FOURTH MEETING

Friday, 24 May 2013, at 09:35

Chairman: Mrs K. TYSON (United Kingdom of Great Britain and Northern Ireland)

1. SECOND REPORT OF COMMITTEE B (Document A66/68)

Mr HAZIM (Morocco), Rapporteur, read out the draft second report of Committee B.

The report was adopted.[1]

2. HEALTH SYSTEMS: Item 17 of the Agenda (continued)

Universal health coverage: Item 17.3 of the Agenda (Document A66/24) (continued from the third meeting, section 3)

Dr USUBUTUN (Turkey) said that it was only through strong and efficient health systems that the burden of noncommunicable and communicable diseases could be reduced, and that the strongest health systems were those that provided universal health coverage. The two interrelated components of universal health coverage were equitable access to quality health services, ranging from prevention to palliative care; and general health insurance covering basic care, or direct public finance providing for free health service delivery. Supplementary health services should also be affordable and accessible.

Under its health transformation programme, Turkey had made remarkable progress since 2003 on various aspects of universal health coverage, with healthcare coverage reaching 98% of the population by 2011. Political commitment had been a key factor in the success of the programme, which showed that major improvements in health system performance could be achieved in a relatively short period of time under the right conditions. The lessons that could be drawn from Turkey's experience included: the need for careful sequencing of sound technical reforms to achieve quick and visible results, and thereby ensure continued political support; the importance of setting up a dedicated team; the building of communication channels at all levels; the management of resistance through evidence-based data; and the development of appropriate incentives for those involved in the reform. A global commitment to universal health coverage would help countries to stay on track to achieve the goal of health for all.

Ms TINOCO (Costa Rica) said that her country had been implementing legislation on universal health coverage for 35 years, and had achieved 92% coverage. In that connection, it was desirable to pay particular attention to indigenous and migrant populations and those living below the poverty line to develop social programmes in conjunction with health programmes, and to establish a single national database. It was also important to guarantee universal health coverage by means of intersectoral policies and to integrate national health policy into national development plans.

[1] See page 311.

Dr CHEN (Chinese Taipei), noting that universal health coverage had become a powerful and unifying focus of the current Health Assembly, said that Chinese Taipei had been implementing a universal health insurance programme since 1995, as a demonstration of its commitment to the Alma-Ata principle of health for all. The programme was effective in health promotion, disease eradication and quality assurance and allowed people to choose the physicians and facilities they wished to use. Everyone in Chinese Taipei, including foreigners, was issued with a card that entitled them to comprehensive care in more than 19 000 facilities. Coverage was effective, affordable and sustainable because it was based on a single-payer system. Chinese Taipei would continue to offer training opportunities for Member States that wished to learn from its experience in that area.

Dr LUCHESI (World Vision International), speaking at the invitation of the CHAIRMAN, said that universal health coverage could be a matter of life or death; many could not afford out-of-pocket payments for essential services, and many of those who could pay experienced severe financial hardship as a result. Greater efforts were needed to remove user fees at the point of use as they were one of the biggest barriers to progress in improving access to health care for poor populations, leading to higher rates of infant, child and maternal mortality and morbidity. Removing user fees could also have an immediate effect on the uptake of services, but governments must ensure that official fees were not merely replaced by informal payments. Health funding should come from prepaid and pooled contributions; social health insurance mechanisms performed badly in terms of covering those outside of formal employment, whereas tax-financed mechanisms had been proven to work regardless of a country's level of economic development. Universal health coverage must be defined as equitable access to appropriate, promotive, preventive, curative and rehabilitative health care for all people when they needed it, at an affordable cost. It should explicitly include the social determinants of health, including access to adequate sanitation, water and nutrition. Where necessary, coverage should be phased in, with an initial emphasis on free maternal, newborn and child health interventions, and the empowerment of families and communities to take control of their own health.

Mrs CALDWELL (International Council of Nurses), speaking at the invitation of the CHAIRMAN, said that universal health coverage of good quality required sufficient and motivated health workers of the right mix, located close to the point of delivery. She expressed concern that too much emphasis was being placed on financing and not enough on the critical shortage of health workers. Nurses were the largest group of health professionals, were closest to the population, and were often the only health professionals available to a population. Research had demonstrated that affordable nursing interventions could effectively contribute to the achievement of Millennium Development Goals and reduce the burden of noncommunicable diseases, including mental health disorders. The strengthening of primary health care services would be essential in order to reach the most vulnerable and marginalized members of society; nurses' roles therefore could not be ignored. The Health Assembly had repeatedly recognized that nurses and midwives were essential to the development of good-quality health policy and implementation of effective health interventions. However, the minimal reporting and inactivity of the Global Advisory Group on Nursing and Midwifery appeared to reflect a reduction in WHO's commitment to support the strengthening of nursing and midwifery globally. Universal health coverage could not be achieved without adequate numbers of appropriately trained nurses, and the involvement of nurses in policy-setting was essential. WHO and governments should ensure adequate pre- and post-registration education to invest in implementing evidence-based nursing interventions and to remove the regulatory barriers to the full integration of nurses in primary health care settings.

Ms SPELLER (Medicus Mundi Internationalis – International Organisation for Cooperation in Health Care), speaking at the invitation of the CHAIRMAN, expressed appreciation of WHO's efforts to tackle the problems of health-care impoverishment and financial barriers to health care access, but was uneasy about the use of the term "universal health coverage" rather than "universal health care". The history of global health policy-making had been characterized by poor choices of direction,

including the UNICEF policy of selective primary health care and the World Bank policy of promoting stratified health care, which had led to the vertical fragmentation of health systems. "Universal health coverage" had been adopted as an umbrella term, but was defined differently by a variety of global institutions, many of which were WHO donors. The World Bank, with which WHO collaborated closely on universal health coverage, had for many years promoted an inequitable system that assigned a prominent role to the private sector in health insurance and health-care delivery. The flaws in that model included the fact that stratified health care weakened social solidarity and the willingness of wealthier people to contribute to the cost of health care for all. Moreover, the regulation of costs, quality and over-servicing was much more difficult in the private sector; mixed health-care provision was associated with fragmentation and duplication in service development and delivery; and private-sector providers had a poor record in implementing the principles of primary health care and addressing the social determinants of health. She emphasized the importance of avoiding another false move in the history of global health policy-making.

Mrs BAUMGARTEN (The Save the Children Fund), speaking at the invitation of the CHAIRMAN, noted that innovations in health care achieved little if services were not of sufficiently high quality and the poorest people continued to be denied access. She commended the statement made by the World Bank Group President, Jim Yong Kim, at the fifth plenary meeting of the current Health Assembly,[1] in which he had acknowledged that even tiny out-of-pocket charges could have a detrimental effect on the uptake of health services by poor people, and that the elimination or sharp reduction of point-of-service payments was a common feature of all systems that had successfully achieved universal health coverage. His acknowledgement was significant because some had continued to advise governments erroneously that charging fees at the point of use was a good model that deterred unnecessary service use. Universal health coverage could be made fairer and more effective in reducing mortality and morbidity if governments established systems that legally required all to contribute according to their ability to pay, so that all could receive health care solely on the basis of their health needs. WHO and the World Bank had complementary roles to play in supporting the steps that Member States needed to take. However, universal health coverage was not the sole preserve of multilateral institutions: many governments were responding to public concerns by delivering health care as a right, not a privilege.

Dr WILEY (International Federation of Medical Students' Associations), speaking at the invitation of the CHAIRMAN, noted with satisfaction the gathering momentum of global support for universal health coverage. Although she supported the current emphasis on financial risk protection as a key component of universal health coverage, she urged WHO to ensure that any definition of such coverage included the development of sustainable, equitable and fair health-care systems. Such systems must be dynamic, guarantee access to health care and give impetus to action on the social determinants of health. Universal health coverage must be based on three principles: achieving equity in health, which required a well-trained, equitably distributed health workforce; development of sustainable health systems designed to be adaptable and responsive to current and future challenges such as climate change, population growth, conflicts and emergencies; and attention to the social and health burdens faced by target groups, including minorities and at-risk populations. Universal health coverage and access were the means by which health as a human right and health equity could be realized.

Ms BENNETT (International Alliance of Patients' Organizations), speaking at the invitation of the CHAIRMAN, said that WHO should develop a clearer definition of universal health coverage, one that included patient-centred health care and acknowledged the key principles of respect for the patient, choice and empowerment, patient involvement in health policy, access to safe, good-quality

[1] See document A66/DIV./7.

and appropriate services and treatments, support for patients' needs, and information. She welcomed the inclusion in the global monitoring framework for the prevention and control of noncommunicable diseases of a target of 80% availability of the affordable basic technologies and essential medicines by 2025. The expansion of universal health coverage was an opportunity to build on WHO's progress towards ensuring access to essential medicines in all WHO strategies, including the post-2015 development agenda. Her organization would continue to support WHO and other interested stakeholders in their efforts to expand universal health coverage.

Dr KIENY (Assistant Director-General) thanked delegates and civil society representatives for their contributions to the debate, which had highlighted the need for universal health coverage to include interventions to ensure the attainment of the Millennium Development Goals, and to address the growing burden of noncommunicable diseases. Many speakers had noted that universal health coverage could not be achieved through the health sector alone: the involvement of other sectors and action on the social determinants of health would be critical. It had also been noted that universal health coverage meant more than health financing, and that interventions spanning promotion, prevention, treatment, rehabilitation and palliative care were required. In the area of promotion and prevention, population-focused action would be as important as interventions targeting individuals. Progress towards universal health coverage would require health system strengthening, with a strong emphasis on equity in the provision of quality health services, access to medicines and financial risk protection. Some Member States had requested the Secretariat to scale up its capacity in the area of health technology assessment and hospital management in order to provide them with better support in maintaining expenses within a reasonable range, and many speakers had stressed the importance of quality in medicines and health technology as well as in services, in a continuum across community, primary, secondary and tertiary care. Speakers had recognized the paramount importance of human resources for health, and some had pointed to the need to review existing national legislative and regulatory frameworks in order to promote progress towards universal health coverage and in particular the financing of services. She thanked the Republic of Korea for its offer of financial support and Brazil for its suggestion that the BRICS countries (Brazil, Russian Federation, India, China and South Africa) might identify experts to work with WHO on a monitoring framework for universal health coverage. The Secretariat was committed to continue working on universal health coverage with Member States, civil society and other United Nations agencies. A technical briefing would take place later that day to clarify the framework proposed by WHO for universal health coverage, and to share with delegates preliminary options for monitoring progress towards its achievement. On the basis of inputs from delegates, the Secretariat would continue to work with the World Bank with a view to proposing a more advanced version of the monitoring framework at the September 2013 session of the United Nations General Assembly.

The CHAIRMAN said that the informal drafting group that was considering the draft resolution proposed at the Committee's third meeting had indicated that it needed more time to conclude its work. She therefore took it that the Committee wished to adjourn its discussion of the item.

It was so agreed.

(For continuation of the discussion and approval of the draft resolution, see the summary record of the sixth meeting, section 2.)

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products: Item 17.1 of the Agenda (Document A66/22)

Mr KLEIMAN (Brazil) thanked Dr Orjiako (Nigeria) for his competent work in chairing the first meeting of the Member State mechanism on substandard/spurious/falsely-labelled/falsified/ counterfeit (SSFFC) medical products, and the Government of Argentina for having hosted the

meeting in Buenos Aires in November 2012. Throughout the intense negotiations on the falsification of medicines within WHO's governing bodies, Brazil had emphasized the importance of focusing on a public health perspective, and of excluding intellectual property or criminal considerations. He noted that in Buenos Aires a Steering Committee had been established to guide the mechanism and make it operational. The mechanism should strive to ensure the integrality of the supply chain of medicines and to improve the exchange of information between regulators; the differences that remained between Member States would be mitigated once the mechanism demonstrated its importance for public health. The starting point of the mechanism's work should be the identification of actions and behaviours that should be prevented and controlled, and he noted with satisfaction that Member States had agreed to establish the Open Ended Working Group for that purpose. He invited countries to contribute comments and suggestions in that regard so that the Group could meet no later than July 2013.

The Member State mechanism should operate in a fully transparent manner, from a public health standpoint, in accordance with its terms of reference.[1] He was concerned that other multilateral forums did not abide by those principles and sought to examine the matter from a criminal or enforcement perspective exclusively. The mechanism could usher in a new method of work within WHO in which Member States also had the responsibility of developing technical work. He urged Member States to reach agreement on the chairing of the mechanism so that it could begin its work as quickly as possible; he proposed rotation among the designated Vice-Chairpersons of the Steering Committee as a possible solution, and reiterated his delegation's suggestion that the mechanism should be designated as the "Buenos Aires Mechanism".

Dr ROZITA HALINA TUN HUSSEIN (Malaysia) expressed full support for the initiatives undertaken to achieve the objectives of the Member State mechanism on SSFFC medical products. She suggested that the Steering Committee should be constituted as a formal rather than an informal body so that its efforts could be coordinated more efficiently, and that meetings should be organized at regional level before the Steering Committee met so that suggestions or concerns from within regions could be conveyed to it by the appointed Vice-Chairperson. Malaysia was able to implement most of the actions listed in the workplan; it had an established regulatory framework and a workable medicine policy, and was willing to share its experience with others. She supported the suggestion that expert facilitators and other stakeholders should be invited to participate in the Member State mechanism as appropriate. Like many other countries, Malaysia faced a variety of problems in relation to the Internet marketing of medicinal products; the mechanism should devise a realistic action plan to tackle the matter in a coordinated manner. She supported the idea of obtaining a commitment from Member States' regulatory authorities to be transparent and willing to share vital information on the status of manufacturers and major players in the supply chain that were involved in cross-border movement of products, as that was vital to protect the integrity of global pharmaceutical industries.

Mr AL-SHEHABI (Bahrain) said that efforts relating to countering SSFFC medical products were designed to protect public health and patient safety. The manufacture, distribution and sale of such products were crimes that endangered human life and undermined the credibility of health systems. A comprehensive strategy must therefore be developed to tackle the problem in collaboration with partners at all levels. Emphasis must also be placed on the quality of health workers and on building their capacity to detect and prevent activities relating to SSFFC medical products, which must be reported, in particular in the event of patients failing to respond to treatment or experiencing unexpected side effects. The Secretariat had an important role to play in providing technical support that would enable Member States to identify gaps in their national legislation and to strengthen the capacities of their regulatory authorities. WHO should strengthen the global surveillance system in the interests of information exchange concerning incidents involving SSFFC medical products.

[1] See resolution WHA65.19, Annex.

Ms MWAPE (Zambia), speaking on behalf of the Member States of the African Region, thanked Argentina and the Director-General for having hosted the first meeting of the Member State mechanism. One of the priority objectives for the African Region was to improve sustainable availability of and access to affordable, high-quality, safe and effective essential medical products. SSFFC medical products were a major public health concern, and the globalization of trade meant that no single country was immune to criminal activity involving such products, which was a threat to national and international security. The Member States of her Region therefore reaffirmed their commitment to the Member State mechanism, particularly considering that the largest share of SSFFC medical products was circulating in the Region's markets. She commended the work done so far to make the mechanism operational and develop the draft workplan, and supported the proposals on the mechanism's structure, governance and funding, including the functions of the Steering Committee. It was to be hoped that the question of the chairing of the Committee would be dealt with amicably and expeditiously in order to avoid undue delay. She reaffirmed the Region's support for the African candidacy for that post.

The elimination of SSFFC medical products was a top priority for the African Region, and its Member States would take an active role in the realization of the objectives of the Member State mechanism. The many challenges faced by countries in that regard included weak regulatory and enforcement systems, limited human resources for health, poor infrastructure to support the pharmaceutical supply chain, and inadequate financing for procurement of essential medicines and regulation. In collaboration with WHO, policies were being or had been developed to strengthen health systems including pharmaceutical services and medicines regulation both at national and regional level. However, there was no simple or standard solution to the problem and she therefore urged Member States to maintain their commitment to the Member State mechanism as a means of securing the integrity and security of the pharmaceutical supply chain.

The CHAIRMAN took note of the call for the question of the chairing of the Steering Committee to be resolved amicably and expeditiously.

Dr YUSUF (Nigeria) said that his country had established a plan to implement its revised national drug policies and national pharmaceutical goals. The manufacture of SSFFC medical products was widespread and had escalated to such an extent that effective international coordination and cooperation were needed to make regional and national strategies more effective. Nigeria had revised its anti-counterfeiting legislation to make the supply chain more secure, and as a deterrent to offenders; it had launched a new drug distribution guideline and a national pharmacovigilance policy, and was implementing innovative technologies to detect SSFFC medical products. The use of a message authentication service to determine the quality of medicines in retail outlets had been piloted and introduced. Nigeria had been the first country to deploy a handheld detection device at its borders and in retail outlets to detect SSFFC medical products; that capacity had since been extended to other countries in Africa and beyond. Nigeria was also the first country to have authorized a structured survey to determine the prevalence of SSFFC medical products, which had been conducted by WHO with support from the Department for International Development of the United Kingdom of Great Britain and Northern Ireland.

Given that a concerted international effort was essential, the establishment of the Member State mechanism was timely and appropriate, and he supported the clear recommendations made at the Buenos Aires meeting, including those on the draft workplan, the method of work and funding of the mechanism, and the establishment of the Steering Committee. The latter should be properly established and enabled to function as soon as possible.

Dr JAIN (India) said that India had consistently voiced concern over the use of the term "counterfeit" and had stressed the need for a common understanding of what was meant by SSFFC medical products. India had also objected strongly to any association of WHO with the activities of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Furthermore, India had

participated in all Health Assembly debates on the subject, in both intergovernmental working groups in 2011 and in the new Member State mechanism in 2012. Medicines from India were exported to more than 200 countries, and vaccines to more than 150 countries, and many Indian manufacturing sites were currently approved by the United States Food and Drug Administration and the European Directorate for the Quality of Medicines. India had a robust drug regulation system, and the national regulatory authority of India and its affiliated institutions had been assessed by WHO against international benchmarks and indicators in December 2012, and had been found to be a functional regulatory system.

Noting with satisfaction that the Member State mechanism on SSFFC medical products had made considerable progress during its meeting in Buenos Aires in November 2012, he said that it was important to take forward the mechanism's activities in accordance with the established time frames, including the convening of a meeting of the Open Ended Working Group and the formal establishment of the Steering Committee. That work should be expedited and adequate resources should be harnessed for that purpose. He supported the proposal by the delegate of Brazil that the Steering Committee should have a rotating chairmanship.

Mr ÁLVAREZ LUCAS (Mexico) said that his country was committed to prohibiting any product of dubious quality that might jeopardize the health of its population, and had taken resolute action, pursuant to its support for paragraphs 2 and 6 of the workplan set out in Appendix 2 to the Annex to document A66/22, to identify medicines that might have adverse effects and cause confusion to health professionals. However, Mexico would not be in a position to comply with paragraph 8(b) of the workplan.

Ms SOSIALINE (Indonesia) said that her country fully supported the outcome of the Buenos Aires meeting and had high expectations that the Member State mechanism would lead international cooperation in the prevention and control of SSFFC medical products. Indonesia favoured the convening of a meeting of the Open Ended Working Group to follow up the discussion on the scope and areas of work of the mechanism on the basis of the proposals adopted at the Buenos Aires meeting. However, the question of the chairing of the Steering Committee should be resolved as quickly as possible to avoid further delay. She urged WHO to give priority to finding solutions for countering SSFFC medical products.

Ms BENNETT (Australia) said that SSFFC medical products were a serious public health and safety concern, and her country greatly appreciated the work of WHO in that area. Having participated in the first meeting of the Member State mechanism, Australia urged Member States to work in a spirit of cooperation to resolve outstanding issues, including the chairing of the Steering Committee, as quickly as possible so that the workplan could be finalized. Her delegation noted with interest and would give consideration to the name change for the mechanism proposed by the delegate of Brazil.

Mr RUSH (United Kingdom of Great Britain and Northern Ireland), speaking on behalf of the Member States of the European Region, regretted the slow pace of progress in the work of the Member State mechanism, which was reflected in the failure to reach agreement on various matters, including the finalization of the workplan and the appointment of a chairperson for the Steering Committee. Those developments had a negative impact on WHO's credibility as a serious protagonist in activities to counter SSFFC medical products. It was to be hoped that those early difficulties could be overcome swiftly and that the first meeting of the Open Ended Working Group would be convened in the near future, ideally in conjunction with the next meeting of the Steering Committee. In that context, he appealed to all Member States to send the appropriate technical experts to the Working Group, from which a positive outcome was to be expected within the time frame of two to six months, as initially envisaged. The Member States of the Region would continue to engage constructively in the proposed activities.

Speaking as the delegate of the United Kingdom of Great Britain and Northern Ireland, he added that the international alert issued by WHO the previous month with regard to the widespread distribution of falsified antimalarial drugs in western and central Africa served as a reminder of the need to make urgent progress in the area of SSFFC medical products.

Ms PATCHAREEWAN PHUNGNIL (Thailand) said that SSFFC medical products had a hugely negative impact on public health as they were a potential cause of treatment failure or even death, and contributed to increased drug resistance. Action to combat such products must focus on improved access to efficacious and high-quality medical products, and SSFFC medical products must be clearly defined so as to leave no room for confusion in relation to questions of intellectual property and trade. Interpretation of the definition must not threaten legitimate and good-quality generic medicines. Success in eliminating SSFFC medical products at the national, regional and global levels would depend on effective collaboration based on trust, and stakeholders must be free from conflict of interest. The increase in Internet sales and false claims relating to medical products in electronic media stimulated the entry of SSFFC medical products into the supply chain. Strong regulatory capacity and effective enforcement by national regulatory authorities were therefore essential. Furthermore, strengthening the existing SSFFC rapid alert system at all levels was an important instrument for consumer protection. Comprehensive action plans should be developed under the Member State mechanism, together with indicators to monitor and assess their implementation. Scheduled activities should be carried out in a timely manner. Following a technical consultation, a formal meeting of the Steering Committee should be held under the chairmanship of a person agreed on by all Member States. The Committee could then submit suggestions on the elements of the workplan to the Member State mechanism, for consideration at the latter's second meeting in November 2013. Members of the Steering Committee must be properly qualified, and the process of appointment should ensure transparency and freedom from conflicts of interest.

Mr JONES (Canada), noting that the Member State mechanism, at its first meeting, had displayed a strong commitment to combating the public health impacts of SSFFC medical products, urged the mechanism to focus on ensuring that Member States' collective efforts yielded tangible benefits in the prevention and control of such products. He supported the proposal of a rotating chairmanship in order to sustain momentum, and emphasized the importance of reaching agreement on the appointment as quickly as possible. He welcomed the proposal to convene an informal meeting of interested Member States following the adjournment of the first meeting of the Open Ended Working Group to consider the actions, activities and behaviours that resulted in SSFFC medical products and contribute to the development of a detailed workplan.

Mr ALEMNEH (Ethiopia) stressed the need for low-income countries to have access to technology for the rapid detection of SSFFC medical products. It was also important to use existing regional frameworks to combat the problem of SSFFC medical products.

Dr AL KALBANI (Oman) endorsed the functions of the Steering Committee of the Member State mechanism, as detailed in Appendix 1 to the Annex to the Secretariat's report (document A66/22), and the elements of the workplan set out in Appendix 2. Oman had taken positive steps to develop monitoring and enforcement guidelines in relation to the unethical promotion of medicines, as referred to in paragraph 6(f) of the workplan, and to adopt legislation aimed at limiting SSFFC medical products. More work was needed, however, to build the capacities of regulatory authorities and quality-control laboratories at the national and regional levels. Member States should pool their experience in those matters.

Mr SILLO (United Republic of Tanzania) commended the work done so far, but expressed concern that failure to decide the chairmanship of the Steering Committee had delayed the first steps

towards implementation of the workplan on SSFFC medical products that had been drafted in Buenos Aires. The matter should be resolved as soon as possible.

The system recently designed by WHO to report, record and analyse incidents concerning SSFFC medical products more accurately through the submission of rapid alerts by the national medicines regulatory authorities enabled countries to obtain a clearer and validated picture of what was taking place at country, regional and global level. The United Republic of Tanzania planned to host a regional training programme on the new system for national regulatory experts from eastern and southern African countries during the second half of 2013. The programme should assist African regulators in identifying products, trends and vulnerabilities, thereby facilitating deployment of resources, development of strategies and vigilance to combat SSFFC medical products. He reaffirmed his country's commitment to combating SSFFC medical products.

Dr VALDEZ (Philippines) said that the Philippines was a pilot country for the SSFFC medical product reporting project and was cooperating actively with WHO in that initiative. The Philippines hoped to provide recommendations with respect to paragraphs 6(f) and (g) of the workplan, on strengthening national and regional capacities in order to ensure the integrity of the supply chain. Adoption of a monitoring and enforcement system in respect of the unethical promotion of medicines and the disclosure of quality, safety and efficacy data for medical products would improve and further strengthen the identification and reporting of SSFFC medical products. In low- and middle-income countries, the need to strengthen access to good-quality, safe, efficacious and affordable medical products could be met by the use of generic medicines no longer covered by patents. However, generic medicines were also at risk from counterfeiting activities and would also require monitoring. She recommended that paragraph 8 of the workplan should be retained.

Mr WANG Zhexiong (China) said that SSFFC medical products were of international concern and China would therefore participate actively in the Member State mechanism, which should operate in accordance with WHO principles. However, SSFFC medical products should be covered by a more precise and widely accepted definition that was compatible with national laws. Activities under the Member State mechanism should be organized in a manner that enabled countries to exchange experiences and engage in joint projects. Information-sharing and coordination of investigative activities were particularly important in major cross-border cases. For countries with capacity requirements, it was important to coordinate international assistance and guidance to improve control and management of the supply chain. WHO-recommended criteria for appropriate law-enforcement equipment and technical support should also be established.

Dr SHOHANI (Iraq) said that the problem of SSFFC medical products must be addressed in national policies in order to guarantee medicine safety. In Iraq all pharmaceutical companies had to provide registration certificates for medicines, which must comply with standards in the country of origin. Samples of medical products were tested and no product was released for sale until established as fit for purpose in accordance with international standards. Efforts were under way to raise public awareness through the media and to exchange expertise with other countries in order to guarantee compliance with the highest manufacturing standards in the interests of safety. Partnership between the public and private health sectors was important for tackling compliance problems, as were stronger partnerships with civil society and international organizations, particularly WHO, for ensuring follow-up and producing reports on compliance and on companies responsible for counterfeiting.

Mr KOLKER (United States of America) said that the Member State mechanism provided an opportunity to work together to confront the issue of SSFFC medical products from a public health perspective, to build cooperation and trust, and to create an effective new method of work. However, the lack of consensus on the appointment of a chairperson for the mechanism was regrettable. He supported the view that the Health Assembly should recommend that the chairing of the Steering Committee should be rotated among the existing vice-chairpersons on an interim basis, pending

agreement on a workable solution at the next meeting of the mechanism. Flexibility on the part of Member States would be a prerequisite for progress in combating the global threat of SSFFC medical products, which would continue to increase in scope and complexity as long as no concrete action was taken.

Mr PIPPO (Argentina), speaking on behalf of the Union of South American Nations, said that public health should be the paramount consideration in combating SSFFC medical products. The establishment of the Member State mechanism was a fitting response to the global dimension of the problem, and required the support and commitment of all Member States. He commended the innovative organizational and governance structure established for the mechanism, which combined plenary meetings open to all Member States with a more executive structure in the form of the Steering Committee, on which the regions would be adequately represented. He noted with satisfaction that the Open Ended Working Group responsible for identifying the actions, activities and behaviours that resulted in SSFFC medical products would work to resolve the persistent questions of terminology that had proved an obstacle to progress. The meetings scheduled to be held in July 2013 should serve to ensure progress in the establishment of the Steering Committee and the formulation of the workplan, without hampering the continuity of work under the mechanism.

Speaking as the delegate of Argentina, he expressed support for the proposal of a rotating chairmanship for the Steering Committee and urged the Health Assembly to take a decision on the matter.

Ms LANTERI (Monaco) said that, in her capacity as a Vice-Chairperson of the Steering Committee, representing the European Region, she supported the proposal of an interim system of rotation of the chairmanship among the existing vice-chairpersons, as it was clear that the Steering Committee could not continue to function on an informal basis. Such a system would enable the Steering Committee to begin belatedly to meet the expectations of countries in need.

Dr TSECHKOVSKY (Russian Federation) said that SSFFC medical products were a transnational threat and that it was therefore important to develop specialized instruments to combat them. He supported the Secretariat's efforts to exchange information on cases involving SSFFC medical products and to develop a universal policy. The pilot global surveillance system designed by the Secretariat to inform Member States of potential threats represented an excellent opportunity to intensify efforts in that regard. Recognizing the importance of increased global collaboration on surveillance and monitoring, the Russian Federation had organized seminars for health-care workers in order to raise awareness of improved surveillance procedures.

Ms JAMEEL (Maldives) expressed support for all measures to ensure the availability of good-quality, safe, efficacious and affordable medical products and, in particular, resolution WHA65.19 which had established the Member State mechanism. She stressed the importance of strengthening national and regional capacities, and national and regional regulatory mechanisms to ensure the integrity of the supply chain. That was of particular relevance to Maldives where no formal capacity currently existed for the production of essential medicines, and ensuring the quality of imported medicines was of the utmost importance.

She called for greater cooperation and sharing of resources between Member States in order to strengthen national and regional capacity for medicine registration, quality control testing and surveillance of SSFFC medical products. The gaps in knowledge among public health professionals in relation to the consequences of such products must be addressed through greater advocacy among relevant stakeholders at the national level.

Dr NABEEL (Pakistan) said that he fully supported the work to combat SSFFC medical products, which was being taken forward by the Member State mechanism. However, consensus must be reached quickly on the appointment of a chairperson for the Steering Committee. In that

connection, the proposal by the delegate of Brazil was an interesting one and deserved consideration. The proposed workplan should be a focal point of discussion at the forthcoming meetings of the Open Ended Working Group and the Member State mechanism. Strengthening national and regional regulatory capacity was a central element of the workplan and must remain a priority.

Dr EL OAKLEY (Libya) expressed regret at the delay in electing a chairperson for the Steering Committee and welcomed the proposal made by the delegate of Brazil that the post should be rotated among the vice-chairpersons.

Ms HELA (South Africa) expressed appreciation of what had been accomplished at the first meeting of the Member State mechanism. However, she too was concerned at the delays and the lack of agreement on a suitable definition of SSFFC medical products. Quoting Albert Einstein, she said that problems could not be solved with the same thinking that had been used to create them.

Mr RUSH (United Kingdom of Great Britain and Northern Ireland) noted an emerging consensus on the idea of rotating the chairmanship of the Steering Committee, as proposed by the delegate of Brazil. He suggested that the Committee should move forward on that proposal.

Ms Li-Ling LIU (Chinese Taipei) said that several strategies had been adopted to combat SSFFC medical products in Chinese Taipei that had achieved positive results. Medicine production and distribution channels were monitored, an interdepartmental task force had been established, a public awareness-raising campaign had been implemented and an initiative had been launched to combat online sales of such products. Recognizing that international cooperation was an effective and essential way to tackle the issue, Chinese Taipei had, since 2012, participated in an Asia-Pacific Economic Cooperation project on medical product quality and supply-chain integrity.

Mr MWANGI (International Alliance of Patients' Organizations), speaking at the invitation of the CHAIRMAN, expressed support for the Member State mechanism and actions under the mechanism to strengthen and build the capacity of national and regional regulatory authorities and quality control laboratories. His organization also supported the commitment of Member States to communication, education and awareness-raising about SSFFC medical products among consumers, health professionals and industry. He encouraged Member States to build on the progress achieved in several of the areas outlined in the proposed workplan by the International Medical Products Anti-Counterfeiting Taskforce. The Member State mechanism should specify how the many stakeholders affected would be involved in combating SSFFC medical products, as a multi-stakeholder approach would be critical to success.

Mr OTTIGLIO (International Federation of Pharmaceutical Manufacturers and Associations), speaking at the invitation of the CHAIRMAN, expressed support for the work of the Member State mechanism and said that the new global agenda on SSFFC medical products must focus on patient safety. Counterfeiters did not discriminate: counterfeit versions of generic and branded medicines had entered the supply chain in both developed and developing countries and the Internet had served to facilitate trade in SSFFC medical products, many of which were sold from illegal sites that concealed their physical address. Experience had shown that a multi-stakeholder and multidisciplinary approach to combating SSFFC medical products would be required at the local and global level. His organization stood ready to play its part.

Ms PYZIK (International Pharmaceutical Students' Federation), speaking at the invitation of the CHAIRMAN, said that as the methods of criminals purveying SSFFC medical products became more sophisticated, it would become increasingly difficult and expensive to detect such products. There must therefore be no delay in taking action. She urged Member States to secure strong leadership and to implement the Member State mechanism workplan in full. Pharmacy students could also play a

useful role in helping to raise awareness of SSFFC medical products. Illegal Internet pharmacies were a dangerous and insidious phenomenon, and she called on Member States to develop a method whereby patients could verify the legitimacy of online pharmacies in countries where they legally existed. Further international cooperation was needed in the context of efforts to ensure patient safety.

Mr BESANÇON (International Pharmaceutical Federation), speaking at the invitation of the CHAIRMAN and on behalf of the World Medical Association and the International Council of Nurses, expressed strong support for WHO's work in ensuring the availability of good-quality, safe, efficacious and affordable medical products, and emphasized that measures taken to monitor and improve medicine quality were crucial not only for Member States but also for other United Nations organizations working to supply medicines to those in need. He therefore urged Member States to ensure the allocation of appropriate resources for those important activities. He expressed concern at the slow pace of implementation of the Member State mechanism, and in particular the delay in finalizing its terms of reference.

Dr KIENY (Assistant Director-General) said that many speakers had highlighted the importance of SSFFC medical products as a public health threat affecting all countries. Concerns had been raised about the appointment of a chairperson for the Steering Committee but a consensus appeared to have emerged on the proposal to rotate the chairmanship among the designated vice-chairpersons, on an interim basis, until the Member State mechanism held its next meeting in November 2013. Preparations were being made for that meeting and for the meeting of the Open Ended Working Group to be held in July 2013. Noting the many worthy actions taken by countries individually to combat SSFFC medical products, she emphasized that the mechanism had been established specifically to drive concerted international action on a problem that was international in nature. Looking forward to the next meeting of the Steering Committee, she said that the first steps were to be taken on implementation of the agreed parts of the workplan, those relating to strengthening regulatory authorities, raising awareness and information sharing. The full workplan would be finalized in due course.

The CHAIRMAN invited the Committee to consider the text of a draft decision concerning the chairing of the Steering Committee of the Member State mechanism, which read:

> The Sixty-sixth World Health Assembly, having considered the report on substandard/ spurious/falsely-labelled/falsified/counterfeit medical products, decided to recommend that the chairmanship of the Steering Committee of the Member State mechanism on substandard/ spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products should operate on the basis of rotation, on an interim basis, without prejudice to the existing terms of reference of the mechanism.

The draft decision was approved.[1]

Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination: Item 17.2 of the Agenda (Document A66/23)

Dr VIROJ TANGCHAROENSATHIEN (Thailand), speaking in his capacity as Chairman of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, said that it formed part of an ongoing process under the global strategy and plan of action on public health, innovation and intellectual property. The outcome of the meeting held in November 2012 – the draft resolution

[1] Transmitted to the Health Assembly in the Committee's third report and adopted as decision WHA66(10).

contained in the Appendix to document A66/23 – provided for a complex, stepwise process of implementation and reporting thereon. Two reports would be drafted in time for the Sixty-seventh World Health Assembly, one on the review of existing coordination mechanisms, as proposed in subparagraph 4(5) of the draft resolution, and the other on the evaluation of existing mechanisms for contributions to health R&D, as proposed in subparagraph 4(6). A further report would be prepared for the Sixty-eighth World Health Assembly on the implementation of health research and development demonstration projects, as proposed in subparagraph 4(4). Another open-ended meeting of Member States would be held prior to the Sixty-ninth World Health Assembly and would report to that Health Assembly on its findings.

He was confident of the viability of the concrete steps detailed in the draft resolution with regard to the development of national and global health research and development observatories for monitoring and identification of gaps as well as effective coordination and reviews of financing. He urged Member States to adopt the draft resolution and to implement its recommendations diligently.

Dr LIU Peilong (China) said that the importance of health research and development financing and coordination was recognized by all and was one of the items attracting the most attention from Member States at the current Health Assembly. He welcomed the draft resolution, which outlined actions that could be implemented immediately at the national and international levels to address the identified gaps disproportionally affecting developing countries. However, there was room for much further progress in implementing the recommendations contained in the report of the Consultative Expert Working Group, contained in document A65/24. Nevertheless, in a spirit of consensus, he was prepared to accept the draft resolution in its current form as an important opportunity to improve the coordination and financing of health research and development.

The report of the Consultative Expert Working Group stated that financing and coordination should build on existing structures whenever possible. He hoped that that guidance would be followed in setting up the health research and development observatory proposed in subparagraph 4(3) of the draft resolution and that observatories at the national and global levels would form an integrated network to monitor global health research and development. With regard to health research and development demonstration projects (subparagraph 4(4)), efforts should be directed not only at developing new medical products urgently needed by developing countries but also at determining health research and development needs and priorities, and ways to mobilize and allocate funds and de-link research and development costs from product prices. On the basis of such an approach, the demonstration projects should serve to develop evidence-based solutions of strategic importance for the long-term financing and coordination of global health research and development.

The draft resolution also requested the Director-General to facilitate the implementation of several health research and developmemt projects through regional consultations and broad engagement with relevant stakeholders, and it would be useful to know whether the Secretariat had any concrete action plans to meet those requirements.

Dr JAIN (India) speaking on behalf of the Member States of the South-East Asia Region, said that the Region had engaged in national and regional consultations that had led to the adoption of resolution SEA/RC65/R3 by the Regional Committee for South-East Asia in November 2012, which had provided the basis for the draft resolution under discussion. The Regional Office for South-East Asia had recently initiated a study to take forward the work of the Regional Committee, with a view to prioritizing its activities, defining global norms and standards and identifying regional projects. The Consultative Expert Working Group had recommended the development of a binding convention, but the discussions at the open-ended meeting of Member States had fallen short of that commitment owing to Member States' differing views on matters such as the framework for the research and development treaty and global health research and development expenditure. The Member States of the Region called for continued discussion to find durable solutions for tackling the unmet health research and development needs of developing countries and to respond promptly to the remaining recommendations of the Consultative Expert Working Group's report.

Mr MAMACOS (United States of America) said that the consensus-based draft resolution before the Committee represented the best opportunity in decades to increase research and development for diseases disproportionally affecting developing countries, and should be adopted as drafted since market forces alone were not sufficient to generate the necessary investment. Member States should turn their attention to guiding the Secretariat in its next steps to implement the proposals, which included setting up a global observatory and developing research and development demonstration projects. For the sake of clarity on the path forward, he proposed supplementing the draft resolution with a draft decision that read:

> Member States direct the WHO Secretariat to convene an advisory meeting including government representatives as well as, at the discretion of the Secretariat, technical experts from external stakeholders and the private sector, at the earliest possible date, in order to take forward action in relation to monitoring, coordination and financing for global health R&D, in accordance with the terms of resolution WHA66.XX. Such a meeting should particularly include members of the biomedical research community at a technical level and those currently involved in managing funds for research and development, with a mandate to (1) assist in the identification of translational research projects and the methodologies for coordinating research for the demonstration projects, in ways that emphasize the de-linkage of cost of R&D from product price and (2) identify ways to promote advocacy for identified R&D needs, and seek voluntary financing for the demonstration projects.

His Government could not undertake to allocate resources to a mechanism that was still not clearly defined and had no record of success. The proposed decision would help inform the research and development demonstration projects and would provide proof of concept. Noting the flexibility contained in subparagraph 4(7) of the draft resolution on the timing of a Member State meeting to be held prior to the Sixty-ninth World Health Assembly, he said that the United States of America would be open to convening such a meeting at an earlier rather than later date if the proposed advisory meeting and the Secretariat could demonstrate progress on a viable mechanism.

Dr ROHINGALAOU (Chad), speaking on behalf of the Member States of the African Region, said that the importance of global health research and development financing and coordination was highlighted by the provisions of resolution WHA65.22 requesting follow-up by the Secretariat. The Annex to document A66/23 showed that the follow-up process had been handled judiciously inasmuch as the open-ended meeting of Member States had benefited from the participation of research institutions, donors and other important actors. The tools at Member States' disposal in the open-ended meeting, including the results of national and regional consultations and reports from regional committees, the Consultative Expert Working Group and the Secretariat, were essential to thorough consideration of the various aspects of health research and development coordination and financing, and monitoring of expenditure. However, consensus could not yet be said to have been reached as the African Region's consultations had included only six of the Region's 46 Member States.

Developing countries had not hitherto received optimum financing for health research and development as allocations had been governed by market forces rather than needs, leading to exorbitant drug prices. Therefore, despite the financial and administrative constraints currently faced by many countries, there was an urgent need to set up a fund for the sustainable financing of health research and development. All existing funding mechanisms must be explored and, pending achievement of a consensus on a funding model, voluntary contributions could be made by Member States, donors and financial institutions to build capacity in developing countries and to ensure better coordination through the establishment of the observatory.

Ms HAGERTY (Ireland), speaking on behalf of the European Union and its Member States, said that Croatia, the former Yugoslav Republic of Macedonia, Montenegro, Iceland, Serbia, Albania, the Republic of Moldova, Armenia and Georgia aligned themselves with her statement. The proposed

draft resolution set out a clear strategy for financing and coordination of health research and development in line with the global strategy and plan of action on public health, innovation and intellectual property to which the European Union and its Member States were fully committed. The draft resolution not only provided a basis for a sustainable solution but allowed Member States and the Secretariat to take immediate action through a few demonstration projects. The evaluation of the projects would provide additional data that could be used to identify challenges relating to effective research and development coordination and financing mechanisms, with a view to ensuring a long-term, sustainable solution for health research and development.

She had noted and would study the draft decision proposed by the delegate of the United States of America.

Dr HORI (Japan), expressing support for the draft resolution, said that the current level of health research and development was insufficient to address diseases that disproportionally affected developing countries. In a bid to tackle the problem, his Government, in cooperation with Japanese pharmaceutical companies and the Bill & Melinda Gates Foundation, had established a public–private partnership mechanism, the Global Health Innovative Technology Fund. The Fund was a clear expression of his Government's commitment to promoting investment and facilitating health research and development. Japan would continue to play an active role in global health research and development by mobilizing its research capacity and extending its global partnerships.

Dr CLAURE (Plurinational State of Bolivia), speaking on behalf of the Union of South American Nations (UNASUR), said that the system of incentives for research and development based on patents had proved to be insufficient to meet the needs of developing countries. UNASUR therefore recognized the value of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, and accepted its recommendations. The proposed establishment of an international research and development framework was the most appropriate structural solution to the problems identified. The proposal to create a global observatory was a positive initiative that would contribute to providing a regularly updated diagnosis of the research and development process. The proposed demonstration projects could usefully explore alternative models for the establishment of incentives, as long as they were in line with the principles and guidelines of the Consultative Expert Working Group. The de-linkage of research and development costs from the price of health products, the use of open and collaborative platforms for research and development and the acknowledgement of research and development and associated information as global public goods must form part of the guiding principles for project design. He underscored the need for consensus and continued dialogue among Member States, and expressed the willingness of the Union of South American Nations to work with the United States of America in order to reach consensus on the proposed draft decision.

Ms STIRØ (Norway) said that the report of the open-ended meeting provided a solid platform for joint action and represented a concrete step in developing the three interlinked areas of monitoring, coordination and financing of global health research and development. She fully supported the goal of ensuring that medical innovation and discoveries met the needs of developing countries. Since economic growth had raised many countries from low- to middle-income status, she looked forward to a more significant response to the call for increased financing from countries of the South.

The strategic workplan set out in the draft resolution provided a clear pathway for progress over the next few years, with a focus on the further elaboration and implementation of deliverables. As the Secretariat was required to report on the lessons learnt from the demonstration projects by 2015, no time must be lost in implementing the workplan. The aim should be to demonstrate positive progress while trying out new and different models, but projects must be designed to fit their designated time frame. She supported the draft resolution.

Mr AL RUBAE (Oman) supported the draft resolution. Oman was the second country in the Eastern Mediterranean Region to have held national consultations on matters relating to the report of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. The recommendations that had emerged from those consultations had been transmitted to the Secretariat. Oman was also working, with WHO guidance, to establish a health research observatory.

Ms SOSIALINE (Indonesia) said that current health research and development activities were inadequate to deal with various global health issues effectively, especially the diverse and complex health problems faced by developing countries. Greater investment, particularly in research and development focusing on diseases disproportionally affecting developing countries, would enhance innovative capacity in those countries and increase the amount of research undertaken and the number of medical products developed; it would also improve health outcomes. Capacity-building in and technology transfer to developing countries were also needed. Such action should be based on joint agendas and priority-setting related to developing countries' health needs and national plans for essential health research. Health research and development and access to health products should be strengthened through investment and sustainable collaboration. Such an approach was particularly important in relation to new drug research and attention should be paid to the de-linkage of research and development costs from the price of health products in developing countries. Lastly, she expressed support for the establishment of a global health research and development observatory.

Ms MATSOSO (South Africa) said that the 2012 report of the Consultative Expert Working Group on Research and Development: Financing and Coordination represented a milestone in a long-standing international effort to close the critical gaps in the development of drugs and other health technologies to meet the health needs of developing countries. She supported the draft resolution, which represented an important opportunity to address market failures through collective action, the pooling of resources and enhanced cooperation; it would create predictability and sustainability, and help to meet the needs of vulnerable populations.

She noted the comments made by the delegates of the United States of America and the Plurinational State of Bolivia and supported their proposals in principle. South Africa had increased its assessed contribution in support of the necessary preliminary work for the establishment of the global health observatory, which she hoped would begin without delay.

Ms JAMEEL (Maldives) commended the work of the open-ended meeting. The subsequent discussions at national and regional level would help to take forward the recommendations of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination. She emphasized the need for all health partners, including governments, academia, the private sector and nongovernmental organizations, to contribute to the proposed global health research and development observatory and to health research and development financing and coordination mechanisms, especially in support of developing countries. Some countries, including her own, had very limited health research and development capacity; it was therefore imperative for them to build partnerships with regional research centres.

The meeting rose at 12:25.