

## **SEVENTH MEETING**

**Thursday, 20 January 2005, at 14:10**

**Chairman:** Mr D.Á. GUNNARSSON (Iceland)

**TECHNICAL AND HEALTH MATTERS:** Item 4 of the Agenda (continued)

**Antiretrovirals and developing countries:** Item 4.9 of the Agenda (Document EB115/32) (continued)

Dr CAMARA (Guinea) endorsed the statement made by the member for Kenya on behalf of the African group the previous day. Although AIDS was a worldwide public health problem, its worst effects in terms of mortality, morbidity and impoverishment were being felt in the developing countries of sub-Saharan Africa. Despite the fact that all the countries concerned had adopted national policies or programmes to combat the scourge, the question of treatment had been neglected and the price of triple combination therapy remained too high for millions of people. For that reason, WHO and UNAIDS were to be congratulated on the “3 by 5” initiative, which aimed to broaden access to treatment.

He thanked Canada, Germany, the United States Agency for International Development, and the Global Fund to Fight AIDS, Tuberculosis and Malaria for their ongoing assistance to people living with AIDS in his country, and welcomed the AIDS initiative launched by the President of the United States of America. Guinea, whose medicines policy was based on generics, supported the policy of local production of antiretroviral medicines. However, because developing countries did not have the facilities to conduct efficient quality control, help from WHO or countries with experience in that area was vital. Fixed prices should not prevent those in need from gaining access to high-quality drugs, and the number of prequalified products should be increased. Sustainable financing mechanisms were needed, and small, poor countries would rely on international solidarity for that to be achieved.

Mr KHAN (Pakistan) commended the commitment of WHO to achieving the target of the “3 by 5” initiative, since the failure to deliver antiretroviral medicines to the millions of people infected with HIV amounted to a global health emergency. The Decision by the WTO General Council on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health was a step in the right direction, because it would help Member States to ensure access to treatment and care.

The activities of WHO in support of local production of high-quality antiretroviral agents were much appreciated. The flexibilities in the TRIPS agreement should be fully used in the light of national situations with regard to patents and prices, and in that respect he supported the comments of the member for the United States of America. Eleven major antiretroviral medicines had recently been included in Pakistan’s essential medicines list and its AIDS control programme included treatment with such medicines.

Considerations of patent rights and profits paled into insignificance when women and children were dying of AIDS; WHO’s endeavours to assist the poor in developing countries needed to be complemented by the efforts of all its Member States. He shared the views expressed by the members for Bolivia, Brazil and Kenya on the matter of generic drugs. More research should be done on HIV/AIDS: at the Ministerial Summit on Health Research (Mexico City, 16-20 November 2004) it had been noted that 90% of the US\$ 100 000 million set aside for research was being used by only 10% of countries, and that that imbalance should be rectified. Countries like Brazil, China and India had tremendous human resources for research and development of medicines to combat AIDS, but

lacked financial resources. Heavily indebted developing countries also required assistance, because they were often forced to spend more on debt servicing than on health.

Dr ACHARYA (Nepal) said that his country was neither a producer nor a large-scale importer of antiretroviral medicines, and only some 100 people infected with HIV were currently receiving such treatment. Nevertheless, it considered that issues related to the quality, production and cost of such medicines should be properly addressed.

The delisting and relisting of medicines on the WHO prequalification list had caused delay and confusion in the procurement and administration of generic drugs under the antiretroviral medicines programmes of developing countries. No country in the South-East Asia Region had used the full range of TRIPS safeguards. Since many antiretroviral agents were relatively new, they were still protected by patents, and as a result cheaper generic versions were not available. In many developing countries the difficulty of obtaining information about the patent status of antiretroviral medicines complicated both local procurement and importation of generic drugs. He therefore urged WHO to look for solutions to those problems, so that the goal of the “3 by 5” initiative could be achieved.

Dr SÁ NOGUEIRA (Guinea-Bissau) said that, like many developing countries, Guinea-Bissau was faced with major public health problems that hampered socioeconomic development. Some 4% of all adults and 30% to 40% of people with tuberculosis were infected with HIV, and, unless a more effective response was found to AIDS-related problems, some 20 000 people might be infected by 2008. His country had supported the “3 by 5” initiative from the start, and would welcome technical assistance from WHO in strengthening its health system, improving access to antiretroviral medicines, enhancing quality control, monitoring treatments and promoting healthier lifestyles. It was already making efforts in those areas under several bilateral and multilateral cooperation programmes and with help from development partners. He endorsed the statement made by the member for Kenya, and supported the recommendations put forward by the members for Bolivia and Brazil.

Professor FURGAL (alternate to Mr Skotnikov, Russian Federation) said that WHO support for local production of antiretroviral agents would go far towards promoting safe, effective AIDS treatment within the framework of the “3 by 5” initiative. The severity of the HIV/AIDS epidemic called for decisive action. Securing high standards of quality for antiretroviral preparations was the sole means of avoiding drug resistance, and WHO should therefore provide more funding in order to strengthen the prequalification project in line with resolution WHA57.14.

Another way of ensuring that antiretroviral therapy was given to those who needed it was to make affordable preparations available. His country was currently engaged in consultations with experts from the Regional Office for Europe in order to strengthen the action of national regulatory bodies as part of a strategy for reducing the prices of antiretroviral preparations, and would therefore welcome information from Member States on their experiences in negotiating lower prices with pharmaceutical companies.

Dr ANTEZANA ARANÍBAR (Bolivia) expressed his gratitude for the cooperation his own and other developing countries had received from the United Kingdom of Great Britain and Northern Ireland and the United States of America, and welcomed the former's announcement of an initiative to make HIV/AIDS medicines more accessible.

The Director-General's decision to create a special department offering technical cooperation and support to developing countries was of the greatest importance, and he hoped that that cooperation would include the financial and human resources necessary.

Regional efforts and international cooperation, including on the part of the pharmaceutical industry, would be very important. Any action by the Organization to make it easier for developing countries to obtain essential medicines would be greatly appreciated.

Ms DLADLA (South Africa)<sup>1</sup> endorsed the statement made by the member for Kenya. The legislative changes made by Canada and Norway to permit the supplying of export markets under compulsory licensing arrangements were commendable; other countries should follow their example. Countries that had little or no domestic capacity to manufacture pharmaceutical products should adopt enabling legislation in order to implement the flexibilities in the TRIPS agreement. The issue of the supply of antiretroviral medicines should be considered in the wider context of access to affordable essential medicines in general and as part of a comprehensive strategy for the management, care and treatment of people with HIV/AIDS.

Dr AGARWAL (India)<sup>1</sup> said that legislation adopted by his Government in 2004 incorporated all the flexibility available under the TRIPS agreement and under the WTO General Council's Decision on the implementation of paragraph 6 of the Doha Declaration.

With regard to prequalification, information on benchmarks used in WHO's assessment of pharmaceutical manufacturers, and on good clinical practice and good laboratory practice parameters might usefully be transmitted to the pharmaceutical industry and drug regulatory authorities in all countries.

Ms THOMPSON (European Commission), speaking at the invitation of the CHAIRMAN, noted that, although more people had access to antiretroviral agents, that access was still limited. Although the pharmaceutical industry had made efforts to bring down prices, and significant reductions had occurred, the financing gap for antiretroviral agents, their continued high cost to poor people and the absence of effective delivery systems were still significant barriers. It was essential to increase local production capacity, promote good manufacturing practices and speed up the prequalification process.

The European Union had supported the adoption of the Doha Declaration and the Decision of the WTO General Council, which represented major steps forward in the supply of antiretroviral agents and other pharmaceutical products, particularly to the least developed countries. In October 2004, the European Commission had submitted a proposed regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries where there was a public health need.

The report expressed concern that the system laid down in the Decision of the WTO General Council might be too complex and might not provide sufficient incentives for manufacturers of generic drugs or for the use of compulsory licences. There was no evidence for that view, however, since the system had not yet come into operation. If all parties concerned recognized the importance of preserving public health and the rights and interests of all economic actors, the new system would achieve its objectives.

Ms GOMBE (Consumers International), speaking at the invitation of the CHAIRMAN, said that the HIV/AIDS pandemic needed a coordinated and comprehensive response, including access to essential medicines, especially high-quality, safe, affordable antiretroviral agents and medicines to treat opportunistic infections. Her organization shared the concerns of countries about the affordability of first-line medicines for the treatment and management of HIV, and about the availability and affordability of second-line medicines since WTO's new rules had come into force in January 2005. It welcomed the establishment of the prequalification project which was an excellent example of rational drug policy at the international level. It had contributed to both the availability of medicines and the simplification of drug regimens, and was particularly useful to countries with a limited regulatory capacity of their own, which were often also the countries hardest hit by HIV/AIDS. The Global Fund to Fight AIDS, Tuberculosis and Malaria had decided to authorize funding only for medicines on the WHO prequalification list. The project, however, was not yet permanently established at WHO, and there were few staff. In its present form, it would not be able to meet the growing needs of countries

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

and provide access to affordable medicines. She therefore called for adequate support for the project, and the necessary resources to expand its work.

Dr BALE (International Federation of Pharmaceutical Manufacturers Associations) said that the pharmaceutical industry was helping to provide AIDS medicines in developing countries by means of funding, access and infrastructural development programmes. An independent audit had found that, as at September 2004, the seven companies that worked with WHO and its partners in the Accelerating Access Initiative had reached more than 330 000 people worldwide, including around 150 000 people in Africa.

Some pharmaceutical companies conducted programmes for children affected by HIV/AIDS. For prevention of mother-to-child transmission of HIV, one company had donated 20 million rapid antibody tests for use in Africa and 49 least developed countries, and another had provided nevirapine free of charge in 48 developing countries. Two paediatric formulations of nelfinavir and saquinavir had been offered to least developed countries in sub-Saharan Africa at no-profit prices. Companies were offering some antiretroviral medicines at cost price, low-cost, free of charge or at prices below those offered by producers of generic drugs. Thus, abacavir and the combination abacavir, zidovudine and lamivudine were being offered at no-profit prices to 63 of the world's poorest countries, and the new formulation of efavirenz was available at a cost of less than US\$ 1 per day in the least developed countries and those hardest hit by the HIV/AIDS pandemic. The antifungal medicine fluconazole had been donated to all developing countries for the treatment of opportunistic infections: to date, six million doses had been donated to treat 110 000 patients in 27 countries in Africa, Asia, the Caribbean and Latin America. Companies were also helping to improve health infrastructures: one had provided US\$ 6 million in grants to 28 nongovernmental organizations since 2002 to support training and capacity-building for the health-care providers hardest hit by HIV/AIDS. Another had provided US\$ 5 million to support practical improvements in HIV care in Brazil, Senegal, South Africa and Thailand. Many more examples were available on the Association's web site.

The pharmaceutical industry reaffirmed its commitment to working with the Secretariat, Member States and relevant nongovernmental organizations in the common fight against the HIV/AIDS pandemic.

Dr LEPAKHIN (Assistant Director-General) thanked members for their constructive comments. WHO would continue to provide appropriate technical assistance for the implementation of the TRIPS agreement, the Doha Declaration and the WTO General Council's Decision on the implementation of paragraph 6 of the Doha Declaration. Its collaboration with ministries of health and trade and with national patent offices, using a multi-agency approach, had proved an effective method of work. It had also cooperated with WTO in technical assistance programmes for the implementation of the TRIPS agreement.

In reply to the member for France, he said that efforts would be increased, in collaboration with regions and countries, to monitor implementation of the TRIPS agreement. WHO's national professional officers would provide technical assistance appropriate to the needs of the country concerned.

The members for Bolivia and Thailand had asked for guidance on the provisions of bilateral agreements on public health. It was intended to carry out a more detailed analysis of that issue.

Replying to comments made by the member for the United States of America, he said that the effectiveness of the WTO General Council's Decision on the implementation of paragraph 6 of the Doha Declaration would depend on the interpretation placed on it by Members of WTO: the report was intended to encourage Member States to adopt the simplest and speediest procedures possible. A public-health-oriented interpretation and implementation of the Decision would help to ensure universal access to essential medicines.

The report referred to several bilateral agreements with intellectual-property-related provisions that might affect the implementation of the TRIPS flexibilities: it was intended to help Member States

to take those flexibilities into account in bilateral trade agreements, as requested in resolution WHA57.14.

The resources needed to maintain and strengthen the prequalification project would continue to be provided, and he thanked the many governments that had given their support. The members for France and Nepal had remarked on the relatively low number of medicines for children on the prequalification list. At present, there were 12 prequalified antiretroviral formulations that could potentially be used for children, nine of them from originator manufacturers and three from manufacturers of generic medicines. The problem was not that the prequalification process had been delayed, but rather that only a small number of paediatric formulations had been submitted for assessment. At present, 48 antiretroviral medicines had been prequalified, and another 150 products were currently in line for assessment. No national drug regulatory authority, not even in the richest countries, had such a large number of products submitted for assessment.

The member for Brazil had asked about the involvement of drug regulatory authorities from developing countries in the definition of prequalification standards. The standards used for prequalification had been drawn up by the WHO Expert Committee on Specifications for Pharmaceutical Preparations, which included members from developing countries. Extensive consultations with national drug regulatory authorities had taken place before the standards were adopted. With regard to starting materials and excipients, a WHO certification scheme for pharmaceutical starting materials had recently been adopted, with guidelines for implementation.

Only one in five of the products submitted for prequalification was approved, thus helping to avoid the submission of poor-quality products. The prequalification project was one of the first in which WHO had concentrated on product quality. All the information obtained had been published on the Internet, and many developing countries had begun to make use of it. The Secretariat would continue to devote considerable attention to the prequalification project.

Two departments had recently been set up, one for technical cooperation in essential medicines and traditional medicines, and the other for policy and standards in medicines.

### **The Board took note of the report.**

### **Draft global immunization strategy: Item 4.10 of the Agenda (Document EB115/13)**

Mr KHAN (Pakistan) observed that immunization was a most effective and cost-efficient public health intervention; at current levels of coverage, it prevented the deaths of two to three million children each year. A further one to two million deaths annually could be prevented by 2015 if countries like his own substantially increased coverage with both current vaccines and those in the late stages of development. He welcomed the initiative to draw up a global strategy on immunization and the five strategic areas proposed; however, special strategies should be developed in order to be able to cover hard-to-reach populations on a regular basis.

Professor FURGAL (alternate to Mr Skotnikov, Russian Federation) welcomed the joint initiative of WHO and UNICEF to draw up a 10-year global immunization strategy, which would complement efforts to achieve the Millennium Development Goals. The subject was a long-standing and important one for WHO and the lessons learnt from the smallpox eradication campaign and the Expanded Programme on Immunization would be built upon. The global strategy should take into account developments for the prevention of vaccine-preventable diseases. Emphasis should be placed on epidemiologically and economically sound approaches, and on programmes for immunizing children against rubella, hepatitis B and *Haemophilus influenzae* type b and pneumococcal infections. Given the time frame envisaged, it might be possible to incorporate newly developed vaccines against HIV infection, malaria, tuberculosis and re-emerging communicable diseases, and it was highly likely that immunization services in public health systems would be strengthened.

He supported the five areas of the draft strategy, but suggested that additional sections might be added under strategic area 2 to deal with strengthening the cold chain, improving technology for safe

immunization, providing more information on the operational framework for immunization in emergency situations, and approaches to vaccinating immunosuppressed people, including those infected with HIV. The recently published practical guide for health staff on immunization set out the methodological basis for some of those issues.<sup>1</sup> The WHO Regional Office for Europe had done valuable work in his country in building new partnerships for strengthening immunization services with nongovernmental organizations and the private sector, one example being a project to immunize children against viral hepatitis.

He asked for further information about the consultative process, in particular the time frame for submission of the draft strategy to the governing bodies of WHO and UNICEF.

Dr HANSEN-KOENIG (Luxembourg) said that vaccines were the safest and most effective tool in the fight against infectious diseases and should be made available where they were most needed at a price the poorest people could afford. She agreed with the five strategic areas proposed, stressing the importance of reaching underserved populations, linking vaccination to other interventions, and promoting synergy between immunization and other health sector services in the interests of efficiency. She looked forward to discussing the draft strategy further at the Health Assembly, and asked for additional information on the time frame.

Ms GIBB (alternate to Dr Steiger, United States of America), noting that in many countries the poor and marginalized children remained unvaccinated and thus carried the greatest burden of mortality from vaccine-preventable diseases, fully supported the development of a global immunization strategy. The setting of specific goals for immunization coverage and disease-specific mortality reduction was essential; failure to do so would limit the credibility of any global strategy and would not encourage the international donor support needed for implementation at national level. Implementation of strategies must, however, contribute to building sustainable health-delivery systems.

In developing new strategies, WHO and UNICEF should expand the existing infrastructure used by the Global Polio Eradication Initiative and the strategic plan for measles mortality reduction so as to reinforce the routine immunization system, and to build surveillance and laboratory diagnostic capacity for all vaccine-preventable diseases and the communications and advocacy capacity needed for strengthening that system. WHO and UNICEF must also seek to strengthen the monitoring of vaccination coverage, disease surveillance and laboratory networks, and make that a visible component of any global strategy. The necessary level of support for capacity-building in that area should also be provided.

Many new vaccines and delivery technologies were at different stages of development. A strong infrastructure for immunization and health systems must be in place if countries were to benefit from those new products. Immunization contacts should be used to deliver other necessary public health interventions, as appropriate, provided that they were effective and cost-efficient. Dialogue was needed with the global and country-level partners specifically involved in order to ensure appropriate cooperation.

Dr QI Qingdong (alternate to Dr Yin Li, China) said that the draft global immunization strategy, which China supported, would help to promote the Expanded Programme on Immunization and achieve the Millennium Development Goals. Immunization was the best way of preventing disease and was extremely cost-effective; the strategy should facilitate high coverage, continued finance and the necessary political commitment.

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<sup>1</sup> *Immunization in practice: a practical resource guide for health workers – 2004 update*. Geneva, World Health Organization, 2004.

He welcomed the consultative process envisaged and requested further information on the regional and intercountry meetings to be sponsored by WHO and/or UNICEF, implementation and management details of the strategy, and plans for its regular review and assessment.

Dr PHOOKO (Lesotho) expressed support for the outlined strategy. A data quality audit carried out in Lesotho in 2004 by independent international auditors had highlighted deficiencies in the areas of field and laboratory surveillance, data collection and analysis, and management information. The findings served to emphasize the need for continued technical and other forms of support from WHO to enable countries, including those previously declared non-endemic for poliomyelitis, to maintain effective strategic immunization activities.

Dr SAM (Gambia) supported the draft global immunization strategy, and emphasized the cost-effectiveness of immunization. A comprehensive approach would discourage the vertical structure of other programmes and prevent many deaths.

Although developing countries did not have the necessary technology, they did have human resources that could be used in the introduction of new vaccines, and should not be excluded from activities under strategic area 2. Linking vaccinations to other interventions (strategic area 3) was highly successful, as demonstrated by the integrated management of childhood illnesses that had been piloted in some countries. In strategic area 4, better outcomes were more likely to result from strengthening health systems than from programmes run by individual organizations.

Dr PREECHA PREMPREE (adviser to Dr Suwit Wibulprasert, Thailand) said that the draft global strategy, which Thailand supported, should include capacity-building for developing countries in the areas of production, quality assurance and management of the vaccine delivery systems. Countries should also be able to decide which vaccines were to be included in the national programme, taking into account the epidemiological situation and cost-effectiveness, and have the capacity, through technology transfer, technical support and training programmes by WHO, donor countries and UNICEF, to provide accurate epidemiological and economic analyses for policy decision-making. He urged WHO to ensure that all the necessary vaccines were available and affordable in the developing countries.

Mrs LE THI THU HA (Viet Nam) endorsed the draft strategy. Increasing immunization coverage and introducing new vaccines into the Expanded Programme on Immunization, however, would depend on the epidemiological situation and availability of financial resources in countries, bearing in mind that new vaccines were often expensive. Countries with limited resources would need support from external partners, at least during the initial period.

Strategic area 1 was broadly acceptable, but should reflect the need to maintain high immunization coverage in countries where that had already been achieved.

Professor FIŠER (Czech Republic) supported the draft global immunization strategy. In his country, compulsory vaccination, carried out free of charge against 10 communicable diseases, prevented some 150 000 cases of disease and more than 500 deaths.

Mr SHUGART (Canada) stressed the need for close coordination between the global immunization strategy and the planned international finance facility for immunization within the Global Alliance for Vaccines and Immunization to ensure that individual countries increased their immunization and maintained it at a sustainable level. Better coordination should also help to reduce the administrative burden on developing countries. He also stressed the importance of providing more information on the expected cost of achieving the goals outlined in the strategy and the projected financing gap.

Mr PALU (alternate to Ms Halton, Australia) supported the development of a global immunization strategy and underscored the need for extensive consultation with Member States, partners and implementing organizations. A new approach should increase synergies in service delivery, but it would be essential to ensure that the roles and responsibilities of different agencies were clearly defined. He urged appropriate consideration of the constraints facing countries in delivering, planning, managing and, in particular, expanding immunization services.

Mrs SICARD (alternate to Professor Dab, France) welcomed the current initiative to expand and strengthen immunization programmes and the preceding wide consultation process. Although the Global Alliance for Vaccines and Immunization had assumed a leading role in that area, WHO also had an important part to play, particularly in extending the immunization coverage of both children and adults.

It was important to increase the availability of basic vaccines to large, impoverished populations in developing countries, particularly the numerous countries with inadequate infant vaccination cover. The global immunization strategy should give priority to resolving the chronic difficulties that beset health services in those countries.

Regarding strategic area 2, the most promising technological advances lay in developing vaccines that did not require a cold chain; reduced vaccination schedules might also be endorsed. France fully supported the WHO initiative, provided that the linkages with the Global Alliance for Vaccines and Immunization and the international finance facility were properly defined. In that connection she had noted the reduced appropriations for immunization and vaccine development in the Proposed programme budget 2006-2007, and would return to that issue during the relevant discussions.

Dr YOOSUF (Maldives) said that, although the present generation of vaccines were safe, they were unaffordable by many countries, as was the cost of the cold chain. It also seemed unlikely that new vaccines produced under strategic area 2 would be any cheaper. Vaccines that were safer, cheaper and easier to administer would be welcome. He supported the proposal by the member for Thailand that the strategy should include capacity-building at country level. Other areas requiring attention were the strengthening of drug and vaccine regulation authorities and bulk procurement of vaccines for the regions in order to reduce the cost, bearing in mind that small countries like Maldives had to pay as much as five times more for some vaccines than the bigger, wealthier nations.

Dr ARGAWAL (India)<sup>1</sup> said that the report highlighted not only the technical issues relating to immunization but also the need to develop and strengthen a harmonious relationship between immunization programmes and health systems in the context of global interdependence. In India the national programme for universal immunization against preventable diseases needed to be assured of an uninterrupted supply of vaccines at affordable prices. To minimize the danger arising from a volatile global market and thereby ensure longer-term national health security, India's national health policy for 2002 had envisaged that not less than 50% of the required vaccines and sera would be sourced from public sector institutions.

Mrs PHUMAPHI (Assistant Director-General) said that, to improve global immunization capacity and coverage at country level, the principal need was adequate coordination between the numerous programmes of partners involved and to take full advantage of other services. The new strategy therefore aimed at bringing together all the epidemiological skills, tools and guidelines that had been developed to deal with immunization programmes; to strengthen the Expanded Immunization Programme; to promote immunization campaigns; and to fund the increased marginal costs of reaching the last 20% of populations in hard-to-reach areas.

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

She would take into consideration members' suggestions. The consultation process had started in 2004 and involved national Expanded Immunization Programme managers and the Global Alliance for Vaccines and Immunization. The World Bank, a partner in the Alliance, was working on costing the strategy, in order to tighten its focus. WHO was working also with global partners on the financing of immunization. As a partner, it was engaged in the background work for the international finance facility for immunization. Partners were working on the global interdependence aspects of immunization such as pricing, research on vaccines with new or improved antigens that did not require a cold chain and other vaccines against prioritized diseases.

Comments had been made regarding the cost of immunization and the fact that some of the system-wide barriers that inhibited access to other health services also inhibited access to immunization. WHO was trying to integrate processes for dealing with such issues into the WHO-UNICEF Global Immunization Vision and Strategy. An attempt was also being made to find new ways of working in countries with other partners to deliver immunization together with other health services. Developing strategies for collaboration for interrelated programmes, strengthening systems and using an integrated approach to child and maternal health programmes would improve the sustainability of Expanded Immunization Programmes.

Some Board members had noted that vaccines with new antigens being offered to the global community were expensive. As WHO could not guarantee low vaccine prices, even where there was overwhelming epidemiological evidence of heavy disease burdens, such as with rotavirus or human papillomavirus infection, it was important to establish partnerships through bodies such as the international finance facility in order to improve access to vaccines.

**The Board noted the report.**

**Malaria:** Item 4.11 of the Agenda (Document EB115/10)

The CHAIRMAN, introducing the item, drew attention to the draft resolution contained in document EB115/10 and an alternative draft resolution proposed by the United States of America, which read:

The Executive Board,  
Having considered the report on malaria;<sup>1</sup>

Noting that few countries endemic for malaria are likely to reach the targets set in the Abuja Declaration on Roll Back Malaria in Africa (25 April 2000) of ensuring that at least 60% of those at risk of or suffering from malaria benefited from suitable and affordable preventive and curative interventions by 2005, but that there is rapidly increasing momentum for expanding malaria-control interventions in African countries,

RECOMMENDS to the Fifty-eighth World Health Assembly the adoption of the following resolution:

The Fifty-eighth World Health Assembly,  
Having considered the report on malaria;  
Concerned that malaria continues to cause more than one million preventable deaths a year, especially in Africa among young children and other vulnerable groups;  
Recalling that the period 2001-2010 has been proclaimed the Decade to Roll Back Malaria in Developing Countries, Particularly in Africa, by the United Nations General Assembly,<sup>2</sup> and that combating HIV/AIDS, malaria and other diseases is included in the

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<sup>1</sup> Document EB115/10.

<sup>2</sup> Resolution 55/284.

internationally agreed development goals, including those contained in the United Nations Millennium Declaration;

Recalling further United Nations General Assembly resolution 59/256 entitled “2001-2010: Decade to Roll Back Malaria in Developing Countries, Particularly in Africa”;

Mindful that the global burden of malaria needs to be decreased in order to reduce child mortality by two thirds by 2015 and to help achieve the other internationally agreed development goals, including those contained in the United Nations Millennium Declaration, of improving maternal health and eradicating extreme poverty,

1. URGES Member States:

- (1) to establish national policies and operational plans to ensure that at least 80% of those at risk of or suffering from malaria benefit from major preventive and curative interventions by 2010 in accordance with WHO technical recommendations so as to ensure a reduction in the burden of malaria of at least 50% by 2010 and 75% by 2015;
- (2) to assess and respond to the need for human resources at all levels of the health system in order to achieve the targets on the Abuja Declaration on Roll Back Malaria in Africa and the internationally agreed development goals of the United Nations Millennium Declaration, and to take the necessary steps to ensure the recruitment, training and retention of health personnel;
- (3) to further enhance financial support and development assistance to malaria activities in order to achieve the above targets and goals;
- (4) to increase, in countries endemic for malaria, domestic resource allocation to malaria control and to create favourable conditions for working with the private sector in order to improve access to good-quality malaria services;
- (5) to pursue a rapid scale-up of prevention with the aim of at least 60% of pregnant women receiving intermittent preventive treatment and at least 60% of those at risk using insecticide-treated nets wherever that is the vector-control method of choice, by applying expeditious approaches, including targeted free, or highly subsidized, distribution of materials and medicines to vulnerable groups;
- (6) to support expanded access to artemisinin-based combination therapy, including the commitment of new funds, innovative mechanisms for the financing and national procurement of artemisinin-based combination therapy, and the scaling up of artemisinin production to meet the increased need;
- (7) to support the development of new medicines to prevent and treat malaria, especially for children and pregnant women; of sensitive and specific diagnostic tests; of effective vaccine(s); and of new insecticides and delivery modes in order to enhance effectiveness and delay the onset of resistance, including through existing global partnerships;
- (8) to support coordinated efforts to improve surveillance, monitoring and evaluation systems so as to better track and report changes in the coverage of recommended “Roll Back Malaria” interventions and subsequent reductions in the burden of malaria;

2. REQUESTS the Director-General:

- (1) to reinforce and expand the Secretariat’s work to improve existing national capabilities, and to cooperate with Member States, in collaboration with Roll Back Malaria partners, in order to ensure the full and cost-effective use of increased financial resources for achieving international goals and targets, including the

internationally agreed development goals related to malaria contained in the United Nations Millennium Declaration;

(2) to collaborate with malaria-affected countries and Roll Back Malaria partners to ensure that countries receive full support for necessary monitoring and evaluation, including the development and implementation of appropriate pharmacovigilance systems;

(3) to collaborate with Roll Back Malaria partners, industry, and development agencies in order to ensure that sufficient quantities of insecticide-treated mosquito nets and effective antimalarial medicines are made available, especially those required for combination therapies;

(4) to strengthen collaboration with partners in industry and academia for development of affordable high-quality products for malaria control, including rapid, easy-to-use, sensitive and specific diagnostic tests; an effective malaria vaccine; novel, effective and safe antimalarial medicines; and new insecticides and delivery modes to enhance effectiveness and delay the onset of resistance.

Dr STEIGER (United States of America) explained that his country's draft resolution proposed additional subparagraphs to paragraph 1 of the original draft resolution, and new language in paragraph 2. The reason for the additional text, which had resulted mainly from consultations held by the Secretariat, was the wish to emphasize access to the new combination therapies and the importance of renewed efforts to increase the provision of insecticide-treated bednets, and in research and surveillance.

In the course of further consultations, three other elements had been identified: first, the recognition that malaria was a growing problem in other regions of the world besides Africa. He therefore proposed an insertion at the end of the second preambular paragraph, that would read: "and that the disease continues to threaten the lives of millions of people in Latin America, the Caribbean, South Asia and other regions of the world".

Secondly, the draft made no reference to the current largest financier of antimalarial programmes in the world, hence, in recognition of its role, he proposed the addition of a final preambular paragraph that would read: "Recognizing that the Global Fund to Fight AIDS, Tuberculosis and Malaria has committed 31% of its grants, or US\$ 921 million over two years, to projects to control malaria in 80 countries".

The third element was the issue of indoor household insecticide spraying in appropriate circumstances, a vector-control measure that several Member States had decided to take. To reflect that situation he suggested the addition of a new subparagraph in paragraph 1, after paragraph 1(5), that would read: "to support indoor household residual insecticide spraying, where indicated by local conditions". For the sake of consistency, a similar subparagraph should be added in paragraph 2, after paragraph 2(3), that would read: "to provide evidence-based advice to Member States on the appropriate use of indoor household residual insecticide spraying, taking into account recent experiences around the world".

Dr HUERTA MONTALVO (Ecuador) expressed his appreciation of the draft resolution on malaria in document EB115/10 and of the proposal by the member for the United States of America, which he endorsed. He welcomed the emphasis on the free distribution of materials and medicines to vulnerable groups and expanded access to artemisinin-based combination therapy. His country needed to acquire more artemisinin to meet its needs. While the problems that malaria posed to Africa should not be minimized, it was important to recognize that malaria was out of control in 21 countries of the Region of the Americas. Concern about the high incidence of malaria in that Region would be reflected in a statement to be issued shortly by the countries of the Latin American and Caribbean Group. A state of alert might perhaps be considered regarding biological vector controls.

Dr SAM (Gambia) said that extensive epidemiological data showed the continuing public health burden of malaria. Other recent data showed that it was also a developmental problem; seen in that light, malaria was involved in all eight Millennium Development Goals. One macroeconomic study had found that the incidence of malaria was indirectly responsible for slowing development by 1.3%. Although 90% of the malaria burden was borne by sub-Saharan Africa, he appreciated that the disease also occurred in other parts of the world.

He welcomed the draft resolution and endorsed some of the amendments proposed by the member for the United States of America. With regard to the supply shortages of artemisinin-based combination therapies referred to in paragraph 12 of the report, efforts to ensure their availability should be focused on areas in which the malaria burden was greatest. Local cultivation of the plant from which artemisinin was extracted and, with the help of technology transfer, local production of the drug, would ensure sustainable supplies for those most affected. The rapid diagnostic tests for malaria that were currently available could not be considered inexpensive, given their considerable cost implications for countries in which the incidence of malaria was highest. The gold standard in the diagnosis of malaria, microscopy, was not expensive, however, and the technique cut down expenditure on artemisinin-based combination therapies since it screened out fevers not caused by malaria. The introduction of rapid diagnostic tests should not replace that gold standard; rather, resources should be invested in increasing the capacity for microscopy by training personnel in the technique and providing microscopes, to ensure that antimalarial medicines were not wasted on non-malarial fevers.

Dr NSIAH-ASARE (alternate to Dr Ahmed, Ghana) agreed that malaria was a developmental as well as a health problem. Efforts to reduce the burden of malaria in endemic countries should take into account the efficacy, accessibility, affordability and acceptability of both preventive and treatment strategies. Households should be enabled to take protective measures and to receive prompt and effective malaria care in order to reduce the cost of the illness. He therefore endorsed the amendment proposed by the member for the United States concerning household residual insecticide spraying as a preventive measure supplementing the use of insecticide-treated nets. Efforts should also be made to facilitate the early detection and rapid and effective treatment of malaria, not only to reduce the cost of treatment, but also to reduce the number of working days lost because of the disease. Increased attention should be given to malaria in the planning of poverty-reduction strategies.

Dr CAMARA (Guinea) said that malaria had a devastating effect in developing countries, including Guinea, which therefore supported all attempts to mobilize resources and commit partners to effectively combating the disease. He endorsed the draft resolution proposed by the United States of America.

Mr KHAN (Pakistan), affirming that for many countries, including Pakistan, malaria was a major public health problem, said that his country appreciated the fact that WHO had constantly given it top priority, and was optimistic that the Roll Back Malaria targets would be achieved. Pakistan's national programme was rapidly moving towards the target of a 50% reduction in the incidence of malaria by 2010 – a goal that would have been unattainable without assistance from the Global Fund to Fight AIDS, Tuberculosis and Malaria. Action must be focused on five areas: early diagnosis and rapid treatment; multiple preventive measures; improved detection and response to epidemics; viable partnerships at national and international levels; and operational research. Funding and implementation were critical to success. The time had come to broaden the focus from a country-by-country to a continent-by-continent approach. For example, it was estimated that to eradicate malaria in the entire African continent would cost some US\$ 500 million, an amount similar to what the developed world spent daily on subsidizing its agricultural sector. There should also be greater emphasis on immunization programmes.

Professor FURGAL (adviser to Mr Skotnikov, Russian Federation) endorsed the report. Some countries of eastern Europe and central Asia faced the renewed risk of importing the disease from malaria-endemic countries such as Afghanistan and Turkey. Hopes for controlling malaria were based on the large-scale application of antimalarial medicines and insecticides. It was particularly important to strengthen monitoring of the sensitivity of vectors and plasmodia when chemoprophylaxis was taken over many years. The scope of laboratory work should also be widened to include differentiation of plasmodial species and cytogenetic analysis of mosquito vectors.

In general, he supported the amendments proposed by the member for the United States of America. He proposed the addition of a new subparagraph 1(5), worded: "to improve coordination between health services in controlling the cross-border spread of malaria from foci in neighbouring countries".

Russian experts were ready to work actively in all areas of that important work, including the training of medical staff in the problems of epidemiological surveillance and malaria control.

Dr QI Qingdong (alternate to Dr Yin Li, China) said that his country attached great importance to malaria control and remained ready to cooperate with WHO and other countries in research, including on the development of easy-to-use artemisinin-based combination therapies, which should be made available as quickly as possible. In that regard, it was hoped that China's programmes to develop such products for use worldwide would receive WHO technical support.

Dr ABDULLA (Sudan) said that malaria was the major cause of death in many developing countries and undermined their already weak economies. Efforts to combat the disease had hitherto not been commensurate with the scale of the problem. WHO must intensify its work, in particular by revising the Roll Back Malaria initiative, for which further funding was needed. The impact of the disease could also be reduced by the provision of artemisinin-based combination therapies and insecticide-treated bednets at affordable prices. WHO could help greatly in that regard by using its advantageous position to make bulk purchases on behalf of other countries and organizations. Accordingly, he proposed adding, at the end of paragraph 2(3) of the draft resolution, the words: "and to study the possibility of WHO undertaking bulk purchases on behalf of Member States".

There should also be greater coordination and collaboration with other organizations, with WHO remaining the technical consultant. To that end, he proposed the addition of a further subparagraph, at the end of paragraph 2, worded: "to further cooperation and create partnerships with countries supporting malaria control programmes to ensure that the funds available to combat the disease will achieve the efficiency and effectiveness sought".

Dr NDONG (Gabon) said that malaria presented a multi-faceted challenge. Although the arrival of combination therapies for treating malaria denoted considerable progress, there remained the problem of making them accessible to large sectors of the population. Cost would always be a major consideration, although the Global Fund to Fight AIDS, Tuberculosis and Malaria had already made a big difference. Referring to paragraph 8 of the report, he pointed out that, for countries such as his own, artemisinin-based combination therapy was expensive, and therefore other combinations had been used, particularly of products such as sulphaguanidine with pyrimethamine, which were effective in children and pregnant women. He asked whether the global subsidy for such therapies (paragraph 12) was a further contribution in addition to funding from the Global Fund. If so, that was excellent, but if not, his concern about cost was still valid.

It was also important that programmes instituted by countries should not function in isolation, but rather have support from the private sector, universities and research centres. When Gabon had discussed replacing chloroquine by combination therapies, such establishments had played a valuable part in the debate. He therefore proposed that, in the draft resolution, Member States should be urged to encourage universities and private and semipublic research centres to support national malaria control programmes.

Dr SUWIT WIBULPOLPRASERT (Thailand) supported the draft resolution contained in the report, but proposed three amendments. First, an additional subparagraph should be added to paragraph 1, reading: “to work closely with neighbouring countries in controlling malaria in border areas”. As a consequential amendment, a fifth subparagraph should be added to paragraph 2, to read: “to provide support for intercountry collaboration for malaria control, particularly along border areas”. Secondly, in subparagraph 1(3), the word “integrated” should be inserted before “human resources”, because the malaria control programme should be part of the strengthened integrated health and human resources system, not a vertical programme. Thirdly, in paragraph 2(3), the word “agencies” should be added after “development”, and the words “under a strictly controlled distribution system” should be added at the end. The purpose was to avoid irrational use of such therapies, which could accelerate the onset of resistance. In Thailand such products could be distributed only under the national malaria control programme.

He welcomed the comments by the member for the United States of America about the Global Fund to Fight AIDS, Tuberculosis and Malaria. In addition to a reference to Latin America and south Asia, south-east Asia, too, might be mentioned. He could support the United States proposals provided that paragraph 1(2) of the draft resolution in document EB115/10 was retained.

Dr PHOOKO (Lesotho) welcomed the report and its draft resolution, and noted the alternative draft resolution. Lesotho supported, in particular, the inclusion of indoor residual spraying as part of integrated vector control. In view of the comments by previous speakers, especially those of the members for Gambia, Guinea and Thailand, he requested more time to consider all the proposals.

Mr PALU (alternate to Ms Halton, Australia) said that malaria remained a debilitating problem not only in Africa but also in Asia and the Pacific. In recent years control programmes in the Pacific countries endemic for malaria, namely, Papua New Guinea, the Solomon Islands and Vanuatu, had faced reduced operational capabilities, while morbidity and mortality increased. He would therefore, like to see a reference to the Western Pacific Region included in the second preambular paragraph of the alternative text. As a strong supporter of the Roll Back Malaria initiative, Australia urged WHO to continue its efforts to assist countries in accelerating the change towards artemisinin-based combination therapies where feasible and appropriate.

Mr RECINOS TREJO (El Salvador),<sup>1</sup> speaking on behalf of the countries of the Region of the Americas, said that those countries noted with concern that the report did not contain any information on the situation concerning malaria in the Americas. According to statistics for the year 2000, 36% of the population in that Region lived in risk areas. A report by PAHO on malaria control programmes in the Americas, which also contained data for the year 2000, stated that 57% of the population of that Region lived in 21 countries in which malaria was transmitted. Eleven of those countries were in South America; seven were situated in Central America; and the other three countries were the Dominican Republic, Haiti and Mexico. It had been calculated that in those 21 countries some 293 million people were at risk of malaria because they lived in areas in which the social, economic and environmental conditions were conducive to transmission of the disease. In the year 2000, 1.14 million cases had been registered, 86% of which had occurred in the Amazonian countries of South America. Although most of the deaths caused by the disease occurred in Africa, it should not be forgotten that malaria could have explosive effects in the Region of the Americas if the problem were not given proper consideration, nor that the countries most affected by malaria in that Region were those that showed marked discrepancies in income, access to health services, education, environmental health and adequate living conditions. The countries of the Region therefore requested that they be kept informed of the planned activities of the Roll Back Malaria initiative, so as to combat malaria, with special emphasis on control in areas of epidemiological concern and on reduction of vector

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

density through the use of means other than insecticides. They supported the amendments proposed by the member for the United States of America concerning reference to other Regions in the draft resolution and the role of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Dr BELLO DE KEMPER (Dominican Republic)<sup>1</sup> endorsed the Thai proposal concerning support for intercountry collaboration for malaria control along border areas, specifically in respect of the border between the Dominican Republic and Haiti. While welcoming the United States proposals, she suggested adding the words “evaluation based on proof that the use of insecticides is effective and harmless to human health and the environment” to the subparagraph on indoor residual insecticide spraying. Indeed, DDT, although effective, had proved to be harmful to human health, and an international convention had been negotiated to limit and eventually discontinue its use.

Dr CHOW (Assistant Director-General), responding to the many members who had mentioned the Global Fund to Fight AIDS, Tuberculosis and Malaria and bilateral donors, said that WHO was working hard to secure concerted action between financial institutes, those providing expertise and private-sector, government and nongovernmental implementing partners. The points on the global incidence of malaria were well taken. Malaria was one of the prime diseases of poverty, and it had an impact in the workplace, exacerbated gender differences, and affected displaced and migrant populations, along border areas in particular.

Valid comments had been made on the cost of medicines, especially artemisinin-based combination therapies and diagnostic tests. Within the Roll Back Malaria partnership, WHO had built a malaria medicines and supplies service, an information network that sought to aggregate supply and demand in order to reduce transaction costs and make bulk purchases. A proposal by the United States Institute of Medicine for a global subsidy was for a mechanism additional to the Global Fund. WHO sought to make rapid diagnostic tests and microscopy broadly available. The situation was most challenging in peripheral areas with little infrastructure and few human resources. The aim was to work with the private sector and implementing agencies to reduce transaction and transportation costs, and to make rapid diagnostic tests and artemisinin-based combination therapies available at little or no cost where feasible.

Artemisinin-based combination therapies were transforming malaria treatment. During a visit to China he had observed the Government’s commitment to improving supplies of the raw ingredient and working with the private sector and implementing agencies to find ways of producing such therapies at a lower cost. He also noted the concern expressed that they should be distributed through a strictly controlled distribution system and used judiciously in the context of a properly functioning health system.

Dr STEIGER (United States of America), responding to a question by the CHAIRMAN, suggested that more time was needed to agree on wording acceptable to all, on the basis of a clean copy of the text, to be prepared by the Secretariat.

The CHAIRMAN took it that the Board agreed to that approach.

**It was so agreed.**

(For adoption of the resolution, see summary record of the twelfth meeting, section 1.)

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

**Public health problems caused by alcohol:** Item 4.12 of the Agenda (Documents EB115/37 and EB115/37 Corr.1)

The CHAIRMAN, speaking as the member for Iceland, introduced a draft resolution on public health problems caused by harmful use of alcohol proposed by Austria, Bahrain, Belarus, Belgium, Bolivia, Canada, China, Cyprus, Czech Republic, Denmark, Ecuador, Estonia, Finland, France, Gabon, Germany, Ghana, Greece, Guinea, Guinea-Bissau, Hungary, Iceland, Ireland, Israel, Italy, Jamaica, Kenya, Latvia, Lithuania, Luxembourg, Maldives, Malta, Nepal, Netherlands, Norway, Pakistan, Poland, Portugal, Romania, Russian Federation, Slovakia, Slovenia, South Africa, Spain, Sweden, Switzerland, Tonga, Turkey and the United Kingdom of Great Britain and Northern Ireland, which read:

The Executive Board,

Having considered the report on public health problems caused by alcohol,<sup>1</sup>

RECOMMENDS to the Fifty-eighth World Health Assembly the adoption of the following resolution:

The Fifty-eighth World Health Assembly,

Recalling resolutions WHA32.40 on development of the WHO programme on alcohol-related problems, WHA36.12 on alcohol consumption and alcohol-related problems: development of national policies and programmes, WHA42.20 on prevention and control of drug and alcohol abuse, WHA55.10 on mental health: responding to the call for action, WHA57.10 on road safety and health, WHA57.16 on health promotion and healthy lifestyles and WHA57.17 on Global strategy on diet, physical activity and health;

Recalling *The world health report 2002*,<sup>2</sup> which indicates that 4% of disease burden and 3.2% of all deaths globally are attributed to alcohol, and that alcohol is the foremost risk to health in low-mortality developing countries and the third in developed countries;

Recognizing that the patterns, context and overall level of alcohol consumption influence the health of the population as a whole, and that harmful drinking is among the foremost underlying causes of disease, injury, violence, disability, social problems and premature deaths, is associated with mental ill-health, has a serious impact on human welfare affecting individuals, families, communities and society as a whole, and contributes to social and health inequalities;

Emphasizing the risk of harm due to alcohol consumption in the context of driving a vehicle, at the workplace and during pregnancy;

Alarmed by the extent of public health problems associated with harmful consumption of alcohol and the trends in hazardous drinking, particularly among young people, in many Member States;

Recognizing that intoxication with alcohol is associated with high-risk behaviours, including the use of other psychoactive substances and unsafe sex;

Concerned about the economic loss to society resulting from harmful alcohol consumption, including costs to the health services, social welfare and criminal justice systems, lost productivity and reduced economic development;

Recognizing the threats posed to public health by the factors which have given rise to increasing availability and accessibility of alcoholic beverages in some Member States;

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<sup>1</sup> Documents EB115/37 and EB115/37 Corr.1.

<sup>2</sup> *The world health report 2002. Reducing risks, promoting healthy life*. Geneva, World Health Organization, 2002.

Noting the growing body of evidence of the effectiveness of strategies and measures aimed at reducing alcohol-related harm;

Mindful that individuals should be empowered to make positive, life-changing decisions for themselves on matters such as consumption of alcohol,

1. REQUESTS Member States:

- (1) to develop, implement and evaluate effective strategies and programmes for reducing the negative health and social consequences of harmful use of alcohol;
- (2) to encourage mobilization and active and appropriate engagement of all concerned social and economic groups, including scientific, professional, nongovernmental and voluntary bodies, the private sector, civil society and industry associations, in reducing harmful use of alcohol;
- (3) to support the work requested of the Director-General below including, if necessary, through voluntary contributions by interested Member States;

2. REQUESTS the Director-General:

- (1) to strengthen the Secretariat's capacity to provide support to Member States in monitoring alcohol-related harm and to reinforce the scientific and empirical evidence of effectiveness of policies;
- (2) to intensify international cooperation in reducing public health problems caused by the harmful use of alcohol and to mobilize the necessary support at the global and regional levels;
- (3) to produce a report on evidence-based strategies and interventions to reduce alcohol-related harm, including a comprehensive assessment of public health problems caused by harmful use of alcohol, to be presented to the Sixtieth World Health Assembly;
- (4) to draw up recommendations for effective policies and interventions to reduce alcohol-related harm and to develop technical tools that will support Member States in implementing and evaluating the recommended strategies and programmes;
- (5) to strengthen global and regional information systems through further collection and analysis of data on alcohol consumption and its health and social consequences, providing technical support to Member States, and promoting research where such data are not available;
- (6) to promote and support global and regional activities aimed at identifying and managing alcohol-use disorders in health-care settings and enhancing the capacity of health-care professionals to address problems in their patients associated with harmful patterns of alcohol consumption;
- (7) to ensure transparency, impartiality and balanced regional and gender representation in the selection of experts for technical consultations on alcohol and in activities of advisory panels, including the Alcohol Policy Strategy Advisory Committee, in accordance with the established rules and procedures;
- (8) to collaborate with Member States, intergovernmental organizations, health professionals, nongovernmental organizations and other relevant stakeholders to promote the implementation of effective policies and programmes to reduce harmful alcohol consumption;
- (9) to organize open consultations with representatives of industry and agriculture and distributors of alcoholic beverages in order to limit the health impact of harmful alcohol consumption;
- (10) to report through the Executive Board to the Sixtieth World Health Assembly on progress made in the implementation of this resolution.

The draft resolution had originally been prepared by the Nordic countries, which had engaged in broad consultations in the course of the session. Many different points of view had been expressed in what had not been an easy discussion; alcohol meant different things in different cultures. Even the title of the resolution had proved controversial: some had favoured the formulation “caused by use of alcohol”, while others would have preferred “caused by abuse of alcohol”. The latter wording presented a problem because pregnant women and drivers, for example, did not need to abuse alcohol to suffer its harmful effects. The text before the Board was a compromise between the many views expressed.

Dr HANSEN-KOENIG (Luxembourg), speaking on behalf of the Member States of the European Union and the candidate countries Bulgaria, Croatia, Romania and Turkey, said that the European Union was deeply concerned about alcohol abuse and its serious medical, social and economic consequences, and in particular about the fact that young people were abusing alcohol at an increasingly early age. However, the 49 sponsors of the draft resolution included only Romania and Turkey of the candidates countries; Bulgaria and Croatia should be added. The European Union looked forward with interest to receiving the report on evidence-based strategies and interventions, which would provide effective guidance.

Dr HUERTA MONTALVO (Ecuador) said that Ecuador was an enthusiastic sponsor of the draft resolution, but had also carefully listened to other points of view. It was important to distinguish between use, abuse and dependence, for alcohol abuse could produce harmful effects without dependence. There was a suggestion to modify the title of the draft resolution in order to establish a strategy on public health problems caused by hazardous and harmful use which would cover the cases of pregnant women and drivers. Furthermore, it should not be forgotten that alcohol consumption could also be beneficial. Statistics were available on the reduced incidence of brain haemorrhages brought about by non-hazardous alcohol consumption. The point was to strike the proper balance.

He was gratified that the item had been included on the Board’s agenda, because one of the criticisms made by tobacco producers had been that the Organization had taken a hard line against smoking but had had little to say on alcoholism. It was important not to take an exaggerated stand on alcohol: a clear statement on what constituted hazardous or harmful consumption and how to avoid it would have a far greater impact on public health.

Mr KHAN (Pakistan) said that alcohol consumption was a leading cause of death and disability around the world. Pakistan shared the concern of all members about the rise in alcohol consumption, especially among young people. With globalization, it had become a global problem. He proposed that the phrase “especially domestic violence primarily targeted against female partners and children” should be inserted after the word “violence” in the third preambular paragraph of the draft resolution.

Strong action, including taxation measures, must be taken against alcohol manufacturers, and advertising agencies and the media should be targeted. In short, a strategy similar to that used for tobacco control could be applied in the case of alcohol.

Dr THAKSAPON THAMARANGSI (adviser to Dr Suwit Wibulpolprasert, Thailand) proposed that the words “harmful use of” should be deleted from the title. He supported the amendment proposed by the previous speaker in respect of the third preambular paragraph of the draft resolution.

WHO’s current alcohol policies had two main defects. First, they came under “Mental health and substance abuse”, implying that the problems caused by alcohol were related only to mental health, whereas in fact alcohol use also caused many physical diseases and impeded well-being on account of its economic and social effects. Secondly, the focus on harm reduction suggested that, provided no harm was caused by drinkers, alcohol consumption was acceptable, which overlooked the adverse effects of alcohol on health. The increasing availability of alcohol, coupled with aggressive marketing, was chiefly responsible for the rise in alcohol consumption, especially in developing countries. Marketing, under free trade agreements in particular, significantly affected the type,

volume, frequency and conditions of consumption, which in turn affected the magnitude and severity of alcohol-related problems and the effectiveness of policies and action for reducing or preventing those problems.

WHO should learn from the experience gained in tobacco control, the time having perhaps come to consider a framework convention for alcohol control. As in the case of tobacco and gambling, most countries already had a legal framework for regulating alcohol, for example by applying excise duty and licensing sales and advertising to curb consumption. He therefore proposed that in paragraph 1(1) of the draft resolution the words “including an appropriate legal framework for marketing control” should be inserted between commas after “programmes”; and, in paragraph 2(1), “formulating, implementing and evaluating alcohol policy and” should be inserted after “Member States in”.

Professor FURGAL (alternate to Mr Skotnikov, Russian Federation) commended WHO's activities in relation to alcohol-related public health problems. Many countries continued to be affected, including his own, where there were more than two million registered alcoholics, alcohol-related diseases were widespread and consumption levels unprecedented. As that was a matter of particular concern to the country's leadership and all social institutions, the Russian Federation was a sponsor of the draft resolution. Future activities should take into account the work done so far. For example, in 1995 the Member States of the European Region had adopted the European Charter on Alcohol and were currently implementing the European Alcohol Action Plan 2000-2005. Further, the European Ministerial Conference on Young People and Alcohol held in Stockholm in 2001 had adopted a Declaration setting specific targets for 2006. The European Region had also issued several useful publications on alcohol and public health. WHO had already shown, in the area of tobacco control, that collaboration among Member States could be most fruitful. It should encourage similar efforts regarding alcohol control, perhaps with a view to a framework convention on alcohol control.

Dr QI Qingdong (alternate to Dr Yin Li, China) said that the widespread harmful use of alcohol was increasing the disease burden and damaging society in many countries. China approved the various strategies set out in the report. The global dissemination of scientific information on the effects of alcohol use was of particular importance. It was also necessary to amplify action to prevent unintentional injury and promote mental health. WHO should play an active role in providing guidance to Member States, collecting evidence and developing early intervention. China supported the draft resolution together with the comments made by the member for Thailand.

Dr ACHARYA (Nepal), indicating that Nepal was a sponsor of the draft resolution, said that as use of alcohol could lead to dependence and hence abuse, both terms, “use” and “abuse”, should be used in the draft resolution. Alcohol consumption caused many public health problems in his part of the world, as elsewhere, with widespread illicit production and consumption, rural alcoholism, “pay-day drinking”, drinking and driving, and poverty resulting from alcohol dependence. Climate also played a role, with people drinking to combat the cold at high altitude. Strategies should focus on demand and harm reduction, with intervention and information aimed at increasing awareness of the effects of alcohol and empowering the individual, the family and the community against external pressures to consume alcohol. Drinking should, in short, be de-glamorized.

Dr CAMARA (Guinea), indicating his support for the amendments already made, proposed several further modifications. Since a policy was adopted, and then programmes and action plans were formulated, he suggested that paragraph 2(4) should become paragraph 1(1) and be amended to read: “to adopt effective policies and interventions to reduce alcohol-related harm and to develop appropriate technical tools to facilitate the implementation and follow-up of strategies and programmes;”. The present paragraph 1(1) would be renumbered 1(2) and read: “to develop effective programmes for reducing the consequences of and the health and social problems related to harmful use of alcohol;”. Finally, it was superfluous to request the Director-General, in paragraph 2(3), to

include a comprehensive assessment of public health problems caused by harmful use of alcohol in a report to be presented to the Sixtieth World Health Assembly, when he was requested in paragraph 2(10) to report through the Executive Board to that Health Assembly on progress made in implementing of the resolution.

Dr AL-SAIF (alternate to Dr Al-Jarallah, Kuwait) welcomed the report and supported the draft resolution.

Dr TANGI (Tonga), observing that his country was a sponsor of the draft resolution, said that he had queried the statement in the second preambular paragraph of the draft resolution that alcohol was “the foremost risk to health in low-mortality developing countries and the third in developed countries”, but had been told that it was cited as such in *The world health report 2002*.<sup>1</sup> The Director-General already selected experts for technical consultations and advisory panels in accordance with the established rules and procedures, so that paragraph 2(7) was redundant and should be deleted. The paragraph read as though it had been included in response to a complaint about selection, perhaps from the alcohol industry. As in the case of tobacco, the alcohol industry should be given no place at the discussion table in view of its clear vested interest. Since decisions should be free of commercial influence, paragraph 2(9) should also be deleted. As to the funding implications of the draft resolution, it was important to ensure that the budget allocations for the areas of work concerning noncommunicable diseases and substance abuse sufficed for implementation.

Dr STEIGER (United States of America) expressed support for WHO’s efforts in the area under consideration. The United States supported the draft resolution in principle and could accept the text as submitted. It would, however, be strongly opposed to a framework convention on alcohol control. Food and alcohol differed from tobacco. Moreover, as stated by the member for Nepal, there was a high level of illicit alcohol production and consumption, which was not addressed by the draft resolution. Such products, sold without regulation, were much more harmful than properly regulated commercial ones. Many countries had stringent regulations and some chose to ban alcohol altogether. It was for Member States to make such choices, but it should be remembered that the prohibition of alcohol enforced by Canada, Norway and the United States of America between 1919 and 1933 had failed and had led to an increase in organized crime and high levels of illicit drinking and bootlegging. The United States supported a strategy with a public health orientation, focusing on the alcohol-induced problems that WHO and ministries of health could do something about. It could not support the deletion of paragraphs 2(7) and 2(9) as proposed by the member for Tonga, since it was not possible to tackle the problems concerned without talking to the alcohol industry – producers, wholesalers and retailers. The Director-General should engage in open, transparent dialogue with the industry. He supported the amendments proposed by the member for Ecuador and endorsed the statement to be made on behalf of the countries of the Region of the Americas. Scientific evidence pointed to benefits from a moderate consumption of alcohol, and it was to be hoped that an appropriate balance could be struck enabling WHO to deal with harmful use without becoming involved in areas beyond its purview.

Dr SÁ NOGUEIRA (Guinea-Bissau), supporting the draft resolution, said that he too favoured retaining paragraph 2(9). In many countries where alcohol was produced by traditional methods, the chemical preparations used were extremely harmful to health. He wondered how that aspect could be reflected in the resolution.

Mr SHUGART (Canada) said that the core of the problem lay in the title. From a logical point of view, the wording was not ideal because of the tautology: if there were public health problems

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<sup>1</sup> *The world health report 2002: Reducing risks, promoting healthy life*. Geneva, World Health Organization, 2002.

caused by use of alcohol, it must be because some uses were harmful. However, it would be best not to tinker with the language of the draft. The credibility of WHO was an important factor because, once adopted, the resolution would be widely disseminated in countries with different cultures. Whatever it contained could be misinterpreted. However, what was important about the resolution was that it called for further evidence to be gathered of the harmful effects of alcohol. No member of the Board would object to that, or to tools being made available to deal with the consequent public health problems. In that sense, the draft resolution was highly practical. The public health problems were manifest in a variety of settings. Putting the resolution as it stood into practice could only be beneficial in the immediate term, and in the longer term, as consensus grew, the language of the text could be reviewed. Clearly, a sore point was the implication in the title that any and every use of alcohol might have harmful effects, and no consensus would be achievable on that. However, he supported the draft resolution as it was, in the belief that the perfect might be the enemy of the good.

Dr YOOSUF (Maldives) said that he could agree with the member for the United States of America on certain points, specifically on the dangers posed by illicit alcohol production, especially in poorer countries, and the likelihood that the consultations proposed in paragraph 2(9) would be more successful if the producers were involved. He was in favour of retaining the title of the draft resolution.

Dr ANTEZANA ARANÍBAR (Bolivia) said that, for the reasons given by the member for Canada and subject to the reservations expressed about the title, he supported the draft resolution. He also agreed with the remarks by the member for the United States. A convention on the subject would be premature given that much more information of the kind proposed in the draft resolution was needed, before any informed opinion on the matter could be reached.

Dr BRUNET (alternate to Professor Dab, France) said that, as a sponsor of the draft resolution, his country was content with the work so far done by the Secretariat. There was no question of going further than the measures proposed in the draft, such as embarking on a framework convention of the kind adopted for tobacco use.

Ms HALTON (Australia) was in favour of retaining paragraph 2(9). All players, including the alcohol industry, should be involved in devising strategies to reduce the burden of disease and injury caused by the harmful use of alcohol.

Dr CAMARA (Guinea) said that paragraph 2(7) was confusing and should be deleted. The Alcohol Policy Strategy Advisory Committee was simply a body called into existence when there was a specific job for it to do.

Dr OÑORBE DE TORRE (alternate to Dr Lamata Cotanda, Spain) supported the draft resolution but drew attention to a possible discrepancy between the English and Spanish versions.

Mr RECINOS TREJO (El Salvador),<sup>1</sup> speaking on behalf of the countries of the Region of the Americas, said that the effects of alcohol consumption could be either harmful or beneficial, depending on the amount consumed and the individual characteristics and clinical profile of the drinker. A resolution on alcohol use must be balanced, and must take both kinds of effect into account. The countries of the Region were therefore proposing that the title of the draft be altered to "Public health problems caused by alcohol abuse". The concept of abuse or excessive consumption of alcohol should then be reflected in the text, with emphasis on the risk of harm being caused by irresponsible and excessive consumption. The countries also wanted to include recommendations recognizing

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

education to be an effective means of developing healthy habits and a responsible attitude towards alcohol. The resolution should also refer to national measures to prevent the consumption of alcohol by those below the minimum age, according to national law.

Mr PETTERSSON (Sweden)<sup>1</sup> said that he appreciated the remarks by the member for Canada. As a matter of logic, the draft was not dealing with the benefits of alcohol, but rather with its misuse. He was against changing the English title.

Dr DANZON (Regional Director for Europe) said that the subject had been chosen as one of the three technical subjects for the next Regional Committee meeting. In September 2005 the European Region would present an update of the action plan mentioned by the member for the Russian Federation. The Region would coordinate its work with headquarters and with the European Commission.

Dr HUERTA MONTALVO (Ecuador) said that the title of the resolution in Spanish was inadequate. It was the harmful use of alcohol that posed a risk to public health; some consumption was not harmful. There were countries where, for religious or cultural reasons, all alcohol use was regarded as harmful, a point of view WHO could not endorse. There should be a clear distinction in both the title and the text of the resolution between the kinds of use which were harmful to health – such as drinking alcohol during pregnancy – and those which were not.

Dr ABDULLA (Sudan) observed that the Arabic version of the title appeared to be a literal rendering of the English.

Dr LE GALÈS-CAMUS (Assistant Director-General), thanking members of the Board for their guidance and comments, said that the discussion had been a useful reminder of the need for precision at all times, including in the title of the draft resolution. The intention, as clearly emerging from a discussion informed by public health principles, was to deal with the consequences of the harmful use of alcohol. The Secretariat would endeavour to meet that objective on the basis of verifiable scientific data and proven methods, mention having been made of inefficacy of total prohibition of alcohol use and the concomitant evil of illicit alcohol production. Both at headquarters and in the Regions, efforts would therefore continue.

The CHAIRMAN, noting that many of the numerous amendments that had been presented were mutually incompatible, suggested that the Board should adopt only two of them: Pakistan's proposal to insert in the third preambular paragraph, after "violence", the phrase "especially domestic violence primarily targeted against female partners and children"; and Tonga's proposal to delete paragraph 2(7).

Dr THAKSAPON THAMARANGSI (adviser to Dr Suwit Wibulpolprasert, Thailand) opposed the deletion of paragraph 2(7).

The DIRECTOR-GENERAL said that he undertook to ensure that the imperative of transparency was embraced, with or without the inclusion of paragraph 2(7).

Dr THAKSAPON THAMARANGSI (adviser to Dr Suwit Wibulpolprasert, Thailand) said that, although transparency was an absolute necessity, he could, in view of the commitment just made by the Director-General, accept the deletion of paragraph 2(7).

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<sup>1</sup> Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

Dr STEIGER (United States of America) said that he, on the other hand, was reluctant to agree to the proposal. If the Director-General pledged transparency, there could be no harm in putting that commitment into writing. The language of paragraph 2(9) was weak: for it to be acceptable, he would like an assurance of WHO's willingness to engage the industry in a serious way on a partnership basis.

The DIRECTOR-GENERAL affirmed that such discussions had been going on for many years, mainly in the Nordic countries, but the point was that the situation differed from that of the tobacco industry. It was premature to discuss a convention and, in dealing with the alcohol industry, engagement was necessary.

After a brief discussion involving Mr SHUGART (Canada), Dr TANGI (Tonga), Mr KHAN (Pakistan) and Dr BRUNET (alternate to Professor Dab, France), the CHAIRMAN said that he took it that the Board wished to adopt the draft resolution, with Pakistan's amendment to the first preambular paragraph and Tonga's proposed deletion of paragraph 2(7).

**The resolution, as amended, was adopted.<sup>1</sup>**

**The meeting rose at 18:50.**

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<sup>1</sup> Resolution EB115.R5.