



THIRTY-NINTH WORLD HEALTH ASSEMBLY

Provisional agenda item 25

WHO'S REVISED DRUG STRATEGY

Report by the Director-General

This paper outlines WHO's drug strategy as revised to implement resolution WHA37.33, particularly reflecting the results of the Nairobi Conference of Experts on the Rational Use of Drugs. The following are the highlights of the strategy:

- Foster fulfilment by each concerned party of its responsibilities as identified at the Conference:

governments; pharmaceutical industry; prescribers; universities and other teaching institutions, professional nongovernmental organizations; the public; patients' and consumer groups; mass media; WHO.

- Support governments in formulating and implementing national drug policies and action programmes on essential drugs:

intensify operational support to countries along the lines approved by the Thirty-fifth World Health Assembly; continue technology transfer; prepare guidelines on national drug policies (including meetings of experts); strengthen market intelligence; support drug procurement by developing countries; provide learning material on rational drugs use; prepare guidelines on communicating with patients (including meetings of experts); health systems research, including socioeconomic research, on drugs and drug practices.

- Expand normative functions:

extend the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, including meetings of experts; update the International Pharmacopoeia; prepare guidelines for small national quality control laboratories and catalyse international cooperation between national laboratories; promote more effective use of International Nonproprietary Names; prepare, for adaptation by countries to national needs, model drug information sheets, a model drug formulary and guidelines on rational prescribing for selected groups of drugs and particular groups of patients (including consultation with and meetings of experts); prepare guidelines for a simple drug regulatory authority (including a meeting of experts), support governments in setting up or strengthening national drug regulatory authorities, and expand the activities of the International Conference of Drug Regulatory Authorities; prepare guiding principles for formulating national drug legislation and support governments in adapting them to national needs; update the ethical criteria for drug advertising established by the Twenty-first World Health Assembly (including meetings of experts); collaborate with the United Nations Secretariat

in implementing United Nations General Assembly resolutions 37/137, 38/149 and 39/229 concerning lists of products that have been banned, withdrawn, severely restricted or not approved by governments.

- Intensify dissemination of information:

broaden the scope of the Drug Information bulletin, produce it more frequently and ensure its availability in developing countries; foster preparation and dissemination of popular information on health care and the proper place and use of drugs; set up a clearing house on counterfeiting.

- Promote better basic education and training of health personnel:

promote intensified training programmes on rational drug use; ensure availability of appropriate learning materials for health personnel and the public; promote clinical pharmacology as a discipline relevant to primary health care; provide fellowships and sponsor seminars.

- Promote collaborative research:

expand areas of involvement in research aimed at developing badly needed new drugs in priority health areas; intensify field research on drug prescribing, consumption and performance; consider establishing a special programme of research on health care technology assessment, including drug assessment.

- Additional resources required:

about US\$ 5 000 000 annually, of which about US\$ 4 000 000 for national drug policies and essential drug programmes and about US\$ 1 000 000 for normative functions, information, basic education and training, and research promotion; a further US\$ 500 000 for developmental activities.

Coordination

1. WHO's revised drug strategy is based on ensuring the cooperative efforts of all concerned parties aimed at the fulfilment by each of them of its responsibilities as identified by the Nairobi Conference of Experts on the Rational Use of Drugs (November 1985). Fulfilling its constitutional role of coordinating authority on international health work, WHO will promote the assumption by each party of its responsibilities. This will imply strengthening national self-reliance in drug matters, particularly by encouraging governments that have not already done so to prepare and implement national drug policies as part of their policy of health for all by the year 2000. Such policies will include the components endorsed by the Thirty-fifth World Health Assembly - for example, the establishment or intensification of an essential drugs programme, the provision of objective information on drugs for prescribers and the public (in local languages as necessary), economic measures, legislation, introduction of ethical criteria for drug promotion and the like.

2. In fulfilment of its coordinating role, WHO will maintain close contacts with the pharmaceutical industry concerning such matters as drug information, promotional criteria, needs of developing countries regarding low-cost drugs and research for the development of badly needed new drugs in neglected fields. It will encourage the appropriate professional nongovernmental organizations, universities and the like to devote greater attention to measures aimed at improving the quality of health care, including better prescribing of drugs. The Organization will intensify contacts with patients' and consumers' organizations

regarding such matters as the relevance and quality of information on drugs for public consumption, vigilance over the respect by all concerned of established criteria for drug promotion, and reporting on infringements to the proper authorities. It will attempt to influence the mass media to improve their reporting on drug matters.

3. In keeping with its constitutional mandate on international health matters, WHO will take measures to ensure that support to Member States from all bodies of the United Nations system in the field of medicinal drugs for human consumption is adequately coordinated.

4. Few additional resources are foreseen for the coordinating activities mentioned above, but their implementation will impose a heavy burden on already heavily taxed staff and a tight regular budget. Resources to support national endeavours will be mainly national, supported by WHO staff and financial resources in the country and the regional office concerned, headquarters' expertise as required, and "enlightened external support" - UNICEF, World Bank, bilateral agencies, intergovernmental and nongovernmental organizations, voluntary bodies and the like. The new regional programme budget policies and the Director-General's guidelines thereon¹ will be useful to this end.

National drug policies and action programmes on essential drugs

5. The first WHO Model List of Essential Drugs was published in 1977, the most recent one in 1985.² A WHO Action Programme on Essential Drugs was formally established in 1981 as an operational programme to support countries in the establishment of essential drug policies. Its aim is to help ensure the regular availability of essential drugs of good quality and at the lowest possible price. In 1982 the Thirty-fifth World Health Assembly endorsed the principles of the WHO Action Programme on Essential Drugs and adopted a plan of action for the Programme.³ More than 80 developing countries now have national lists of essential drugs, in most instances stratified to the different levels of the health service. About 40 developing countries, several of them with small populations, have formulated national essential drugs policies with or without accompanying drug legislation. Others are implementing essential drugs programmes as part of primary health care. In many of these countries emphasis has been laid on ensuring the availability of essential drugs and improving their use through training and supervision. A number of other countries, however, even some with national lists of essential drugs, have neither started on the formulation of drug policies nor taken steps to improve the availability of essential drugs to the majority of the population. The role of the WHO Action Programme on Essential Drugs and Vaccines is described in further detail in document WHO/CONRAD/WP/2.5.⁴

Operational activities

6. The following additional operational activities will be carried out:

Support to governments in formulating and implementing national drug policies;

Accelerated promotion of national essential drug programmes:

cooperation with countries in programme implementation along the lines approved by the Thirty-fifth World Health Assembly, including support for the establishment or strengthening of national drug regulatory authorities and for the formulation of national drug legislation based on the guiding principles established by WHO;

country missions;

seminars;

dissemination of information;

preparation of material in local languages;

¹ Document WHA38/1985/REC/1, Annex 3.

² WHO Technical Report Series, No. 722, 1985.

³ Document WHA35/1982/REC/1, resolution WHA35.27 and Annex 6.

⁴ See document A39/12 Part IV.

Support to countries in carrying out technical and economic feasibility studies on local production;

Support to developing countries in mobilizing resources to purchase drugs and in overcoming problems deriving from the lack of hard currency;

Monitoring/evaluation of country programmes;

Technology transfer through training activities:

20 national seminars;

5 interregional seminars;

intercountry training through collaborating centres.

Support activities

7. The following activities will be carried out in support of the above:

Preparation of guidelines on national drug policies:

preparatory work, two meetings;

Strengthening of market intelligence, including information on the world drug situation, on the prices of drugs and raw materials, and on research costs;

Support to procurement of essential drugs by developing countries at the lowest possible cost;

Making available learning material for improved training of health workers in rational drug use and helping countries to use it;

Preparation of guidelines on how to communicate with patients in different socioeconomic and cultural settings:

preparatory work and two meetings;

Health systems research, including socioeconomic research, on drugs and drug practices.

8. Additional resources required for all the above over the next four years are as follows (figures are approximate):

Staff:

three professional staff, headquarters
two support staff, headquarters
three professional staff in the regions
six field officers

US\$ 1 million annually

Operational and support activities

US\$ 2 650 000 annually

plus - developmental activities spread over the first two years

US\$ 250 000

Normative functions

9. WHO has long exercised a normative function in relation to nomenclature, standards of manufacture and quality assurance of pharmaceutical products. More recently it has supported governments in their regulatory function by promulgating the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, by disseminating information on national regulatory decisions of global relevance and by developing the International Conference of Drug Regulatory Authorities as a forum for advancing collaboration and harmonization. The advisory functions of the Organization have also assumed a strong socioeconomic dimension with the promotion of the essential drugs concept

and the promulgation of the WHO Model List of Essential Drugs. The Certification Scheme is described in detail in document WHO/CONRAD/WP/2.6 and the other functions are reviewed in documents WHO/CONRAD/WP/1.1 and 1.2.¹

10. Promotion of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce will be intensified and guidelines formulated for users. The scheme will be extended and possibly formally amended to include exchange of approved product information and to provide (subject to feasibility) for certification of bulk materials. Consultations with, and meetings of, experts will take place for this purpose.
11. Quality control. Promotion of the International Pharmacopoeia and the associated model small national quality control laboratory will be intensified. The International Pharmacopoeia will be updated and revised, as necessary, to assure its relevance to developing countries. It will also be expanded to include monographs for dosage forms of essential drugs. Guidelines for the operation and management of small national quality control laboratories will be prepared. Possibilities of financing development of national laboratories - possibly through country programme budget allocations - will be canvassed. Mechanisms for international technical cooperation between national laboratories will be catalysed.
12. International Nonproprietary Names (INNs). The designation of INNs for new drug substances will continue. More effective usage of INNs, particularly in the labelling of pharmaceutical products, will be promoted. The further development of the nomenclature will be protected by urging countries to reject applications for trademarks similar to INNs.
13. Model drug information sheets/model drug formulary. Existing model drug information sheets will be revised and governments will be further supported by the compilation, frequent updating and dissemination of information on essential drugs for doctors, pharmacists, nurses and non-professional health workers. New activities will include the preparation of a model drug formulary which will describe the uses and limitations of drug therapy, and measures for disease prevention and health promotion, as well as specific information on drugs. The exchange among countries of information on essential drug formularies will be facilitated. Guidelines will be developed on rational prescribing of selected groups of therapeutic agents, e.g., antibiotics. Information will be provided for particular groups of patients such as the elderly, pregnant women, and users of contraceptives. Wide and representative consultative mechanisms and meetings, as necessary, will be set up to subserve these functions.
14. Drug registration and regulation. Guidelines for a simple drug regulatory authority analogous to those prepared on quality control will be developed and a meeting of experts convened for this purpose. Support will be provided to governments in the setting up of national regulatory authorities. Guiding principles for formulating national drug legislation, in the form of points to be considered, and monographs on specific issues will be prepared. Information on national legislation will be disseminated, and governments will be helped in adapting and updating legislation.
15. Closer contact will be maintained with formally designated national liaison (information) officers, and more detailed terms of reference will be formulated regarding their activities. To reinforce the intergovernmental infrastructure for exchanging information and promoting collaborative activities, the work of the International Conferences of Drug Regulatory Authorities (ICDRA) will be expanded; a broader range of subjects addressed; and financial support offered to facilitate attendance of more representatives from developing countries and to provide for simultaneous translation and interpretation in a number of official languages.
16. Ethical criteria for drug promotion. WHO will convene a group of experts to review and update the ethical criteria established by the Twenty-first World Health Assembly, and will submit them for approval to a Health Assembly as soon as possible. This will require a good deal of preparatory work and probably two meetings of the group.
17. United Nations consolidated list. Close collaboration with the United Nations Secretariat in relation to all provisions of United Nations General Assembly resolutions 37/137, 38/149 and 39/229 will be maintained. Consultative procedures newly established with

¹ See document A39/12 Part IV.

governments on the "United Nations consolidated list of products that have been banned, withdrawn, severely restricted or not approved by governments" will be systematized to ensure efficient updating of entries. The WHO Secretariat will analyse each notification received and, when necessary, append a commentary to ensure that the information is placed in global perspective.

18. Additional resources required for the above normative functions are as follows (figures are approximate):

Staff:

three professional and three support staff at headquarters US\$ 200 000 annually

Activities:

meetings, consultants, information documents, publications,
duty travel US\$ 250 000 annually

ICDRA:

support for participation from 30 developing countries US\$ 90 000
simultaneous interpretation, translation in these languages US\$ 60 000
total for each conference US\$ 150 000
plus developmental activities spread over first two years US\$ 250 000

It is hoped that much of the support to developing countries in setting up national drug regulatory authorities will be provided by more developed countries with well established regulatory authorities, using the guidelines mentioned in paragraph 14 above.

Dissemination of information

19. At present WHO disseminates information on drugs on a selective, pragmatic basis in its quarterly bulletin Drug Information, and it complements this with a "monthly mailing" to national drug regulatory authorities. It will now aim to disseminate information more systematically; produce the Drug Information bulletin more frequently; and provide details of and background to more regulatory decisions. It will also broaden the scope of the bulletin to include economic aspects of drug regulation and drug procurement; book reviews; and question and answer sections. It will make special efforts to ensure that developing countries have access to this information, including measures to ensure its availability in local languages. The Organization will launch initiatives for the preparation of popular information material on health care for public consumption, including the proper place and use of drugs. This might be carried out by appropriate nongovernmental organizations and collaborating centres. It will also set up a clearing house to collect data and inform governments about the nature and extent of counterfeiting.

Basic education and training of health personnel

20. WHO will promote intensified programmes on training in the rational use of drugs, managerial techniques, drug regulation and distribution. This will be accompanied by teaching/learning materials that bring the concept of essential drugs to doctors, pharmacists, other health workers and the public. The Organization will promote clinical pharmacology as a specialty having relevance to primary health care. It will seek to provide more fellowships for, and to convene and sponsor more seminars on, education and training on rational drug use, drug regulation, quality control, drug information and economics.

Research

21. WHO will promote collaborative research on an international basis aimed at developing badly needed new drugs in priority health areas in addition to its current involvement in, for example, tropical diseases, diarrhoeal diseases and human reproduction. It will intensify field research on drug prescribing, drug consumption and drug performance (e.g., adverse reactions) in different settings in both developed and developing countries. This work will be accomplished mainly by research institutions, with WHO support. Consideration will be given to the establishment of a special research programme on health care technology assessment, including drug assessment.

22. Additional resources required for the above activities concerning dissemination of information, training and research are as follows (these approximate figures do not include funds that would be required if an action programme on basic education and training - as suggested during the Nairobi Conference - and a special research programme were set up):

Staff:

one professional and one support staff at headquarters	US\$ 100 000 annually
three professional and three support staff in the regions	US\$ 300 000 annually

Activities:

publications, consultants, meetings, duty travel, support to NGOs, collaborating centres and research institutions	US\$ 300 000 annually
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23. The accomplishment of basic training of health personnel will rely heavily on collaborating centres. It is hoped that some extrabudgetary funds will be forthcoming for training and research. The pharmaceutical industry will be expected to undertake its share of research. Some of the field research mentioned in paragraph 21 above will be carried out in certain regions, e.g., Europe, which is engaged in studies on drug prescription and consumption. If a special research programme is set up as mentioned in paragraph 21 above, most of the financial resources would have to come from extrabudgetary sources.

Priorities and resources

24. The above is intended to convey a feel for priorities; in the final analysis, these will have to be determined by the World Health Assembly. The following is a very rough résumé of the financial resources that have been identified so far as being needed to carry out the above broad strategy:

Additional staff	about	US\$ 1 700 000 annually
Ongoing activities	about	US\$ 3 300 000 annually
Rough estimate of total	about	<u>US\$ 5 000 000 annually</u>

Nearly US\$ 4 000 000 of the above is for activities related to national drug policies and action programmes on essential drugs. About US\$ 1 000 000 is for normative functions, information, basic education and training and research promotion. In addition, developmental activities will require the investment of about US\$ 500 000. Some of the funds for developmental activities will be provided from the Director-General's Development Programme. To complete the picture, attached (as Annexes 1 and 2) are tables showing WHO's budgets for the programmes on medicinal drugs for the 1986-1987 biennium.¹

25. The above figures should be considered as orders of magnitude only at this stage of the formulation of WHO's revised drug strategy. The source of financing is a cause for concern. WHO's regular budget will at best not increase in the next few years. Heavy reliance will therefore have to be made on extrabudgetary funds. If an action programme on training is set up, and a special research programme established on health care technology assessment including drug assessment, additional thought will also have to be given to the availability of human resources.

Schedule of implementation

26. A precise schedule for carrying out the strategy cannot be defined at this stage, since the availability of funds will to a large extent dictate the pace of implementation. Moreover, much of that implementation will depend on activities being carried out by bodies outside WHO's control and the Organization will have to secure their cooperation - in itself an integral part of the strategy. Account will also have to be taken of the priority that Member States will accord to this strategy in relation to other priority areas in their strategies for health for all by the year 2000, as well as the capacity of Member States to absorb the activities devolving to them. The capacity of WHO to encompass all the additional activities devolving upon it also has to be considered. Despite these concerns, it is proposed to complete the developmental activities, including the preparation of the guidelines and criteria mentioned in the strategy, within two years.

¹ Extracted from document PB/86-87.

12.2 ESSENTIAL DRUGS AND VACCINES (continued)

Country	Estimated obligations					
	Regular budget				Other sources	
	1984-1985	1986-1987	Increase (decrease)		1984-1985	1986-1987
	US \$	US \$	US \$	%	US \$	US \$
Africa	654 200	921 100	266 900		2 900	
Americas					272 000	34 800
South-East Asia	585 700	689 500	103 800			
Europe						
Eastern Mediterranean	616 300	802 200	185 900		22 600	24 000
Western Pacific	448 700	678 500	229 800		13 200	
	<u>2 304 900</u>	<u>3 091 300</u>	<u>786 400</u>	<u>34.12</u>	<u>310 700</u>	<u>58 800</u>
Intercountry and regional						
Africa	1 188 000	881 300	(306 700)			
Americas					422 100	595 100
South-East Asia	90 000	30 000	(60 000)		189 000	150 000
Europe	373 100		(373 100)		139 300	
Eastern Mediterranean	315 800	314 800	(1 000)			
Western Pacific	229 500	363 600	134 100		417 400	285 000
	<u>2 196 400</u>	<u>1 589 700</u>	<u>(606 700)</u>	<u>(27.62)</u>	<u>1 167 800</u>	<u>1 030 100</u>
Global and interregional activities	1 142 000	1 115 600	(26 400)	(2.31)	940 100	727 700
Total	<u>5 643 300</u>	<u>5 796 600</u>	<u>153 300</u>	<u>2.72</u>	<u>2 418 600</u>	<u>1 816 600</u>
			Real increase (decrease)	(405 700)	(7.19)	
			Cost increase (decrease)	559 000	9.91	

12.3 DRUG AND VACCINE QUALITY, SAFETY AND EFFICACY (continued)

	Estimated obligations					
	Regular budget				Other sources	
	1984-1985	1986-1987	Increase (decrease)		1984-1985	1986-1987
	US \$	US \$	US \$	%	US \$	US \$
Country						
Africa	42 000	70 000	28 000			
Americas	255 800	304 700	48 900		995 300	544 900
South-East Asia	415 200	584 200	169 000		334 900	200 000
Europe						
Eastern Mediterranean		488 200	488 200		5 700	
Western Pacific	319 300	233 000	(86 300)		98 800	
	<u>1 032 300</u>	<u>1 680 100</u>	<u>647 800</u>	<u>62.75</u>	<u>1 434 700</u>	<u>744 900</u>
Intercountry and regional						
Africa	40 200	29 800	(10 400)			
Americas	173 600	290 700	117 100		162 200	170 400
South-East Asia						
Europe		391 900	391 900		105 200	405 900
Eastern Mediterranean						
Western Pacific	13 000	70 400	57 400			
	<u>226 800</u>	<u>782 800</u>	<u>556 000</u>	<u>245.15</u>	<u>267 400</u>	<u>576 300</u>
Global and interregional activities	2 235 800	2 247 900	12 100	0.54	117 000	
Total	<u>3 494 900</u>	<u>4 710 800</u>	<u>1 215 900</u>	<u>34.79</u>	<u>1 819 100</u>	<u>1 321 200</u>
			Real increase (decrease)		1 014 000	29.01
			Cost increase (decrease)		201 900	5.78