SIXTH MEETING

Wednesday, 19 January 2005, at 14:30

Chairman: Mr D.Á. GUNNARSSON (Iceland)

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

Procedures and guidelines: Item 4.7 of the Agenda

- **International Nonproprietary Names: revised procedure** (Document EB115/11)

The CHAIRMAN drew attention to Annexes 1 and 2 of the document which contained, respectively, the revised Procedure for the selection of International Nonproprietary Names (INN) for pharmaceutical substances and the revised General principles for guidance in devising them.

Dr STEIGER (United States of America) expressed his appreciation for the work done by the Secretariat and said that he found the revised procedure very satisfactory.

Professor KARAULOV (adviser to Mr Skotnikov, Russian Federation) emphasized the importance of a revised procedure in order to avoid confusion arising from similar names. Most of the proposals made during consultations on the revised procedure had been taken into account; the Board should therefore adopt the revised text. Further work was needed, however, to make the document more widely known.

Mrs GILDERS (alternate to Mr Shugart, Canada) said that from the outset her country had strongly endorsed the aims of the INN programme, which had played an increasingly important role in safe prescription, dispensing and use of medicines. The goals had gained greater prominence in recent years, with concerted efforts by regulatory authorities and health professionals to complement WHO's work in reducing the avoidable consequences of medication and prescription errors caused by similarities between names. She applauded recent efforts to provide a more streamlined and transparent process for the selection of INN and in regard to the exceptional substitution of such names. The revised procedures more clearly defined the compelling circumstances and processes under which proposals for revised names could be considered while also providing for the engagement of key parties in the selection process. Canada therefore endorsed the adoption of the revised procedure.

Dr ANTEZANA ARANÍBAR (Bolivia) unconditionally supported the revised procedure, which provided clear, universally understood language for communication between and within countries and for use by drug regulatory authorities. The work on INN had been very effective. It was particularly important to avoid confusion by ensuring that any new trade names created did not closely resemble INN.

Ms HALTON (Australia), strongly endorsing the views expressed by previous speakers, stressed the importance of the work under way in ensuring that no confusion arose when prescribing and dispensing medicines. Australia and New Zealand had already agreed that they would adopt the approach set forth in the revised procedure: where no INN existed for a particular product, they would use the appropriate naming conventions and policies.

Dr THAKSAPON THAMARANGSI (adviser to Dr Suwit Wibulpolprasert, Thailand) applauded the efforts of the Expert Group in framing the procedures and guidelines for INN. Given the benefits of the system to the health profession, he welcomed any way of speeding up or revising the process. Action must be taken to ensure that INN were used extensively among professionals and understood by the public. Accordingly, INN should be simplified and made more attractive than the trade name; their use should be actively promoted; and Member States should be supported in their efforts to popularize INN through legislation and social measures. He approved the revised procedure.

Dr LEPAKHIN (Assistant Director-General) stressed the importance of having the same names for the same products worldwide to prevent errors and confusion and save lives. The guidelines were intended to make the process more efficient and speed up the procedure and he thanked all those countries that had helped in their preparation and expressed support for INN. Responding to the suggestions made by the member for Thailand, he affirmed that WHO would do its best to make names attractive. There was a need to enhance knowledge of INN in the medical profession and the Secretariat looked forward to collaborating with Member States on that matter.

The CHAIRMAN said that he took it that the Board wished to adopt the revised Procedure for the selection of recommended International Nonproprietary Names for pharmaceutical substances contained in Annex 1 of document EB115/11 and proposed a resolution to that effect, which read as follows:

> The Executive Board,
> Having considered the report on the International Nonproprietary Names,
>
> ADOPTS the revised Procedure for the selection of recommended International Nonproprietary Names for pharmaceutical substances.

The resolution was adopted.[1]

The CHAIRMAN said that he also took it that the Board wished to note the revised General principles for guidance in devising International Nonproprietary Names for pharmaceutical substances, set out in Annex 2 of document EB115/11, together with the report on the feasibility studies contained in the document.

It was so agreed.

- **Dependence-producing psychoactive substances: supplementary guidelines**
  (Document EB115/12)

Ms HALTON (Australia) said that one of her Government's key priorities and areas of spending over the past eight years had been prevention of the use of illicit drugs and the provision of effective treatment for users. In that context, Australia thanked the Secretariat for preparing the supplementary guidelines in consultation with other United Nations bodies; it appreciated that they had been developed in an effort to provide technical clarification of the existing Guidelines but was concerned that they might have the unintended effect of restricting access to important drugs used to treat drug addiction.

The existing Guidelines had served expert committees well for many decades; however, the supplementary guidelines might result in policy changes, the effect of which was unclear, rather than

[1] Resolution EB115.R4.

the intended technical clarification. Her country therefore preferred that the existing Guidelines should remain unchanged.

Professor KARAULOV (adviser to Mr Skotnikov, Russian Federation) recalled earlier attempts to resolve the long-standing problem of lack of regulation. The issue had been debated by the Board at its 105th session in January 2000.[1] The current draft supplementary guidelines were a further step in the process of producing a single, unified convention covering the content of three relevant United Nations Conventions. Paragraph 5, providing for changes to the existing status of substances subject to control, was unacceptable, because that function, according to the Single Convention on Narcotic Drugs, 1961, lay within the competence of the International Narcotics Control Board and not WHO. If that paragraph were deleted, he could accept the remaining text.

Dr STEIGER (United States of America) endorsed the view of the member for Australia that it was not at present necessary to supplement the existing Guidelines.

Mrs GILDERS (alternate to Mr Shugart, Canada) said that, although the supplementary guidelines addressed concerns about the different classification of drugs in the 1961 and 1971 Conventions, she supported the Australian proposal to maintain the existing Guidelines.

Mr KHAN (Pakistan) agreed that it was imperative to maintain the existing system.

Professor DAB (France) said that the illicit use of psychoactive substances was a matter of serious concern for France, which was also concerned that sick people worldwide should receive proper treatment for pain. The fact that the several existing conventions were not perfectly aligned made the Secretariat's task difficult. It might be better to consolidate the conventions, because the proposal before the Board might pose more problems than it solved. For example, the words "unduly" and "legitimate medical and scientific purposes", in paragraph 5 of the proposal, were obviously open to a variety of interpretations. He therefore shared the view of previous speakers that the existing Guidelines should be maintained.

Dr QI Qingdong (alternate to Dr Yin Li, China) said that the supplementary guidelines, which dovetailed with the international conventions in force, met a need and the Secretariat should therefore continue consultations with Member States in order to reach a consensus on them. The 1961 and 1971 Conventions differed on the classification of some of the substances they regulated. Cannabis, for example, was not regulated by the 1961 Convention, yet tetrahydrocannabinol was regulated in the 1971 Convention; he would welcome clarification of such apparent differences.

Dr THAKSAPON THAMARANGSI (adviser to Dr Suwit Wibulpolprasert, Thailand) said that current Thai legislation was in line with all three United Nations Conventions and the guidelines proposed in 2004. Although Thailand had no quarrel with the supplementary guidelines, it agreed that some further clarification was necessary.

Dr AGARWAL (India)[1] fully supported the supplementary guidelines on dependence-producing psychoactive substances. There was a need to develop adequate training programmes and modules for primary care workers and a comprehensive education programme in that regard. India's national drug de-addiction programme and its national programme on substance abuse addressed the issues of treatment, detoxification and rehabilitation.

[1] See document EB105/2000/REC/1, Decision EB105(3) and Annex 9.

Professor GHODSE (International Narcotics Control Board), speaking at the invitation of the CHAIRMAN, said that after the tsunami in December 2004, the Control Board, in line with its mandate and in order to prevent shortages of medical supplies, would grant requests for additional supplies of essential narcotic drugs and psychotropic substances expeditiously. It had transmitted to all the countries affected by the disaster the Model Guidelines for the International Provision of Controlled Medicines for Emergency Medical Care developed jointly with WHO several years previously; some governments were already making use of them.

The insufficient availability of opioid analgesics for the treatment of pain in developing countries remained a matter of great concern to the Control Board. Although global consumption of morphine had increased significantly between 1984 and 2003, the availability of opioids globally was still characterized by a marked imbalance: developing countries accounted for about 80% of the world's population, but for only about 5% of global consumption of morphine. In addition, some regions of the world did not receive an adequate supply of essential anxiolytics and other psychotropic agents through regular distribution channels. He called on governments to ensure a sufficient supply of those substances for medical purposes through adequately controlled distribution channels. In order to address the problem, in 2004 WHO and the Control Board had started to formulate a global strategy against pain which aimed to help developing countries to build capacity in and raise awareness of the use of opioids in pain treatment.

It was essential that any process to review the supplementary guidelines on dependence-producing psychoactive substances should not conflict with the United Nations Conventions, nor trespass on the responsibility of other United Nations bodies. The original supplementary guidelines were fully in line with the Conventions and respected the mandates of WHO, the Commission on Narcotic Drugs and the Control Board. He therefore asked the Executive Board either to approve the original supplementary guidelines prepared by the WHO working group in cooperation with the United Nations Office on Drugs and Crime and the Control Board, or else to delete paragraph 5 of the revised version, which was not in line with the United Nations Conventions. There would be no objection, however, if the Executive Board decided to maintain the status quo.

Dr LEPAKHIN (Assistant Director-General) recalled that the supplementary guidelines had been prepared for the purposes of greater clarity. Some countries were concerned that technical clarification could unintentionally undermine the existing Guidelines. Others thought that work should continue in order to improve the supplementary guidelines. The situation was paradoxical in that work on the supplementary guidelines had started at the request of the WHO Expert Committee on Drug Dependence, which had asked for specific guidance on the choice between the three United Nations Conventions. While WHO and the Expert Committee could no doubt manage without the supplementary guidelines, they would be left in a difficult position, as the need for clarification remained. It would therefore be worthwhile to continue working on the matter with a view to providing the Expert Committee with the guidance it had requested.

The CHAIRMAN, noting that most speakers had preferred to maintain the status quo, suggested that the Board should agree to maintain the revised Guidelines for the WHO review of dependence-producing psychoactive substances for international control approved by the Executive Board in decision EB105(3), and to ask the Secretariat and the Expert Committee on Drug Dependence to continue their work on the issue.

It was so agreed.

Global smallpox vaccine reserve: Item 4.8 of the Agenda (Document EB115/36)

Professor FURGAL (adviser to Mr Skotnikov, Russian Federation) supported the proposal to establish a reserve. The concern at the gravity of the current situation was entirely justified: nobody under the age of 25 years was protected from a natural outbreak or terrorist release of smallpox.

Moreover, the smallpox vaccine formerly in widespread use was no longer appropriate for mass immunization because of the potential for complications in immunocompromised people, including those infected with HIV. WHO had therefore taken the only appropriate decision, namely, to set up a two-component strategic stock of smallpox vaccine supplies. The reserve would provide a total of 205 million doses, a figure established on the basis of epidemiological studies. It would be necessary to develop, as soon as possible, clear legal, procedural, technological, financial and organizational mechanisms for the two components. Vaccine quality should be high, and delivery to countries with divergent legislation for registration and use should be regulated. The experience gained in the centralization of clinical trials and evaluation of the quality and efficacy of antiretroviral agents for prequalification should ensure that the reserves of smallpox vaccines were of standard quality. The establishment of a reserve should in no way preclude research into a new generation of safer and more effective smallpox vaccines.

Professor DAB (France) endorsed the comments made by the previous speaker. The world was fortunate to have an effective instrument for dealing with the continuing threat of smallpox. The establishment of a global reserve was therefore a logical step in enhancing the capacity for international response, given that most countries were unable to build and maintain a national stock of high-quality vaccines. As in many other areas, any prevention strategy that focused on a single country was likely to fail. France therefore supported the proposal to establish a global reserve, with WHO playing a leadership role. On the occasion of the fifth meeting of the Global Health Security Initiative (Paris, 10 December 2004), his country's Minister of Health had announced that France would make available to WHO five million doses of smallpox vaccine out of the national strategic reserve but the vaccine would be stored and maintained on French territory. The quality of the vaccines would be monitored regularly and only vaccines found to be of high quality would be provided in the case of an emergency. France would continue to support WHO's efforts in the area.

Dr QI Qingdong (alternate to Dr Yin Li, China) endorsed the proposal in principle. All possible measures should be taken to prevent accidental release of smallpox virus from laboratories holding stocks. WHO should develop rules and regulations to govern the maintenance of virus stocks, exercise stringent management of vaccine stocks, and establish sound supervision and surveillance mechanisms to deal with any possible spread of smallpox in the case of an outbreak. The status of laboratory administration should be reported to the Board and the Health Assembly on a regular basis. WHO should also arrange a meeting of experts to consider standards and protocols for smallpox vaccine manufacture, and formulate and disseminate appropriate regulations. Member States should be kept informed in a timely manner of progress in the establishment of a global reserve. Some countries had already started developing strategic national reserves.

Dr STEIGER (United States of America) commended the progress made on the proposal to establish a global reserve, and endorsed the operational framework set out in the report. The United States had joined other countries at the Paris meeting of the Global Health Security Initiative in making a contribution to the reserve, with a pledge of 20 million doses from the national stockpile. As in the case of France, the vaccine would be maintained in the United States under national quality-control procedures until required for use. While procedures and protocols had been established for maintaining a small reserve at WHO and for accepting donations from Member States, there were still no clear plans or protocols for action in the event of an unintentional or intentional release of smallpox virus that would require distribution of vaccine. In that context he drew attention to a recent high-level international exercise held in Washington, which had posited a multinational release of smallpox virus. It had quickly become apparent that most countries had no capacity for producing smallpox vaccine, that there was none available for purchase and that there was no mechanism for sharing vaccines with others in an emergency. There was also no agreement on whether vaccines could be diluted to extend coverage. Clearly there was still work to be done to ensure that the world was ready to respond to a smallpox emergency.

Mrs GILDERS (alternate to Mr Shugart, Canada) commented that the WHO operational framework addressed preparedness for the response to a smallpox outbreak but, as the previous speaker had indicated, there were still some matters outstanding. Moreover, the report did not reflect the full scope of the discussions during the recent meeting of the WHO Ad Hoc Committee on Orthopoxvirus Infections or its recommendations. Quality control of vaccines held in the reserve and preparedness plans for their distribution when needed were important components of the initiative. Canada had donated funds to WHO for the establishment of the vaccine reserve and supported the establishment of a strategic group dealing exclusively with smallpox within the Global Outbreak Alert and Response Network and the continuing development of the operational framework and emergency plan. Canada served as the secretariat for the Global Health Security Initiative, and was consulting with the Secretariat on the possibility of arranging a briefing on the Initiative's activities.

Mr DE CASTRO SALDANHA (alternate to Dr Buss, Brazil) supported the establishment of a smallpox vaccine reserve. Brazil expected to complete the establishment of a minimum national stock of 183 000 doses of smallpox vaccine, the level considered necessary to contain a national smallpox outbreak, during 2005. In line with the recommendation set out in paragraph 9 of the report, and thanks to the donation of viral strains by the National Institutes of Health in the United States of America, Brazil was in a position to start producing smallpox vaccine quickly if necessary. International support to finance local manufacture would be needed, however.

Dr PREECHA PREMPREE (adviser to Dr Suwit Wibulpolprasert, Thailand) supported all efforts to ensure prompt control measures to minimize the health impact of any smallpox outbreak. He supported the establishment of the vaccine reserve but requested WHO to undertake research to determine a realistic estimate of potential vaccine demand, since the figure of 200 million doses mentioned in paragraph 1 of the report was based on 1979 population figures.

Dr TANGI (Tonga) thanked the Secretariat and the developed countries for their work, which would benefit small countries such as his own. He requested clarification of the scope of the term "bioterrorism" as used in the report, and expressed the hope that existing stocks of the smallpox virus were held in extremely secure laboratories.

Mr KHAN (Pakistan) remarked that it would be important to establish global smallpox vaccine reserves on several continents in order to ensure timely distribution of vaccines to any part of the world in the event of an emergency. Pakistan was collaborating with the National Institutes of Health in the United States of America and, together with India and other countries around the world, such as Brazil, had the capacity to participate in the initiative. Bioterrorism should not be accorded undue prominence because it was not the only possible cause of a smallpox outbreak: a natural disaster might also trigger an emergency.

Dr OÑORBE DE TORRE (alternate to Dr Lamata Cotanda, Spain) supported the establishment of the reserve. WHO should be in a position to control smallpox vaccine manufacture and storage. He therefore supported decisive action to investigate and coordinate control of existing stocks, thereby avoiding an uncoordinated rush by countries to augment strategic national reserves. The approach should be the same for all global public health threats, regardless of the cause, whether unintentional, as in the case of avian influenza, or intentional, as in the case of terrorism.

Dr AGARWAL (India)[1] supported the establishment of a global reserve of smallpox vaccine together with the necessary supplies of diluent for vaccine reconstitution and bifurcated needles for vaccination. Procedures for maintaining the reserve must be transparent. India had the capacity to

[1] Participating by virtue of Rule 3 of the Rules of Procedure of the Executive Board.

manufacture smallpox vaccine but would require supplies of appropriate seed strains and the transfer of the advanced technology required to prepare safe and potent vaccines. Those needs should be given further consideration.

Dr ASAMOA-BAAH (Assistant Director-General) thanked the Board for accepting the proposal for an expanded global smallpox vaccine reserve. He paid tribute to all who had encouraged the endeavour and made generous pledges in its support. The work to establish a vaccine reserve was only beginning, but it was necessary to prepare for the kinds of eventualities mentioned by the members for China, Pakistan and Tonga. He had also taken note of the observation that the vaccines at present available were not ideal, and that the ongoing work to establish the reserve should not be allowed to derail efforts to develop newer and safer vaccines. As stated, those efforts should be subject to the best international scrutiny, and vaccines donated to the reserve should be of the highest quality. He noted that some countries, specifically Brazil and India, were capable of producing vaccines if international funds were made available for the purpose. He looked forward to working with Member States on developing the vaccine reserve. The aim was not merely to possess the vaccine, but to ensure that all Member States were prepared in the event of a smallpox outbreak.

The DIRECTOR-GENERAL observed that in addition to the two known stocks of smallpox virus, in the Russian Federation and the United States of America, there might be other unknown stocks elsewhere, which in itself was a problem. Moreover, it was possible that the virus was being kept in some form as a weapon. Vaccine production had stopped when smallpox was eradicated in 1979-1980, with the result that people were no longer protected against a highly virulent and sometimes lethal virus. It should also be borne in mind that the seed virus from which the vaccine was made was a different strain from the smallpox virus itself. Finally, members should be aware that a second edition had been published of WHO's manual on public health response to biological and chemical weapons.[1]

The CHAIRMAN invited the Board to note with appreciation the report and the progress made in establishing a global smallpox vaccine reserve, and to request that the work be continued.

It was so agreed.

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

The CHAIRMAN, introducing the item, explained that the topic had been placed on the agenda at the request of a Member State, following the discussion held at the 114th session of the Board.[2]

Mr DE CASTRO SALDANHA (alternate to Dr Buss, Brazil), referring to the flexibilities allowed in respect of intellectual property rights by the Doha Declaration on the TRIPS Agreement and Public Health, said that the Doha Declaration must be implemented by developing countries in such a way as to ensure the effective participation of local producers of generic drugs. He had several recommendations for WHO in that respect.

In helping Member States to make the best use of those flexibilities and the WTO General Council's Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration, WHO should allow at least 10 years for local producers of generic drugs to adjust to the technical demands of producing antiretroviral agents.

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[1] *Public health response to biological and chemical weapons: WHO guidance*, 2nd edn. Geneva, World Health Organization, 2004.

[2] See document EB114/2004/REC/1, p. 83.

The labelling and packaging requirements in the Doha Declaration must be translated into suggested specifications, to be adapted to the technical conditions in which local producers of generic drugs operated, while conforming to health standards laid down by WHO. That would keep the production of patented drugs economically viable should compulsory licensing, as permitted by the Declaration, be introduced.

When legal instruments were devised to incorporate the flexibilities allowed by the Doha Declaration into the legal systems of developing countries, some thought should be given to establishing machinery for government procurement that would facilitate the definition of local producers of generic drugs.

In its efforts to improve the quality of locally produced generic drugs, WHO should consider preparing legal regulations and standards for sound manufacturing practices, and for stability and bioequivalence in the prequalification of generic drugs. The regulations and standards could then be adopted by a technical committee of representatives of WHO and local regulatory agencies, which would also devise technical solutions to ensure the quality of locally produced antiretroviral agents. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should include prequalification inspection not only of raw-material producers but also of intermediaries, so as to guarantee quality in all phases of the production of antiretroviral agents.

Dr GAKURUH (Kenya), speaking on behalf of the African group, said that the members of that group were encouraged by the emphasis the report placed on technical cooperation in the two key areas of implementation of the TRIPS agreement and promoting the quality, safety and efficacy of medicines.

She urged WHO to continue supporting action by Member States to implement the Doha Declaration and the WTO General Council's Decision on the implementation of paragraph 6 of the Declaration in such a way as to encourage efforts to make medicines affordable. Effective use of the flexibilities available under the TRIPS agreement required an integrated and coordinated approach by the agencies responsible for public health, trade and patents. She noted the efforts by WHO, in its technical cooperation and country support work, to promote a multi-agency approach. Its work in those areas had helped to incorporate public health objectives into the implementation of the TRIPS agreement, and should continue to be a priority. The cheaper the medicines, the more patients could be treated and the more sustainable the treatment would be. A key factor in bringing down the prices of antiretroviral agents was effective procurement strategies, which included overcoming patent barriers when necessary, and encouraging competition in generic drugs. Since that would require accurate and up-to-date information on the prices, quality and patent status of the medicines, she urged WHO to increase its efforts in that regard.

The African group noted the listing of the use made by Member States of the TRIPS flexibilities. In many cases, they had been used to promote the manufacture of fixed-dose combinations of antiretroviral therapy. The use of such combinations was in line with WHO's recommended treatment guidelines, but because of patent barriers the recommended first-line fixed-dose combinations were available only from generic manufacturers. WHO should continue to support the use of such combinations. In African countries, it was crucial to make compliance with treatment as easy as possible. Taking fewer pills each day helped, tending to improve clinical results and reduce the risk of drug resistance. Fixed-dose combinations were also relatively easy to procure and to store.

In improving the quality, safety and efficacy of medicines, building and strengthening capacity for national drug regulation were crucial. The group therefore requested continuance of technical assistance and capacity-building for drug regulatory authorities. The WHO Prequalification Project, originally intended as a service for United Nations procurement agencies, had proved a useful tool for developing countries, giving them a choice of quality medicines assessed against standards agreed by the world's leading regulatory agencies. It had also helped such countries to secure access to affordable medicines, especially antiretroviral agents. However, in view of the continuing HIV/AIDS crisis, the Prequalification Project needed further strengthening, in accordance with resolution WHA57.14. It should remain a permanent feature of WHO's work.

Finally, noting the formation of a new Department of Technical Cooperation for Essential Drugs and Traditional Medicine, she urged the Director-General to ensure that adequate resources were allocated to its work.

Dr ANTEZANA ARANÍBAR (Bolivia) noted that the report took into account the concerns and frustrations experienced by the developing countries with respect to production of antiretroviral agents. The assistance given by WHO, the Regional Office for the Americas and PAHO in the negotiations carried out by the Andean Group on the purchase of antiretroviral agents had contributed to the satisfactory results.

The HIV/AIDS pandemic most severely affected countries with the scarcest financial, human and technological resources. That presented a challenge to international solidarity, which was the very essence of an organization like WHO. The Latin American countries had so far received good assistance, for which thanks were due. Treatment for people living with HIV/AIDS was provided by the State in Latin America: in other words, it was free of charge. States were taking on an increasing number of commitments and in many instances would be unable to cope without the negotiations to reduce the price of antiretroviral therapy and without the assistance of other countries. He thanked Brazil in that respect for giving his country cheaper access to such medicines.

The discussion was not about intellectual property rights alone but about access to medicines that were a matter of life or death. It was not about who could pay and who could not, but rather about who would and who would not live. Amid all the talk about negotiations, one might ask whether health was negotiable, or whether the heart of the matter was solidarity with HIV-infected people and finding a way to help them. If the solution lay in parallel imports, local production or compulsory licensing, that would be all to the good. The point was to provide medicines that worked, to give infected people the necessary therapy and to establish a mechanism within WHO to facilitate access to the drugs they needed.

He asked for confirmation that the Secretariat would pursue further negotiations to establish such a mechanism.

Dr CAMPBELL FORRESTER (alternate to Mr Junor, Jamaica), speaking on behalf of the Caribbean countries, said that building local manufacturing capacity, particularly for antiretroviral agents, was beyond their reach since the requisite investment capital, technology, raw materials, research and development capacity were as yet unavailable. What was therefore needed was access to high-quality, affordable drugs from elsewhere.

A few countries in the Caribbean and Latin America had taken initiatives that might result in cheaper and sustainable access to medicines, and those initiatives were being followed with interest. The implications of the imminent opening of the CARICOM Single Market and Economy and the Free Trade Area of the Americas would have to be analysed; bilateral agreements would need to be reviewed and mechanisms set up to facilitate the flow of benefits between countries within the same economic space. WHO, through the Regional Office for the Americas, should provide guidance in that respect.

Jamaica had gained access to funding for the provision of antiretroviral agents through the Global Fund to Fight AIDS, Tuberculosis and Malaria, World Bank and other sources and was duly grateful, but it was concerned about sustainability and the lack of human resources and adequate infrastructure. Donor funds came with restrictions that did not cover some aspects of the process that needed to be made operational. That problem should be addressed through WHO.

Dr QI Qingdong (alternate to Dr Yin Li, China) said that control measures and generic medicine production by developing countries could guarantee patients access to high-quality antiretroviral agents, thereby facilitating the prevention and control of HIV/AIDS. China was participating in the "3 by 5" initiative and had been able to produce five medicines that did not involve intellectual property rights; and through international cooperation projects it had been able to supply medicines to children.

China supported research and development of new antiretroviral agents and was working hard to provide medicines free of charge for poor rural dwellers, with the ultimate goal of drug provision free of charge to all patients needing treatment. Training for health professionals had been conducted and equipment purchased to make it easier to identify patients in need of treatment.

Statistics showed that more than 20% of patients who had received first-generation antiretroviral medication had had to stop treatment because of strong side effects. WHO should work harder on that problem and on helping developing countries to resolve the issue of patents in promoting the use of new antiretroviral medicines.

Dr HUERTA MONTALVO (Ecuador) said that a common theme running through the discussion on technical and health matters was therapeutic safety and how to achieve it. Access to high-quality medicines was central to the progressive realization of the highest attainable standard of health. The fact that one of the greatest threats to health was HIV/AIDS explained the continuing effort to elaborate relevant standards and to provide technical support to national pharmaceutical regulatory bodies. The Prequalification Project and activities to promote the quality of active pharmaceutical ingredients and finished-dosage-form antiretroviral agents represented a step forward.

Together with the provision of medicines, another means of fighting HIV/AIDS was condom use. It was therefore encouraging to see the recent report in the Spanish newspaper *El País* that the Roman Catholic Church had condoned the use of condoms to prevent transmission of HIV. Why had the Church, which had long resisted such use and even called it sinful, changed its mind? Because it had seen that there was no alternative. That was an important sign of the times.

Ms VALDEZ (alternate to Dr Steiger, United States of America) said that the report appeared to criticize aspects of the health solution represented by the decision adopted on 30 August 2003 by the General Council of WTO. That solution was designed to meet the objectives noted in the report, namely, to provide a simple and speedy legal procedure and a wide choice of quality generic medicines. It was not a complex solution, and she objected to the reports so describing it. In fact, most of the procedural steps required were not only straightforward but essential to ensuring that medicines were not diverted from their intended markets. Nothing in the solution detracted from the economic incentive for generic manufacturers to produce drugs under compulsory licences, as shown by the fact that royalty payments were tied to the economic value in the importing market rather than the market where the drugs were produced. The implication that the solution somehow substantially reduced the economic incentives to produce generic drugs was incorrect. Its purpose was fundamentally humanitarian, not commercial, as the Chairman's statement accompanying the 2003 decision had made clear.

The report also took issue with aspects of bilateral and regional trade agreements. It mischaracterized the language adopted by the Fifty-seventh World Health Assembly as expressing the concerns of Member States over specific provisions. In fact, Member States had agreed to encourage bilateral trade agreements to take into account the flexibilities of the TRIPS agreement and the Doha Declaration.

Her country supported the Secretariat's activities that promoted local production of high-quality medicines. That was a good use of scarce resources and more appropriate than an advocacy role with WTO in implementing the TRIPS agreement. The United States also appreciated the efforts to make the prequalification process more transparent: the disclaimer at the end of each prequalification listing, for example, was helpful to manufacturers and governments. Her country's Food and Drug Administration was working with the research-based and generic pharmaceutical industries, regulatory authorities in countries badly affected by HIV/AIDS and the international community to make a reality of safe and effective fixed-dose combination antiretroviral therapy of high quality and at low cost. Her country looked forward to working more closely with WHO in sharing practices and results for the best possible quality assurance of antiretroviral agents.

Mrs LE THI THU HA (Viet Nam) said that increasing access to life-saving treatment was the single most pressing challenge in the fight against HIV/AIDS, particularly in developing countries with limited resources. According to a recent estimate in Viet Nam, 15% of the 215 000 people living with HIV/AIDS were believed to be in need of antiretroviral therapy. The cost of antiretroviral medicines purchased by the Government and imported from international pharmaceutical companies approached US$ 5000 per person per year. Under its new national HIV/AIDS strategy, her Government aimed to provide antiretroviral medicines to 70% of people living with HIV/AIDS. To reach that target, however, it would have to reduce the price of antiretroviral therapy and make it easily and cheaply available to those in need. The Global Fund to Fight AIDS, Tuberculosis and Malaria had approved a US$ 12 million project to strengthen care and treatment in the 20 most affected provinces of the country, under which antiretroviral medicines would be provided to 2000-3000 people in need over the coming two years. The Minister of Health had requested WHO to procure the drugs some months before. On account of the declassification of some of the prequalified antiretroviral agents from WHO's list, both generic and branded products were in short supply and WHO had so far been unable to procure antiretroviral medicines.

Viet Nam welcomed the Secretariat's recent activities to promote local production with assured quality and to support Member States in making optimal use of the flexibilities allowed by the TRIPS agreement. The Government had received support from WHO and the Ford Foundation to review the legal and trade issues surrounding the provision of affordable antiretroviral medicines in Viet Nam. The report on that review had provided considerable insight into the question of patents on antiretroviral agents and had concluded that changes in Vietnamese patent law and in the interpretation and practice of domestic and international law would make such medicines more accessible and affordable.

Her Government was willing to strengthen its own capacity in antiretroviral production to enable its industry to reach prequalification status – a slow and costly process for small companies. Another issue was access to second-line treatment. International harmonization should be sought to avoid leaving the onus of such problems on individual countries.

While it was uncertain how production of generic antiretroviral agents would be affected by WTO's new rules, it was worrying that efforts to bring antiretroviral treatment to AIDS patients in developing countries might be threatened by the implementation of that new regulation. She therefore supported the statement by the member for Brazil.

Ms CHA-AIM PACHANEE (adviser to Dr Suwit Wibulpolprasert, Thailand) thanked the Secretariat for providing technical assistance to Member States in using the TRIPS flexibilities and improving the quality of locally produced generic medicines, which would give countries access to affordable and high-quality antiretroviral agents and hence attain the "3 by 5" target. Partnership among countries was also necessary for accessibility to antiretroviral medicines, as reflected during the XV International AIDS Conference (Bangkok, 11-16 July 2004) when Brazil, China, Nigeria, the Russian Federation, Thailand and Ukraine had signed a commitment concerning the acquisition of significant technical, scientific and technological experience in the fight against HIV/AIDS.

Thailand appreciated the efforts made by Canada and Norway to amend their national legal framework concerning implementation of compulsory licensing and exporting of drugs to developing countries.

At a time when many countries were negotiating to establish free trade areas, it was important that such negotiations take into account the use of TRIPS flexibilities. Any requests for provision beyond TRIPS, the "TRIPS-plus" provisions, should be considered with great concern and safeguard measures should be established to protect accessibility to essential medicines, including antiretroviral agents. She urged WHO to be active in that respect both nationally and internationally.

Effective access to antiretroviral medicines depended on good health infrastructures and comprehensive training of medical doctors and health personnel. WHO should work closely with all donors to advocate systematic and sustainable development of health-care infrastructures, including human resources for health, in order to support efficient delivery of HIV/AIDS care.

Thailand strongly supported the WHO prequalification scheme. It was regrettable that a significant delay had occurred in implementing it and that the Essential medicines area of work in the Proposed programme budget 2006-2007 did not include the expected results of that scheme. She expressed the hope that the programme budget 2006-2007 would be revised accordingly before the forthcoming Health Assembly. She requested the Director-General and supportive donors to consider the issue seriously and provide strong leadership and budgetary support for the scheme. She also requested that the Secretariat work proactively in providing support to developing countries in improving the production process of generic medicines in order to achieve prompt prequalification.

Dr BRUNET (alternate to Professor Dab, France) said that France strongly supported WHO's activities to promote broad access to high-quality drugs, particularly antiretroviral medicines. The implementation of the TRIPS agreement from 1 January 2005 and the flexibilities it provided for would modify the capacities of the developing countries to produce generic drugs; the flexibilities should offer a solution to the supply of antiretroviral medicines to developing countries. It was, however, still too early to know whether those flexibilities would enable the countries' needs to be met. Success or failure would depend on the mobilization of Member States and the Secretariat in particular to ensure that the resources obtained through the flexibilities could be used to meet local needs.

Data were lacking on the nature, type and origin of antiretroviral agents, and on the volume of medicines used for the treatment of HIV/AIDS in the world. The report said nothing about the quantities and distribution of exports from laboratories for which prequalification had already been given, simply because such data did not exist. In order to assist in the establishment of up-to-date global data in that area, France would provide WHO with support including a financial contribution of €600 000 in the coming financial period. Within the European Union, France also supported alignment of the TRIPS agreement with Articles 95 and 133 of the Treaty on European Union to ensure uniform implementation of the Agreement in all Member States.

Regarding the WHO prequalification programme, the fact that some antiretroviral medicines had been removed from the WHO list after inspections under the WHO programme had shown up difficulties or even fraud by subcontractors conducting bioequivalence studies reflected the efficiency of the programme that France had supported from the start, and which was valid not only for anti-HIV/AIDS medicines but those also for treating malaria and tuberculosis. France had earmarked €1 335 000 for financing that programme.

Too few generic drugs had been prequalified to date, a situation that would tend to push prices up. WHO had a deadline of March 2005 for prequalification of antiretroviral agents in generic form, and particularly in paediatric formulation. It was therefore essential that enough compounds were prequalified. He requested a report on the question indicating the number of prequalified paediatric forms existing at present and the short-term trends. France was ready to support the Secretariat in developing a system of information on antiretroviral supplies clearly indicating what medicines were produced and how many were used and developed.

Mr PALU (alternate to Ms Halton, Australia), commending the valuable work done by WHO, said that Australia supported increasing accessibility to affordable high-quality antiretroviral and other essential medicines. It also supported the right of WTO members to use the full TRIPS flexibilities for the purpose of protecting public health and in particular promoting access to medicines for all. Australia welcomed the WTO General Council's Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health in its entirety, and the strong emphasis in the report on ensuring that the products in question met international standards. It urged the international community to continue to be uncompromising on quality and to resist demands for urgent action that jeopardized the quality of generic antiretroviral medicines. The cost of allowing poor-quality antiretroviral medicines to be produced threatened entire treatment programmes.

The meeting rose at 17:35.