies that support in the pharmaceutical sector will be consistent with national drug policy; if a policy framework has not yet been established, WHO, as the agency in the United Nations system for health, with its extensive experience in national drug policy development support, has a clear mandate for technical advice and cooperation.

Legislation and regulation. In many countries regulatory control systems for the pharmaceutical sector are still outdated or nonexistent, causing increasing concern as free-market economies gather momentum. Drugs must not be treated like other goods, and governments have a responsibility to regulate their import, manufacture, distribution, marketing and use. WHO is already cooperating with States in updating or devising adequate and enforceable legislation. Regulatory control is a key element of national drug policy, and this must be recognized by governments and all those contributing to development of the pharmaceutical sector.

Quality assurance of drugs. Substandard drugs and counterfeit drugs continue to be a cause for concern; collaboration at national and international levels must be reinforced to ensure a better understanding of the extent of problems and ways in which they may be tackled.

Research, monitoring and evaluation. Research on the many problems relating to drug supply and use is needed, together with careful monitoring and evaluation of the impact of different approaches, intervention strategies and national policies on the world drug situation. WHO plays a vital role through its support to operational research and design of methodology for analysing the drug sector. Academic institutions throughout the world should be encouraged to contribute to research in this field of high priority.

VIII. MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

122. This paragraph drew the attention of the Health Assembly to the progress made and the efforts of WHO, governments and other bodies to improve access to essential drugs and the rational use of drugs within the framework of a national drug policy. Continued action by all interested parties is needed to attain all the objectives of a national drug policy: access to essential drugs of good quality, rational use of drugs, sufficient human resources, adequate information and education of prescribers and consumers, and up-to-date and enforceable pharmaceutical legislation.

123. Moreover, responses are sought to the many new challenges in an increasingly complex pharmaceutical sector, including the impact of structural adjustment policies and economic recession, the changing share of the public and private sectors in health care including the provision of drugs, assessment of the viability and long-term effects of new financing strategies and other interventions, and strengthened coordination at international and national levels to ensure that policies and the contributions of donors support public health goals.

124. The attention of countries, aid agencies, nongovernmental organizations and the pharmaceutical industry is drawn to these crucial areas of concern and to the need to mobilize resources and all interested parties to ensure improved access to drugs and their rational use, recognizing WHO's leadership and coordinating role.

ANNEX 4

WHO Ethical Criteria for Medicinal Drug Promotion[1]

Report by the Director-General

[A47/7 - 21 March 1994]

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INTRODUCTION

1. The meeting requested in resolution WHA45.30 was jointly organized by WHO and CIOMS in Geneva, from 5 to 7 April 1993. Each of the interested parties, as defined in the resolution, was represented at this consultation.

2. Background papers were prepared by WHO. Further papers describing the results of relevant studies or giving views on key issues were prepared by participants representing, in particular, industry, regulatory and academic bodies and consumers. The report of a preliminary meeting on the complementary matter of the provision and dissemination of "independent" drug information was also brought to the attention of participants. The full proceedings of the consultation will become available during 1994.

3. The report of the consultation (Appendix) reflects the spirit of the debate. It was prepared on the basis of contributions made during the meeting and further comments during the drafting process. It is constructive and forward-looking. It focuses primarily on the application of the criteria in developing countries. It does not dwell on the deficiencies of the past. It sets out a commitment as agreed between the parties and outlines tasks for the future. It also defines an overriding ethical precept: the right to be informed.

[1] See resolution WHA47.16.

FUTURE ACTIVITIES

4. The recommendations of the consultation are broad in scope. They relate to education and communication, the interface between promotion and regulation, the framing of national policies, and international collaboration. All the interested parties apparently accept the validity of the WHO ethical criteria and are prepared to work collaboratively to further their implementation.

5. It was generally appreciated that challenging problems will continue to emerge; that the policies and programmes of the interested parties will also change; and that the ethical criteria themselves will need to be adapted to changing circumstances. It was recognized that if collaborative efforts to promote the use of the criteria are to succeed they must not only be concerted, but also responsive to change; and they must be given time to work.

6. It was recognized throughout the consultation that progress will be dependent upon the leadership provided by WHO. The Organization is particularly well-placed to appreciate the needs and circumstances of national drug regulatory authorities as part of national drug policies and to further develop dialogue on ways in which control of advertising can best be integrated into the process of drug registration. It must be achieved without limiting the capacity to meet other vital objectives of the registration process, including the need to assure quality and to prevent trade in substandard, spurious and counterfeit products.

7. WHO is already promoting application of the Ethical Criteria from the regulatory standpoint through:

- promulgation of its Guiding principles for small national drug regulatory authorities,[1] and preparation of model legislation and a model software package for drug registration, which provides a means of controlling drug promotion through the establishment of an approved scientific data sheet;

- development of *WHO model prescribing information*, its system of information exchange on national regulatory decisions, and its contribution to the *United Nations consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by governments*;

- field-testing of recently prepared guidelines for use of the Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, which now contains provision for exchange of drug data sheets and for approved labelling.

8. WHO remains concerned, however, about the paucity of "independent" factual and authoritative information directed to prescribers and to patients and other users of drug products in many countries.

9. WHO is also providing information to Member States on national initiatives to compare labelling of locally manufactured drug products that are produced for the domestic market and for export to developing countries, respectively.

10. The following statement, issued after the Consultation by a meeting of the International Committee of Medical Journal Editors (Chicago, August 1993), is encouraging:

> *Most medical journals carry advertising, and advertising generates income for owners of journals, but advertising must not be allowed to influence editorial decisions. Editors must have full responsibility for advertising policy, and readers should be able to distinguish readily between advertising and editorial matter. Juxtaposition of editorial and advertising material on the same product or subject should be avoided wherever possible. Finally, editors should consider for publication all criticisms of advertisements.*[2]

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[1] In, *WHO Expert Committee on Specifications for Pharmaceutical Preparations. Thirty-first Report.* Geneva, World Health Organization, 1990. (WHO Technical Report Series, No. 790, Annex 6).

[2] *British Medical Journal*, 1993, 307: 795.

11. Further discussion of activities and on progress made in implementing the recommendations of the CIOMS/WHO consultation on ethical criteria are contained in Annex 3 of the present volume.

MATTERS FOR PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

12. In this paragraph the Health Assembly was invited to note progress in advancing the principles and improving application of WHO's ethical criteria for medicinal drug promotion, with particular attention to the recommendations contained in the Appendix of the present report.

Appendix

CIOMS/WHO CONSULTATION

WHO ETHICAL CRITERIA FOR MEDICINAL DRUG PROMOTION

Geneva, 5 to 7 April 1993

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I. BACKGROUND

The CIOMS/WHO Consultation on WHO Ethical Criteria for Medicinal Drug Promotion (Geneva, 5 to 7 April 1993) was attended by representatives of national drug regulatory agencies, the pharmaceutical industry, health professionals, consumer advocates, editors of scientific journals, and the secretariats of WHO and CIOMS.

The meeting was held in response to resolution WHA45.30 (1992) that requested WHO, in collaboration with CIOMS, to convene a meeting of interested parties to discuss possible approaches to advancing the principles embodied in WHO's Ethical Criteria for Medicinal Drug Promotion.

In his opening remarks, the Director-General of WHO called for the participants to build their contributions upon "dialogue" and "consensus". An important opportunity would be lost if participants dwelt on the symptoms of the problems posed by drug promotion, rather than on the causes that underlie them. Only if these causes were fully analysed, and appropriate solutions identified, would the outcome of this consultation be of lasting value.

The Chairman pointed out the major tasks of the consultation to the participants:

- to examine the problems that surround inappropriate promotional practices as they conflict with WHO's Ethical Criteria for Medicinal Drug Promotion, with special reference to developing countries;
- to consider what further steps are required to understand more fully the nature of those problems, keeping in mind the ways in which the problems vary according to a country's social, economic, commercial and health development;
- to explore what concrete actions might be undertaken to remedy those problems, keeping in mind that short-, medium- and long-term strategies would be required, taking into account both the limitations and the particular strengths of developing countries;
- to forward to the Director-General a report of the deliberations for his consideration for further action.

II. PREAMBLE

WHO's Ethical Criteria for Medicinal Drug Promotion are built upon health care imperatives that themselves have an ethical base. Equity is the fundamental value underlying the development of public health services, according to which there should be universal coverage and care according to need.

An essential part of such services is to ensure that physicians and patients should have knowledge about and access to therapies that are appropriate to their needs. Two further concerns bear on the nature of these services:

- the regulation of medicinal drugs must ensure the quality of drugs and information relating to them;
- the promotion of medicinal drugs must be consistent with their rational use.

The World Health Assembly, in resolution WHA41.17 (1988) that endorsed the ethical criteria, urged Member States

(1) to take account of these ethical criteria in developing their own appropriate measures to ensure that medicinal drug promotion supports the aim of improving health care through the rational use of drugs;

(2) to monitor and enforce, where appropriate, the implementation of the measures they have developed.

In 1992 the Health Assembly adopted resolution WHA45.30, which noted with concern the lack of information on progress and urged Member States to intensify their efforts to implement the principles embodied in the ethical criteria. The challenge to the Consultation, therefore, was to define impediments to application of the criteria. Several aspects were identified, including inappropriate promotion of medicinal drugs; limitations in the capabilities of developing countries to establish drug regulatory and

monitoring systems; and inadequate communication of the existence, meaning and purposes of the Ethical Criteria.

A further challenge involved exploring the potential for more constructive interaction among the relevant parties in order to support efforts of countries to ensure that medicinal drug promotion does not conflict with the rational use of drugs, to adopt measures based on the WHO Ethical Criteria as appropriate, and to monitor and enforce such measures.

A critical reference point with respect to the Ethical Criteria is that they should be an integral part of a comprehensive national drug policy as defined and recommended by WHO:

> *To ensure an adequate supply of safe and effective drugs of good quality, every country should have a national drug policy as an integral part of its health policy. Appropriate legislation and regulations will be needed to help implement such a policy.*[1]

Such a national drug policy would include provisions to control drug promotion, disseminate reliable independent information, and ensure the quality of available drugs.

Rights to information emerged as an issue of fundamental importance. The participants concurred that an ethical precept inherent in the Ethical Criteria is that patients and prescribers have a right to information about medicinal drugs that is factual and supportable, and provides specific directions for appropriate drug use and monitoring of therapy. Positive claims for a product must always be balanced by information concerning important side-effects, contraindications, warnings, etc. The information should be provided in such a way as to allow patients to decide whether they wish to receive the therapy. This right to information should be emphasized and preserved.

The right to objective and balanced information is an essential element of national drug (and health) policy, and is ensured through the establishment of a national regulatory capability, preferably as part of an integrated drug policy, as proposed in WHO's Guiding principles for small national drug regulatory authorities.

Another issue of serious concern in the drug field is the production, promotion and distribution of spurious and counterfeit drugs. The participants urged that WHO should continue its work with Member States and other parties to combat this problem as a follow-up to the Joint IFPMA/WHO Workshop on Counterfeit Drugs (Geneva, 1 to 3 April 1992).

The spirit and proceedings of the Consultation reflected a common commitment to enhancing the positive contributions of medicinal drugs to the well-being of people in all countries, with special concern for those of the developing world, and ensuring that this contribution is not impeded by inappropriate drug promotion.

III. TOPICS RECOMMENDED FOR FURTHER ACTION

A. Education and communication

The Ethical Criteria should be widely disseminated, well understood, and function in support of improvement of health care through the rational use of drugs. Education and communication about the Ethical Criteria are essential.

1. **Materials for the education of health personnel and other appropriate parties.** Educational materials relating to the rational use of drugs and to WHO's Ethical Criteria are currently limited in both

[1] *Guidelines for developing national drug policies,* Geneva, World Health Organization, 1988. Introduction.

appropriateness for and availability to the varied audiences who need to be reached, including health personnel, the general public, marketing managers, sales representatives and the media.

2. **Roles of universities and other educational institutions in furthering the use and effectiveness of the Ethical Criteria.** Universities are in a crucial position to contribute to greater understanding of the Ethical Criteria by health personnel. Thus, promoting an awareness of problems associated with drug promotion, and developing critical appraisal skills concerning pharmaceutical promotion and other sources of information about drugs should be an integral component of undergraduate and continuing education for health personnel. Universities can also undertake research on such relevant questions as the extent to which drug promotion complies with WHO's Ethical Criteria.

3. **Guidance for prescribers.** Health personnel with responsibilities for prescribing medicinal drugs often lack up-to-date knowledge of drugs and their rational use. An international collaborative approach can be followed in the preparation and provision of guidance to prescribers, such as assisting in the production of therapeutic guidelines that provide information that is independent and comparative, and explains the Ethical Criteria and their application to prescribers and other parties.

4. **Clearinghouse functions for materials relating to WHO's Ethical Criteria and to medicinal drug promotion.** Several kinds of material could be helpful to countries and organizations working toward more effective approaches to the application of WHO's Ethical Criteria: existing legislation relating to medicinal drug promotion; national and organizational codes relating to ethics and medicinal drug promotion; materials available from drug regulatory agencies; and educational programmes that promote the criteria and develop critical appraisal skills. Additionally, information concerning regulatory action taken by national authorities could be of use both to other regulatory authorities and national and international organizations. These materials are often widely dispersed and access to them is difficult.

Recommendations

Given the critical importance of education and communication about WHO's Ethical Criteria, the Consultation recommended:

- that relevant educational materials should be prepared and disseminated both nationally and internationally by WHO, universities and other interested parties;
- that WHO should alert Member States to the importance of this role for universities and other educational institutions and collaborate with them in developing educational programmes;
- that WHO should take a leading role in promoting the provision of therapeutic guidelines for prescribers, including information that is independent and comparative, and includes explanations of the Ethical Criteria;
- that WHO, Member States' regulatory authorities, the International Federation of Pharmaceutical Manufacturers' Associations (IFPMA), the World Federation of Proprietary Medicine Manufacturers (WFPMM), the International Organization of Consumer Unions, Health Action International, and other interested parties should explore ways in which clearinghouse functions relating to WHO's Ethical Criteria and medicinal drug promotion can be established, identifying specific areas in which interested parties can fulfil these functions. WHO, for example, could act as a clearinghouse for regulatory and legal information.

B. Studies in relation to WHO's Ethical Criteria and drug regulation and promotion

Although many of the problems associated with inappropriate promotion are well known, the understanding of others would be assisted by further studies. Studies on the implementation and monitoring of WHO's Ethical Criteria would also be beneficial.

5. **Implementation and monitoring in relation to WHO's Ethical Criteria.** Resolution WHA41.17 urges Member States to take the Ethical Criteria into account as they develop measures to ensure that medicinal drug promotion supports the rational use of drugs, and to monitor and enforce those measures. WHO and Member States have also been concerned about the limited awareness and use of the Ethical Criteria. Thus, at issue are both the monitoring of the quality of promotion, and the monitoring of the implementation of WHO's Ethical Criteria.

6. **Periodic review of WHO's Ethical Criteria.** The Ethical Criteria should be reviewed periodically and modified as appropriate. Such review and modification should be undertaken judiciously, after careful study of the Ethical Criteria and their effectiveness internationally and at country level, and of the effect of changes on related policies of WHO, governments and other interested parties.

7. **Study of the content, flow and use of information relating to medicinal drugs.** The relationship between the quality of information related to medicinal drugs and those who would stand to benefit from it is often dysfunctional. People need accurate, independent and comparative drug information. At times, however, the information is inappropriate, whatever its distribution. At others, the information is appropriate, but it does not reach those who could use it. Or, the potential user may not have the capacity to absorb and benefit from the information. These problems suggest the usefulness of a study of the flow, content and uses of drug-related information.

8. **Formulation of a typology of countries with respect to their current capability for appropriate drug regulation and control of promotion.** Developing countries vary greatly in their capability for drug regulation and control of drug promotion. Establishment of a typology that identifies the characteristics of countries at different stages in this field, and the sequence of developmental steps required to increase competence would provide an analytical method for improving understanding of these problems.

Recommendations

To promote and carry out studies appropriate to the effective implementation of WHO's Ethical Criteria, the Consultation recommended:

- that WHO, in consultation with interested parties, should determine how to proceed with monitoring the implementation of the Ethical Criteria, should continue its work to design performance indicators in this area, and should consider what remedial measures should be taken when there is noncompliance with the content of the Ethical Criteria;
- that WHO, in consultation with interested parties, should periodically review the Ethical Criteria;
- that WHO, in consultation with interested parties, should explore the possibility of initiating studies of the content, flow and use of information relating to medicinal drugs;
- that WHO should take the lead in formulating a typology of the current capability of countries for appropriate drug regulation and control of promotion, and in using the typology for studying capacity-building in this field.

C. National policies and actions

Each country must have its own national drug policy in order to ensure an adequate supply of safe and effective drugs of good quality, an integral part of which will be legal and procedural arrangements for ensuring the appropriate use and promotion of medicinal drugs. These arrangements will involve interactions with other interested parties, including pharmaceutical companies and their associations, distributors, health professionals, consumer groups and universities.

9. **Drug regulation, drug quality, drug promotion.** The central features of a national drug policy encompass responsible approaches to drug regulation, drug quality, the quality of information, the rational use of drugs, the provision of affordable drugs, and drug promotion. A vital element of national policy and

legislation is the capability to regulate and control drug labelling and drug promotion through a product licensing system. Additional crucial components of national drug policy include provision of independent information and education about drugs; development of critical appraisal skills in health professionals and consumers; monitoring of ethical standards of pharmaceutical promotion, and auditing of the quality of medicinal drug use. Thus, WHO's Ethical Criteria become an integral part of such national drug policies.

10. The establishment of national drug policy committees. A national drug policy committee can strengthen capability for formulating policies, procedures and programmes that will lead to responsible national pharmaceutical programmes. Such committees may begin as *ad hoc* arrangements and devolve specific major responsibilities to legally established bodies. They should involve all interested parties: government, manufacturers, health professionals and consumers. Other structural approaches to the framing of drug policies also need to be explored.

11. The establishment and strengthening of national pharmaceutical industry associations. Corporate practices consistent with WHO's Ethical Criteria should be promoted by national pharmaceutical industry associations.

12. Medical representatives, symposia and other meetings. The Ethical Criteria lay down explicit guidelines for acceptable training and conduct of medical representatives and for the conduct of symposia and other meetings to ensure that they are educational rather than promotional.

13. The complementarity of self regulation and national regulation. Self-regulatory codes with appropriate sanctions rigorously applied can assist in application of the Ethical Criteria. An interactive combination of self-regulation by companies and national regulation by governmental authorities is often a constructive arrangement. One functioning without the other can be suboptimal. The value of autonomous bodies to set ethical standards, review and/or clear promotional material, and adjudicate complaints is recognized.

Recommendations

In view of the importance of national actions relating to WHO's Ethical Criteria, the Consultation recommended:

- that WHO and all interested parties should emphasize the importance of having the Ethical Criteria incorporated in and supported by national drug policies;
- that governments should consider the establishment of national drug policy committees;
- that national industry associations should be set up and that international industry associations should help to establish such associations;
- that WHO, in concert with Member States, consumers, IFPMA and other associations representative of pharmaceutical companies, and national medical associations should design approaches for tackling problems associated with medical representatives and symposia, including further development and adoption of codes of training and conduct of medical representatives and conduct of symposia, in ways that are consistent with the Ethical Criteria.

D. International collaboration

Although national level regulations, procedures and other arrangements for promoting the rational use of drugs are essential, contributions are also needed at international level. Important questions arise on ways in which international organizations and interested parties could interact in order to support national activities in furthering these important efforts.

14. Roles of WHO. WHO plays a central role in collaborating with Member States in order to establish and strengthen their programmes for ensuring the quality and rational use of drugs. The Ethical Criteria

for the Promotion of Medicinal Drugs represents additional potential support for national drug policies. The further design by WHO of performance indicators, monitoring procedures, and educational modules would assist in the implementation of the Ethical Criteria.

15. Editorial policies. The peer-reviewed journals have played a pivotal role in ensuring the scientific integrity of published materials. Editors of professional journals can contribute further to rational health care not only by publishing good scientific work on medicinal drugs but also by ensuring that all drug advertisements in their journals accord with WHO's Ethical Criteria.

16. Relationships between international and national associations. IFPMA, WFPMM, and bodies representing generic manufacturers are key partners in the international effort to ensure responsible promotion of medicinal drugs in accordance with WHO's Ethical Criteria.

17. Codes of international and national associations and local companies. Codes that govern the promotion of medicinal drugs in ways that are consistent with and supportive of WHO's Ethical Criteria make an important contribution to their application. Consultation among the involved parties is required to establish, maintain and update such codes so that they achieve their intended purposes.

18. International, national and local consumer groups. Consumer groups have key roles to play in this field by, *inter alia,* promoting awareness of WHO's Ethical Criteria, encouraging their use, developing training and educational materials, and monitoring promotion. International and local consumer groups can be mutually supportive in these efforts, taking account of possibilities to collaborate with all concerned parties.

19. National and international coalitions of concerned parties. In recent years the various parties concerned with improving health care through the rational use of drugs have increased their collaboration. Now the challenge is to further cooperation among these parties so as to strengthen understanding of and compliance with WHO's Ethical Criteria.

Recommendations

Important contributions can be made at international level to arrangements for promotion of medicinal drugs and implementation of WHO's Ethical Criteria. Accordingly, the Consultation recommended:

- that WHO should continue its constructive role in this important field;
- that scientific journals should draw up advertising guidelines similar to the guidance they provide to authors, in order to ensure compliance with the Ethical Criteria;
- that IFPMA and WFPMM and other bodies should direct their further efforts and positive influence towards the formation and activities of national associations of pharmaceutical companies in their respective areas;
- that IFPMA, WFPMM, national associations and local companies should continue to formulate their own codes relating to the promotion of medicinal drugs in ways that are consistent with WHO's Ethical Criteria;
- that international, national and local consumer groups should continue to play key roles in working with government and industry toward constructive action relating to WHO's Ethical Criteria, particularly pursuing studies of promotion, monitoring compliance with the Ethical Criteria, and working to create a critical awareness among consumers;
- that WHO, CIOMS and other interested parties, including donor organizations, should consider ways in which these national and international interests and resources could be brought into more

effective interaction in relation to WHO's Ethical Criteria, including, as one possibility, the convening of regional meetings to consider this matter.

IV. REFLECTIONS ON THE CONSULTATION

The Health Assembly endorsed WHO's Ethical Criteria for Medicinal Drug Promotion in the expectation that they would strengthen national and international capabilities for controlling inappropriate drug promotion and support the rational use of drugs.

However, WHO and relevant parties have been concerned that WHO's Ethical Criteria have not been widely disseminated and implemented, and that they have played a lesser role in controlling inappropriate drug promotion than had been expected. Accordingly, the Assembly requested WHO, in collaboration with CIOMS, to convene a consultation in order to explore further steps that might be taken to advance the principles embodied in the Ethical Criteria.

Although the Consultation focused primarily on the problems of developing countries in responding to WHO's Ethical Criteria, the Consultation was also concerned with the ways in which these problems apply to industrialized countries.

An underlying reality of this field relates to the tensions that exist between industry, governmental regulators and consumer advocates on a variety of matters, including drug promotion. Such tensions can have positive effects in that all parties have a common commitment to the well-being of the public, though their viewpoints and approaches are often different.

One of the challenges to this Consultation was to capitalize on the common commitments and substantial strengths of the interested parties and to identify the areas in which agreement could be reached and collaboration could proceed.

The Consultation was considered by all who attended to have been a success in bringing participants into substantial agreement on a number of issues and on actions to be taken. One overriding ethical precept (that of rights to information) and the recommendations for further action form the core of the report of the Consultation. The recommendations have a wide range - education and communication in relation to WHO's Ethical Criteria; studies in relation to the Criteria and drug regulation and promotion; national policies and actions; and international collaboration.

This report has been carefully constructed on the basis of contributions made during the Consultation and the further commentary of participants during the drafting and finalizing of this document.

It should be clear, however, that the larger part of the work in this field still lies ahead. The recommendations of the Consultation set the stage. The Executive Board and the Health Assembly can take the policy decisions necessary to carry the recommendations, modified as they see appropriate, toward implementation, including the important step of encouraging Member States to act in full support of the recommendations.

It is apparent that the relevant parties - national drug regulators, industry, consumers, health professionals, international organizations, professional and general media - are prepared to work collaboratively toward greater effectiveness in this field. But such collaboration will not follow automatically. Challenging problems will continue to emerge. WHO's Ethical Criteria will not be static, nor will the policies and programmes of the interested parties. Effective collaboration will require concerted attention, persistence in pursuing key issues (such as identification of measures and procedures for monitoring, and related research), and continued openness to concerted action.

These steps and relationships will build upon the growing realization that all parties have a common responsibility, based on fundamental ethical principles, for the well-being of patients individually, and of the public collectively.

ANNEX 5

Real Estate Fund[1]

Report by the Director-General

[A47/24 - 25 March 1994]

I. STATUS OF PROJECTS UNDERTAKEN PRIOR TO 31 MAY 1994

1. Regional Office for Africa

1.1 The installation of the new telephone exchange in the Regional Office has been satisfactorily completed and it is fully operational. Subject to the settlement of final accounts it is expected that the project will cost approximately US$ 1 275 000 instead of the previously estimated amount of US$ 1 208 000.[2]

1.2 The replacement of the drinking-water pipes on the Djoué estate of the Regional Office has commenced and the first phase has been successfully completed. The second phase has been somewhat delayed due to local circumstances but should be completed in 1994 within the previously estimated amount of US$ 135 000.[3]

2. Regional Office for the Americas/Pan American Sanitary Bureau

2.1 The renovation of the emergency systems has been completed within the previous estimate involving a contribution from the Real Estate Fund of US$ 81 500.[4]

2.2 The initial work for the renovation of the concrete façade of the Council Chamber of the Regional Office revealed substantially more damage to the inner structure than had previously been envisaged. This will result in an additional cost to which the contribution from the Real Estate Fund is expected to be US$ 110 250 over and above the previously estimated amount of US$ 113 750.[5]

2.3 The roof covering of the Council Chamber will be replaced after the work on the façade is completed. The contribution to the cost from the Real Estate Fund is expected to remain at US$ 20 000.[5]

3. Regional Office for South-East Asia

3.1 Some difficulties were encountered in analysing the bids received for the replacement of the two lifts in the Regional Office. These have now been overcome and it is expected that the contract will be awarded shortly. The costs are not expected to exceed the initial estimate of US$ 71 000.[6]

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[1] See resolution WHA47.25.

[2] Document EB87/1991/REC/1, p. 81.

[3] Document EB91/1993/REC/1, p. 35.

[4] Document WHA43/1990/REC/1, p. 84.

[5] Document EB89/1992/REC/1, p. 45.

[6] Document EB89/1992/REC/1, p. 46.

3.2 Architectural drawings and plans for the addition of one floor to the Regional Office building have been submitted to the local government authorities for approval. As soon as this is received bids for construction will be invited. It is expected that the costs of the project will remain within the previously estimated amount of US$ 145 000.[1]

3.3 The technical specifications for the replacement of the air-conditioning plant in the Regional Office have been reviewed by a consulting engineer. On the basis of his recommendations a bid document has been established against which suppliers will be requested to make precise quotations. The installation of the equipment should be completed in 1994 within the initially estimated amount of US$ 250 000.[2]

4. Regional Office for Europe

4.1 Technical specifications are being established for the improvement of security arrangements in the Regional Office. Once these have been finalized bids for the contract will be invited. It is expected that the work should be completed before the end of 1994 within the previously estimated amount of US$ 150 000.[3]

5. Regional Office for the Eastern Mediterranean

5.1 After discussions with local authorities a project to construct, jointly, a building to be shared by the Ministry of Culture and the WHO Regional Office in Alexandria is under serious consideration. The Health Assembly will be kept informed of the revised plans and cost estimates.

II. ESTIMATED REQUIREMENTS FOR THE PERIOD 1 JUNE 1994 TO 31 MAY 1995

6. Headquarters

6.1 The air-conditioning equipment at headquarters uses the cooling gas Freon 12. This gas is known to be harmful to the environment and its use has been banned by several governments. Local legislation requires that it should be replaced by an environmentally safer gas as soon as possible. In addition, Freon 12 will gradually become more difficult to obtain as production ceases. Rather than wait for the legislative deadline, the Director-General feels that WHO should set an example in the protection of the environment and proceed with its replacement forthwith. He has consequently approved the related project for financing from the Real Estate Fund as foreseen by paragraph 3(ii) of resolution WHA23.14 and informed the Executive Board of this action at its ninety-third session. The estimated cost of this project is SFr. 330 000, or US$ 231 000 at the present rate of exchange.

6.2 The road in front of the main building is built in its entire length over a tunnel used for delivery and dispatch of goods. It was constructed in 1962 taking into consideration the current and foreseeable load-bearing capacity requirements. With the introduction of larger transport vehicles, in particular the tractor-trailer variety, the load-bearing requirements have changed considerably. After 30 years of use there has also been some water seepage which has contributed to weakening the supporting structure. In 1991 WHO requested a local firm of construction engineers to test the continued reliability of the road's load-bearing capacity. The engineers' report indicated that the structure had weakened in several places and no longer met the security requirements for the passage of heavy-duty vehicles. They recommended that the problem should be solved within a year or two to prevent further deterioration, which would make the road dangerous. Given the nature of the problem and despite the current financial constraints, the Director-General considers that the strengthening of the underground structure can no longer be delayed. He

[1] Document EB89/1992/REC/1, p. 46.

[2] Document EB91/1993/REC/1, p. 36.

[3] Document EB91/1993/REC/1, p. 35.

therefore presents this project for approval, the current estimated cost being SFr. 1 500 000, or US$ 1 049 000 at the present rate of exchange.

7. Regional Office for the Americas

7.1 The building being used by the Caribbean Programme Coordination (CPC) in Barbados was constructed in 1793 and no longer satisfies the minimum requirements of safety and long-term viability. CPC is responsible for the coordination of PAHO/WHO's resources assigned to Barbados, the Eastern Caribbean, the French Antilles and French Guyana. It has been determined that in the longer term it would be more cost-effective to construct a new building than to carry out major structural repairs to the present one. The construction costs of such a building are estimated at US$ 1 300 000, the land being donated by the Government of Barbados, which will also pay part of the construction costs. The contribution of the Real Estate Fund to this project, 25% of total costs, will amount to US$ 325 000.

7.2 The Office of the PAHO/WHO Representative in Mexico is currently located in rented accommodation. The accommodation and the facilities are found to be inadequate, particularly for the large document centre housed in the building. It is also expected that the rent will be raised considerably when the present lease expires in 1995. It is considered that the construction of a new building will not only solve the present problems but will also be an investment that could be recovered over a period of ten years. The estimated costs of such a building are US$ 1 000 000 - the Government of Mexico donating the land and sharing in the costs of construction. The share of the Real Estate Fund to this project, 25% of total costs, will be US$ 250 000.

III. SUMMARY

8. To summarize, on the basis of the foregoing considerations, the estimated requirements of the Real Estate Fund for the period 1 June 1994 to 31 May 1995 are as follows:

	US$
- Additional cost of renovation of the concrete façade of the Council Chamber of the Regional Office for the Americas	110 250[1]
- Replacement of the Freon gas in the headquarters air-conditioning system	231 000[2]
- Strengthening of the supporting structure below the access road to the headquarters building	1 049 000[2]
- Construction of an office for the Caribbean Programme Coordination, Barbados, Region of the Americas	325 000
- Construction of an office for the PAHO/WHO Representative in Mexico, Region of the Americas	250 000
Total estimated requirements	1 965 250[4]
Unencumbered balance of the Real Estate Fund, including accrued interest, as at 31 December 1993 (see Appendix), rounded off	244 000[3]
Shortfall which it is proposed to cover by appropriation by the Health Assembly	1 721 250[4]

[1] Amount indicates excess expenditure requiring financing from the Real Estate Fund.

[2] Amount modified to reflect latest exchange rate.

[3] Amount shows final unencumbered balance of the Real Estate Fund.

[4] Final amounts reflecting changes resulting from notes 1, 2 and 3.

IV. MATTERS FOR THE PARTICULAR ATTENTION OF THE HEALTH ASSEMBLY

9. This paragraph invited the Health Assembly to consider the resolution on the Real Estate Fund recommended in resolution EB93.R15, the text of which had been revised to take into account changes in the figures in the operative paragraphs. The recommended resolution was adopted as resolution WHA47.25.

Appendix

REAL ESTATE FUND

SITUATION AS AT 31 DECEMBER 1993

(expressed in US dollars)

		1 January 1970 - 31 December 1989	1990-1991	1992-1993	Total (from inception)
1.	**BALANCE AT 1 JANUARY**	-	2 892 234	5 922 950	-
2.	**INCOME**				
	Balance of Revolving Fund for Real Estate Operations (resolution WHA23.14)	68 990	-	-	68 990
	Casual income appropriated (resolutions WHA23.15, WHA24.23, WHA25.38, WHA28.26, WHA29.28, WHA33.15, WHA34.12, WHA35.12, WHA36.17, WHA37.19, WHA39.5, WHA42.10)	17 115 436	-	-	17 115 436
	resolutions WHA43.6, WHA44.29	-	5 798 750	-	5 798 750
	resolution WHA46.22	-	-	145 000	145 000
	Transfer from Part II of the Working Capital Fund (resolution WHA23.15)	1 128 414	-	-	1 128 414
	Rents collected	5 674 083	856 474	775 431	7 305 988
	Interest	4 602 345	735 300	254 290	5 591 935
	Other	1 567	-	-	1 567
	Total income	28 590 835	7 390 524	1 174 721	37 156 080
	Total funds available	28 590 835	10 282 758	7 097 671	-
3.	**OBLIGATIONS AND EXPECTED OBLIGATIONS** (see Attachment to this Appendix)	25 698 601	4 359 808	6 853 566[a]	36 911 975[a]
4.	**BALANCE AT 31 DECEMBER**	2 892 234	5 922 950	244 105	244 105

[a] Including an amount of US$ 1 781 187 in abeyance for the Regional Office for the Eastern Mediterranean (Extension of Regional Office building, resolution WHA43.6), pending finalization and approval of revised plans.

Attachment

REAL ESTATE FUND

OBLIGATIONS AND EXPECTED OBLIGATIONS FROM INCEPTION (1 JANUARY 1970) TO 31 DECEMBER 1993

(expressed in US dollars)

Purpose	Relevant authorization (resolution/ decision)	Obligations				
		1 Jan 1970-31 Dec 1989	1990-1991	1992-1993		Total
				Obligated	Earmarked	
1. Maintenance, repairs and alterations to houses for staff	WHA23.14, para. 3(i)					
Regional Office for Africa		3 592 123	576 718	596 036	73 998	4 838 875
Regional Office for the Eastern Mediterranean		145 806	15 613	19 636	-	181 055
		3 737 929	592 331	615 672	73 998	5 019 930
2. Major repairs, and repairs to the Organization's existing buildings	WHA23.14, para. 3(ii)					
Headquarters:						
Current repairs		903 101	-	-	-	903 101
Restoration of the structural safety of the eighth floor of the main building	WHA35.12 & WHA36.17	363 193	-	-	-	363 193
Renovation of the headquarters' roofing and the technical installations built thereon	WHA39.5	335 757	-	-	-	335 757
Remodelling of the headquarters' eighth floor	WHA39.5	1 527 073	23 290	-	-	1 550 363
Replacement of the telephone exchange	WHA42.10	-	2 071 272	128 461	15 267	2 215 000
Regional Office for Africa		1 619 005	97 215	-	-	1 716 220
Regional Office for the Americas		59 220	108 250	215 250	-	382 720
Regional Office for South-East Asia		122 257	120 054	326 217	230 752	799 280
Regional Office for Europe		428 053	536 426	593 674	196 091	1 754 244
Regional Office for the Eastern Mediterranean		156 658	1 158	-	-	157 816
Regional Office for the Western Pacific		892 922	-	-	-	892 922
		6 407 239	2 957 665	1 263 602	442 110	11 070 616
3. Acquisition of land, construction/extension of buildings	WHA23.14, para. 3(iii)					
Headquarters						
Main building:						
Transfer to Headquarters Building Fund for part settlement of litigation with Compagnie française d'Entreprise	WHA23.18	655 140	-	-	-	655 140
Acquisition of land	WHA23.17	1 000 095	-	-	-	1 000 095
Second prefabricated building	WHA24.22	689 791	-	-	-	689 791
Third prefabricated building	WHA28.26	1 799 575	-	-	-	1 799 575
Architectural studies for proposed extension of main building	WHA24.22 & WHA25.38	243 832	-	-	-	243 832
Alterations to "V" building	WHA33.15	102 658	-	-	-	102 658
Additional car park	WHA33.15	104 564	-	-	-	104 564
Construction of a building to house the kitchen and restaurant	WHA36.17	2 728 844	-	-	-	2 728 844
Regional Office for Africa						
Construction of additional staff housing	WHA23.16	936 937	-	-	-	936 937
First extension of Regional Office building	WHA23.16	751 585	-	-	-	751 585
Second extension of Regional Office building	WHA28.26	930 588	-	-	-	930 588
Acquisition of land for additional staff housing	WHA24.24	13 517	-	-	-	13 517
Conversion of staff housing	WHA34.12	292 955	-	-	-	292 955
Construction of small office building and staff housing in Malabo, Equatorial Guinea	WHA34.12	599 287	-	-	-	599 287
Third extension of Regional Office building	WHA37.19	855 840	7 712	-	-	863 552
Purchase of five staff houses in Namibia	WHA43.6	-	353 740	611	-	354 351
Replacement of the telephone exchange	WHA44.29	-	-	1 275 400	-	1 275 400

Purpose	Relevant authorization (resolution/ decision)	Obligations				
		1 Jan 1970-31 Dec 1989	1990-1991	1992-1993		Total
				Obligated	Earmarked	
Regional Office for the Americas						
Construction of Zone Office, Brasilia (WHO's contribution)	WHA25.39	100 000	-	-	-	100 000
Construction of a building for the Caribbean Food and Nutrition Institute (WHO's contribution)	WHA35.12	300 000	-	-	-	300 000
Regional Office for South-East Asia						
Extension of Regional Office building	WHA24.25	137 331	-	-	-	137 331
Fire-fighting equipment and emergency generator	WHA28.26	63 172	-	-	-	63 172
Installation of new telephone exchange	EB63(8)	120 557	-	-	-	120 557
Extension of Regional Office building, including new air-conditioning plant and electrical substation	WHA34.12	673 497	-	-	-	673 497
Additional stand-by generator	WHA35.12	84 791	-	-	-	84 791
Addition of one floor at the Regional Office building	WHA45.9	-	-	6 098	138 902	145 000
Regional Office for Europe						
Renovation of additional premises:	WHA27.15 &					
39 Strandpromenaden	WHA29.28	93 213	-	-	-	93 213
33 Strandpromenaden	EB63(8)	91 546	-	-	-	91 546
Installation of new telephone exchange	WHA29.28	190 000	-	-	-	190 000
Preliminary architectural study for extension of Regional Office building	WHA34.12	63 707	-	-	-	63 707
Lift and toilet facilities for disabled persons in the Regional Office	WHA34.12	38 102	-	-	-	38 102
Regional Office for the Eastern Mediterranean						
Extension of Regional Office building	WHA25.40	39 634	-	-	-	39 634
Additional extension of Regional Office building	WHA38.9	190 000	-	-	-	190 000
Architectural study for the extension of Regional Office building	WHA41.13	10 000	-	-	-	10 000
Construction of an annex at the Regional Office	WHA43.6	-	50 241	549 572	1 781 187[a]	2 381 000[a]
Regional Office for the Western Pacific						
Installation of fire detection and control equipment	WHA27.16	25 097	-	-	-	25 097
Extension of Regional Office building	WHA29.28	537 437	-	-	-	537 437
Additional extension of Regional Office building	WHA33.15	1 090 141	-	-	-	1 090 141
Construction of an annex at the Regional Office	WHA43.6	-	398 119	706 414	-	1 104 533
Total acquisition of land, construction/extension of buildings		15 553 433	809 812	2 538 095	1 920 089	20 821 429
TOTAL OBLIGATIONS AND EXPECTED OBLIGATIONS		25 698 601	4 359 808	4 417 369	2 436 197	36 911 975

[a] Of which an amount of US$ 1 781 187 is in abeyance pending finalization and approval of revised plans.

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[1] Bilingual list, as issued in document A47/DIV/3 Rev.1 on 7 May 1994, with the incorporation of corrections subsequently received.

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Dr F. ODDO, Ministère de la Santé
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(Chief Delegate from 2 to 5 May 1994)

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