World Health Organization

SIXTY-FIFTH WORLD HEALTH ASSEMBLY **A65/B/PSR/4**
COMMITTEE B **13 August 2012**

PROVISIONAL SUMMARY RECORD OF THE FOURTH MEETING

Palais des Nations, Geneva
Friday, 25 May 2012, scheduled at 14:30

Chairman: Professor M.H. NICKNAM (Islamic Republic of Iran)
later: Dr E. TAYAG (Philippines)

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FOURTH MEETING

Friday, 25 May 2012, at 14:30

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1. ORGANIZATION OF WORK

The CHAIRMAN asked whether the Committee was willing to accept the transfer from Committee A to Committee B of agenda items 13.8 (Global mass gatherings: implications and opportunities for global health security) and 13.11 (Elimination of schistosomiasis).

It was so agreed.

2. TECHNICAL AND HEALTH MATTERS: Item 13 of the Agenda (continued)

Draft global vaccine action plan: Item 13.12 of the Agenda (Documents A65/22, A65/22 Add.1 and EB130/2012/REC/1, resolution EB130.R12) (continued from the third meeting, section 4)

Dr NORHAYATI RUSLI (Malaysia) said that, once adopted, the draft action plan would dictate rather than guide government policy-making. Malaysia did not support objectives 1 and 2 of the plan's six strategic objectives. Under objective 1, for example, requiring a legal framework that guaranteed financing for immunization would place a burden on governments should they need to borrow funds for that purpose. Also, while appreciating the need for an independent technical advisory group, she would not want the recommended list of actions to become mandatory. With regard to objective 2, despite her Government's sensitivity to the health needs of its citizens, it could not agree that immunization should be promoted as a "core component of the right to health", which the public could "demand". Careful study of issues such as vaccine efficiency, cost-effectiveness and suitability for inclusion in a national immunization plan, rather than emotional demands, should be the primary consideration. Similarly, the proposal to offer cash and other incentives to health care workers and households in order to promote vaccination programmes required careful study. The suggested establishment of a system for pooled procurement and short-term credit based on models used elsewhere called for discussion both within and between countries, as it would involve an agreed contractual financing mechanism. Negotiations with vaccine producers should be conducted collectively at the regional level while procurement should remain the responsibility of individual countries.

Vaccination was an effective tool for disease prevention but sometimes created a false sense of security since children could still become infected with microorganisms against which the vaccine did not confer protection. Early identification and referral of suspected cases of infectious diseases should therefore be strengthened and integrated management of childhood illness taught, especially in remote areas. Rather than offering monetary and in-kind incentives to encourage vaccine use, which placed an additional burden on implementing agencies and governments, efforts should be made to raise socioeconomic status, educational level and health awareness, particularly among women.

WHO must maintain its leading role in setting standards for vaccine production and quality control. It should support middle- and lower-middle-income countries in the production of affordable

vaccines that were as safe and effective as those produced in high-income countries, thereby ensuring the sustainability of immunization programmes.

Dr BORWORNSOM LEERAPAN (Thailand) said that a strong immunization programme was an integral part of a well-functioning health system. However, a major structural barrier to vaccine self-reliance in low- and middle-income countries was the high cost of new vaccines, whose production was often in the hands of a monopoly. As a result, access to new vaccines was blocked until a generic version became available, often years later. Vaccine production capacity should therefore be expanded in the developing countries in order to reduce the cost, and incentive mechanisms set up to separate research and development costs from vaccine prices. A voluntary patent pool, public–private partnerships in production, differential pricing for segmented markets, advance market commitments and regional-level pooled procurement were also needed and should be included under strategic objective 5 of the action plan. The celebration of World Immunization Week could be an effective advocacy tool, even though immunization should be promoted year-round. He was concerned, however, that the vaccine industry might take advantage of the Week to market unsuitable or irrelevant new products, giving rise to undue social pressure and unnecessary public demand. Activities during the Week should therefore focus on basic immunization, to the exclusion of commercial interests.

Mr ÁLVAREZ LUCAS (Mexico) welcomed the immunization activities in Member States and the harmonization of regional consultations by the Secretariat and host countries in the context of the Decade of Vaccines. Mexico had hosted the Regional Consultation of the Americas, at which participants had acknowledged the importance of multisectoral coordination in that strategic area of public health. The action plan offered a new vision for achieving universal coverage and access to immunization and countries would reap significant benefits from its adoption. His Government pledged to step up immunization efforts in accordance with the guidelines and priorities set out in the action plan.

Dr HEMMATI (Islamic Republic of Iran) said that sustainability and availability to all eligible groups were the most important criteria to consider when screening new vaccines for introduction into national immunization programmes. Were they to act as screening agents, WHO and UNICEF would be playing a key role, since implementation of short-term immunization programmes, without screening of new vaccines, might undermine national or even regional programmes. National programmes should be financed by the national budget and reliance on other sources limited to particularly important immunization campaigns for which domestic funding was unavailable, or to international crises such as a pandemic. WHO and UNICEF should consider providing technical and financial support to modernize the cold-chain system in line with strategic objective 4 of the action plan. “Reaching every district” and “reaching every community” programmes could have been successful had greater investment been made in them, particularly in technical areas. Reactivating such programmes, especially in remote and marginal areas, could significantly boost immunization coverage. Periodic intensification of routine immunization would be successful only if it helped to expand coverage sustainably. The role of new vaccines in controlling outbreaks was not clear and should be clarified by WHO as soon as possible.

Ms POLL (Costa Rica) said that Costa Rica had good health indicators despite being a developing country. It had made significant progress in vaccination coverage, which had risen to at least 95%. Collaboration within the national health system between the health ministry, the social security administration and the private sector to implement the objectives of the draft action plan had been successful, although there was room for improvement. For example, the country’s information and registration system required strengthening, for which PAHO was offering support. The positive results achieved under the Global Immunization Vision and Strategy offered a sound foundation on

which to build the draft action plan and the Decade of Vaccines. Success depended, however, on the adherence of all interested parties and coordination with Member States to ensure commitment to the plan as a whole.

Ms MATSAU (South Africa), speaking on behalf of the Member States of the African Region, said that many countries in the Region had yet not reached the 90% coverage target set by the Global Immunization Vision and Strategy despite the significant gains made in recent years. The Region still faced a number of challenges, which had to be addressed if the goals of the action plan were to be reached.

First, the poorest, most vulnerable children were not being reached by immunization programmes, a problem that could only be solved with new innovative strategies and funding sources. Secondly, health systems in many countries had inadequate infrastructure, staff skills and delivery; addressing those issues must become an integral part of efforts to bolster immunization services. Thirdly, clinical and laboratory surveillance, which was vital for screening new vaccines, was inadequate and costly. Fourthly, many vaccination programmes remained vertical and continued to target children under two years of age. Lastly, the life-cycle approach to immunization would require a shift in thinking for policy-makers and managers and a commitment to finding new opportunities for integrating other services into immunization schemes.

Despite the GAVI Alliance's recent success in securing significant global funding, the countries in the Region would still have to draw on their own resources to purchase vaccines and run immunization programmes, even as they faced the global economic crisis and competing national priorities. That was a particular challenge for low- to middle-income countries that were not eligible for GAVI funding and had to negotiate vaccine prices with producers on their own. In many countries, funding for immunization programmes was under threat; innovative funding mechanisms, such a revolving fund, modelled on that of PAHO, or new tax initiatives must therefore be sought. Establishment and strengthening of national regulatory authorities and technical advisory groups was vital to the development of national vaccine strategies which, together with global strategies to support vaccine production capacity, should ensure effective implementation of the action plan. World Immunization Week was a worthy endeavour and, whenever possible, should be aligned with Child Health Week. The proposed ban on vaccines containing thiomersal, the amount of which was too low to have an environmental impact, would rule out the use of multi-dose vaccines, thus significantly increasing immunization programme costs, which in turn would affect child mortality.

Mr MESBAH (Algeria) said that immunization was a right and a duty of all Algerians and was provided free of charge. Particular attention should be paid to ensuring that populations living in border regions were vaccinated, not only during epidemics but also through routine immunization programmes; WHO should provide assistance for developing and implementing effective strategies to that end. In a middle-income country such as Algeria, access to vaccines, in particular new vaccines, was limited by their high cost which threatened to undermine any progress made. In the spirit of the GAVI Alliance, WHO should guarantee vaccine affordability under the action plan. The solution was fourfold: ensure that global vaccine producers made vaccines affordable, set up pooled procurement mechanisms based on best practice, promote local production of high-quality vaccines, including through partnership mechanisms, and remove intellectual property restrictions.

Dr KWAK Jin (Republic of Korea) commented that the international community had made great strides in reducing vaccine-preventable diseases through immunization in the past decade. It was now time for a new strategy to further reduce the burden of and, eventually, to eradicate those diseases. His Government had been working to raise vaccination coverage rates and reduce the disease burden by: increasing funding for the national immunization programme; expanding the school-entry immunization certificate programme; improving immunization management for vulnerable populations; developing a register-management system; and ensuring the regularity of the

immunization recall and reminder system. It had also joined efforts to establish poliomyelitis- and measles-eradication plans in the Western Pacific Region and had reorganized its national certification committee accordingly. His Government was committed to the process of finalizing and implementing the global vaccine action plan.

Dr MOHAMED (Oman), welcoming the draft action plan, said that there was nothing more effective and equitable, from an economic and social perspective, than vaccination; however, many countries in the Eastern Mediterranean Region were not GAVI-eligible and thus could not afford to buy sufficient amounts of vaccine, leaving many women and children unvaccinated. It was unacceptable that, in the 21st century, millions of children were dying or suffering from vaccine-preventable diseases. He hoped that WHO and its partners would put programmes in place to ensure that vaccines were accessible to all.

Dr ST. JOHN (Barbados) recalled that her Government had sponsored the draft resolution on World Immunization Week, adopted by the Board at its 130th session in January 2012. The immunization programme in Barbados reflected the principles and objectives of the draft action plan. Her Government had committed itself to an expanded programme on immunization involving a public–private partnership. It had broadened the range of antigens delivered free of charge to citizens with the help of the PAHO Revolving Fund. It had also expanded its life-cycle approach to immunization, paying particular attention to vulnerable groups and frontline public-sector workers. The national immunization programme was embedded in the primary health care system, both public and private, and had a dedicated line in the annual budget.

Annual meetings of immunization programme managers, convened by the Caribbean Epidemiology Centre, ensured common standards across the Caribbean region as well as continuing professional education. During Vaccination Week in the Americas, Barbados had focused on improving its programme to cover vaccination gaps, educate health providers and raise public awareness.

She urged WHO and its regional committees to support countries in implementing the action plan. Diseases such as poliomyelitis should not be allowed to re-emerge, as that could easily undermine the progress made in reducing the burden of vaccine-preventable diseases. The recent measles outbreak in the Americas was a reminder of how quickly such a situation could arise.

Dr ZAKARIAH (Ghana) said that the action plan represented a paradigm shift towards greater coordination among all stakeholders in the field of immunization, at all levels, and had led to significant gains to the African Region. In Ghana, progress had been made under the Expanded Programme on Immunization and all children under one year of age were now vaccinated against 11 lethal diseases. Improved routine immunization and large-scale campaigns had helped to prevent transmission of vaccine-preventable diseases and had significantly reduced the related morbidity and mortality rates. Ghana had had no recorded cases of infection with wild poliovirus since 2008 and no deaths due to measles since 2003. Maternal and neonatal tetanus had recently been eliminated leading to a remarkable decrease in the under-five mortality rate, which had freed up resources for reallocation to other pressing concerns. Healthier children also meant happier caregivers, which in turn gave rise to greater productivity and wealth. Many actors had helped to make the immunization programme a success: the Government and the ministry of health, health workers (particularly nurses), women, local partners and international stakeholders like the GAVI Alliance. Such cooperation was necessary to ensure immunization services for all.

Dr ORHII (Nigeria) proposed two amendments to the draft resolution contained in document A65/22. In subparagraph 2(1), the words “paying particular attention to improving EPI performance and” should be inserted following “national health strategy and plans,”. In paragraph 3, a new subparagraph 3(1)*bis* should be added to read: “to ensure that support to the Global Vaccine

Action Plan's implementation at regional and country level includes a strong focus on strengthening routine immunization".

Dr SUNDARANEEDI (Trinidad and Tobago), endorsing the global action plan and the draft resolution contained therein, said that his Government was committed to the eradication of all vaccine-preventable diseases. Within the past two decades, his country had embarked on an expanded programme of immunization for all age groups, implemented through Government-funded health programmes with some private sector support. Despite the emergence of new antigens in the past 10 years, their high cost had proved to be prohibitive and had limited the possibility of integrating them into the country's vaccination programme. He asked WHO and the international community to give priority to the issue of vaccine cost.

Ms PEREIRA MAGNO (Timor-Leste) highlighted the many challenges that her country faced in relation to vaccine-preventable communicable diseases, including access to vaccines, qualified health professionals and a sound infrastructure. Her Government had begun implementing the six strategic objectives of the draft plan and was fully committed to eradicating vaccine-preventable diseases. An increase in the general State budget, together with donor funding for the country's health services, would make it possible to prepare a sustainable development plan to reduce mortality and morbidity rates in the future.

Ms KINDE GAZARD (Benin), endorsing the draft resolution, said that with support from the GAVI Alliance, Benin had been introducing new vaccines regularly and also planned to recruit new health care personnel. The African Region had recently organized a second vaccination week, in which people had been identified who had not been vaccinated against measles and poliomyelitis. The next challenge was to strengthen the country's routine immunization programme, which should become a daily activity. Her Government considered the global action plan to be a priority and called on WHO and other partners to move ahead with its preparation.

Dr YAKUBU (United Nations Children's Fund) evoked the remarkable progress made in global immunization since the adoption of the Global Immunization Vision and Strategy. UNICEF would remain an active partner in international efforts to achieve the new goals set out in the draft action plan and to ensure that every eligible individual received the requisite vaccines, regardless of their circumstances. Adoption of the plan was an important, and necessary, step in meeting the demand for developing new vaccines and reaching new target populations, and a clear definition of each stakeholder's accountability in carrying out the plan was needed. Implementation should be accelerated and efforts to mobilize resources increased in order to support all countries in introducing new vaccines and reaching every child. World Immunization Week was an opportunity to advocate globally for immunization and to create a demand for it in all communities in order to ensure equal access to vaccines. He hoped that the draft resolutions on World Immunization Week and on the global vaccine action plan would be adopted.

Dr Ho-Sheng WU (Chinese Taipei) said that Chinese Taipei had focused on community awareness as a means of increasing vaccination coverage rates. Its communicable disease control act had made funding for both standard and new vaccines completely independent. Collaboration among professionals and stakeholders regionally and internationally was vital to maximizing the benefits of immunization research and development. In an increasingly mobile world, regular information exchange and collaboration on vaccination policy should continue among Member States and regions in order to improve coverage and facilitate cross-border cooperation. WHO could help by facilitating international cooperation on immunization programmes and by supporting communities in meeting vaccine coverage targets. Chinese Taipei was willing to share its experience in implementing immunization programmes as a contribution to the draft action plan and World Immunization Week.

Dr BIGGER (International Federation of Pharmaceutical Manufacturers and Associations), speaking at the invitation of the CHAIRMAN, said that in order to achieve the vision of the Decade of Vaccines, the draft global vaccine action plan, which she welcomed, should be refined, interactions and partnerships clarified, objectives prioritized and opportunities for synergies identified. Resource requirements and funding sources should be identified and further discussion held on targeted indicators, a monitoring mechanism, and an accountability framework to define stakeholders' roles and responsibilities. Equitable, sustainable access to high-quality, safe, effective vaccines could be ensured by a well-functioning competitive market system in which innovation was rewarded and sustainable investment and collaboration sought. Recognition of current pricing and procurement mechanisms that had contributed significantly to improving access to affordable vaccines was one such example. Although the voluntary transfer of vaccine technology and know-how had potential value, an environment that supported future immunization research and development through the protection of intellectual property rights had to be preserved. The objectives of the Decade of Vaccines could not be achieved by countries alone. The Federation was ready to contribute to a country-led collaborative approach and to work with mutually accountable partners to achieve the goals of the plan.

Ms BERGER (The Save the Children Fund), speaking at the invitation of the CHAIRMAN, welcomed the reference to the right to health and the emphasis on addressing the inequality in immunization coverage in the preamble to the draft resolution. By adopting it, Member States would be pledging to reducing that inequality. National immunization strategies should include disaggregated targets in order to reach the poorest, most vulnerable populations. The emphasis in the draft plan on strengthening health systems was welcome as health workers were central to achieving expanded coverage. The approach that had been used of holding broad consultations prior to drafting the global plan was commendable and should guide the process of translating the plan into country strategies and programmes. Steps must be taken to establish a transparent mutual accountability framework, to be coordinated by WHO, including a requirement for annual reports on progress towards disaggregated equity targets.

Ms ELDER (MSF International), speaking at the invitation of the CHAIRMAN, welcomed the renewed focus on immunization in the Decade of Vaccines and supported the draft action plan. Providing infants with the most basic package of vaccines was a significant challenge owing to weaknesses in routine immunization systems in some developing countries where children were disproportionately affected by vaccine-preventable diseases. She therefore urged Member States and other stakeholders to address the problem of unvaccinated children. To optimize vaccination coverage, the action plan should focus on boosting routine immunization and expanded programmes of immunization. Furthermore, since better data were needed for planning and setting priorities, donors in developing countries should invest in building their data collection and assessment capacities. Developing countries also needed immunization products that were easier to use and better designed. MSF International advocated an approach that acknowledged the problems faced by communities, and provided practical solutions.

Dr BELL (International Federation of Red Cross and Red Crescent Societies), speaking at the invitation of the CHAIRMAN, said that the Federation was working closely with its partners to ensure that every child had access to vaccination, which was the best way to achieve Millennium Development Goal 4. Member States were urged to take action in four main areas. First, resources for civil society organizations had not been included in the action plan's cost estimates even though the support of civil society was needed in any comprehensive immunization programme. Secondly, transparency and inclusiveness in discussions and decision-making nationally and internationally must be ensured. Thirdly, local capacity in vaccine development and production should be promoted, and vaccine purchasers should ensure that their procurement practices stimulated competition to bring

vaccine prices down to affordable levels. Fourthly, vaccine coverage should be optimized, and the introduction of appropriate, easy-to-use vaccines for developing countries should be accelerated. Her organization supported the draft plan and was convinced that it could be implemented.

Dr EVANS (GAVI Alliance), speaking at the invitation of the CHAIRMAN, said that funds invested in cost-effective, proven interventions could have a huge impact. Member States' collective efforts to accelerate the uptake of new vaccines was laudable. A country-driven approach was inherent to the vision and strategy of the action plan, as the success of a new vaccine depended on routine immunization and a strong health system. The GAVI Alliance had been instrumental in reducing the gap between the time a vaccine became available in high-income countries and the time it became available in low-income countries, in accordance with the principle set out in the action plan of ensuring equity in vaccine coverage. Equity could nevertheless be improved even further with the aid of firm country leadership. The action plan targets must be achieved to ensure the success of the Decade of Vaccines, and that would require careful monitoring. The GAVI Alliance fully supported the call in the draft resolution for a special session of each regional committee to track progress, and was ready to play an integral part in that process.

Dr BUSTREO (Assistant Director-General) commended the valuable input to the draft action plan provided at regional consultations during the past year by more than 1000 leading experts in the field of immunization, representing 142 countries, and the participation of the Permanent Missions of the United Nations offices in Geneva and New York. Countries had made remarkable efforts to increase vaccine coverage, thus providing life-saving interventions to many women and children.

Replying to Member States' comments, she said that WHO would set the norms and standards referred to in the draft plan and support the preparation of regional and national action plans. Governance of the process would be handled by existing partnerships and coordination mechanisms, so that no new structure would be required. Progress would be monitored and reported to the Health Assembly and the regional committees through an accountability framework. To build the framework, the roles and responsibilities of stakeholders and the recommended indicators and targets for monitoring were being refined. A draft framework was expected to be submitted to the Strategic Advisory Group of Experts on immunization in November 2012, and a report would be submitted, through the Executive Board, to the next Health Assembly.

She assured the delegates of India and Malaysia that the Secretariat had taken note of their concerns regarding some of the proposed indicators. Adjustments would be made to those indicators in individual country action plans, in accordance with national contexts. Resolution EB130.R12 on World Immunization Week did not seek to promote inappropriate marketing of products by vaccine manufacturers but to increase advocacy for existing vaccines and to strengthen immunization systems.

The significant contributions that had been made by United Nations agencies, nongovernmental organizations and other partners to the draft global vaccine action plan would provide a framework for successful implementation, should the Health Assembly decide to adopt the draft resolution.

The CHAIRMAN invited the Secretary of the Committee to read out the proposed amendments to the draft resolution contained in resolution EB130.R12.

Dr ONDARI (Secretary) said that two amendments had been proposed to the draft resolution. In the second line of the seventh preambular paragraph, the word "is" should be replaced by "was", and in subparagraph 2(1), the word "ensure" should be replaced by "assure".

After a brief exchange of views, Dr PABLOS-MÉNDEZ (United States of America) reiterated that his proposed amendment was to replace "assured" by "ensured".

The CHAIRMAN said that, in the absence of any objections, he would take it that the Committee wished to approve the draft resolution.

The draft resolution, as amended, was approved.[1]

The CHAIRMAN asked the Secretary to read out the proposed amendments to the draft resolution contained in document A65/22.

Dr ONDARI (Secretary) said that the delegate of Nigeria had proposed that in subparagraph 2(1), the words "paying particular attention to improving EPI performance and" should be inserted before the words "according to the epidemiological situation in their respective countries". The same delegation had proposed that in paragraph 3, a new subparagraph 3(1)*bis* should be inserted to read "to ensure that support to the global vaccine action plan's implementation at regional and country level includes a strong focus on strengthening routine immunization". The delegate of the United Arab Emirates had proposed that in paragraph 3, a new subparagraph 3(5) should be inserted to read "to mobilize more financial resources in order to support implementation of the global vaccine action plan in low-income and middle-income countries".

Dr FIKRI (United Arab Emirates), speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the amendment just read out had been proposed on behalf of the Region.

The CHAIRMAN said that, in the absence of any objection, he would take it that the Committee wished to approve the draft resolution.

The draft resolution, as amended, was approved.[2]

Dr Tayag took the Chair.

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products: report of the Working Group of Member States: Item 13.13 of the Agenda (Documents A65/23 and EB130/2012/REC/1, resolution EB130.R13)

Mrs HANJAM DA COSTA SOARES (representative of the Executive Board), introducing the item, reported that at its 130th session in January 2012, the Executive Board had considered the report of the Working Group of Member States on Substandard/Spurious/Falsely-Labelled/Falsified/ Counterfeit medical products and had adopted resolution EB130.R13. Both the report and the resolution acknowledged and reaffirmed WHO's role in the area of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products and proposed the establishment of a new, transparent Member State mechanism to encourage international collaboration in ensuring access to affordable, safe, efficacious and quality medical products and in the prevention and control of SSFFC products and associated activities. Many countries had expressed support for the draft resolution contained in resolution EB130.R13, and one Member State had pledged to participate in the mechanism on a voluntary basis. The Board had welcomed the proposal by the Government of Argentina, supported by the delegate of Brazil, to host the first meeting of the Member State

[1] Transmitted to the Health Assembly in the Committee's second report and adopted as resolution WHA65.18.

[2] Transmitted to the Health Assembly in the Committee's second report and adopted as resolution WHA65.17.

mechanism, on the understanding that a preparatory meeting would be held in Geneva. The Health Assembly was invited to consider the draft resolution contained in resolution EB130.R13.

Ms KRARUP (Denmark), speaking on behalf of the European Union and its Member States, the acceding country Croatia, the candidate countries Turkey, The former Yugoslav Republic of Macedonia, Montenegro, Iceland and Serbia, the countries of the Stabilization and Association Process and potential candidates Albania and Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova, Armenia and Georgia, congratulated the Working Group on breaking the deadlock on the issue of SSFFC medical products, an area in which WHO had an active role to play. The European Union supported the draft resolution and hoped that the new Member State mechanism would be set up swiftly and provide an effective, results-oriented platform for coordinated, multisectoral cooperation to prevent SSFFC medical products from undermining the credibility of health systems. The mechanism should be practical, adapted to the needs of Member States and based on transparent consultation and collaboration with stakeholders; any meetings that it held outside Geneva must be cost-efficient. The dates of the first meeting should not overlap with those of the 15th International Conference of Drug Regulatory Authorities, which was a partner in the combat against SSFFC products. The European Union endorsed WHO's fundamental role in ensuring the quality, safety and efficacy of medical products and in promoting access to affordable, quality, safe and efficacious medicines, and was actively cooperating with developing countries in that regard. It requested WHO to identify, using transparent methods, adequate funding for the fight against SSFFC medical products under the approved Programme budget for 2012–2013.

Dr HASAN (Bahrain) said that her country's activities relating to SSFFC medical products were focused on providing protection for potential victims. WHO had a key role to play in ensuring the quality of medical products but lacked sufficient resources to do so. Pharmaceutical products should be sold at reasonable prices. She supported the establishment of a subcommittee of the WHO Expert Committee on Specifications for Pharmaceutical Preparations to provide technical advice on SSFFC medical products. Product monitoring was a collective responsibility and cooperation was required among all stakeholders, including governments and civil society, in order to train health workers and build capacities to reduce the availability of poor-quality medicines. Measures taken by her Government to control SSFFC medical products included laboratory monitoring of products that entered the country and studying the by-products of those products. In addition, the countries in the Gulf region and the Regional Office for the Eastern Mediterranean would be working together to monitor medical products. She supported the draft resolution.

Dr KUDO (Japan), endorsing the draft resolution, said that the Organization's efforts to prevent and control SSFFC medical products were among its most important activities for attaining the goal of improving the quality of and access to medical products and technologies, and should be expanded. In view of the involvement of international organized crime and the piracy of trademarks and product design, cooperative efforts among the various stakeholders combating SSFFC products – including the private sector, and in particular the pharmaceutical industry – must be strengthened and transparency and accountability ensured. Japan was providing technical cooperation to some developing countries to improve their access to medicines, but SSFFC products were always more affordable and accessible. Comprehensive measures to provide greater access to affordable, quality medicines were needed, including ensuring the integrity of the supply chain, developing more effective monitoring systems, raising public awareness and improving health systems. Japan would willingly join in international efforts to implement the new Member State mechanism.

Dr RONQUILLO (Philippines) asked the Committee to include in the draft resolution a reference to the importance of information-sharing among Member States and to reconsider use of the SSFFC rapid alert system to fight against counterfeit medical products. Regional regulatory

infrastructure and capacity must be strengthened in order to tackle cross-border regulatory issues and combat intelligence operations and terrorism. Participation on a voluntary basis in the proposed new mechanism would demonstrate Member States' commitment to its operation and funding.

Dr CUI Enxue (China) said that effective cooperation was required to combat SSFFC medical products, which posed a threat to human health. National medicine regulatory bodies should strengthen their information exchange and communication networks and enhance cooperation in order to bolster their capacities to prevent and control SSFFC products. A more accurate and more widely acceptable definition of SSFFC products was needed in order to combat them effectively. Furthermore, SSFFC products should be defined in accordance with national laws, taking into account the criteria of affordability, efficacy and safety. His Government welcomed the draft resolution, in particular the establishment of a mechanism to strengthen cooperation between the Secretariat and Member States, in which it planned to participate actively.

Ms MWAPE (Zambia), speaking on behalf of the Member States of the African Region, said that rapid globalization had exacerbated the long-standing problem of SSFFC medical products, from which no country was immune. Despite the complexity of the matter and the challenges arising from interpretation of terms, she was confident that agreement on working definitions could be reached quickly. WHO had a vital role to play in providing technical guidance, and its commitment to support national capacity-building was welcome, as was the proposal to establish a Member State mechanism. According to the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), counterfeiting was most prevalent in countries where regulatory and legal oversight was weak. The potentially lucrative business of counterfeiting attracted organized crime, and the penalties in most countries were not severe enough to act as a deterrent. Moreover, counterfeit medical products were becoming more difficult to detect owing to advances in manufacturing technology. Other challenges included flaws in the systems designed to manage pharmaceutical supply chains, corruption and lack of transparency in procurement practices, unregulated marketing of medicines on the Internet, and weak national and international cooperation mechanisms. The Member States of the Region pledged to join forces to combat the proliferation of SSFFC medical products and were willing to cooperate with WHO and other stakeholders at all levels to that end. They supported the draft resolution and expressed confidence that sufficient funds would be mobilized to support the establishment and operation of the Member State mechanism.

Dr ORHII (Nigeria), endorsing the draft resolution, said that no country was free from the current proliferation of SSFFC medical products, which undermined efforts in Africa to treat malaria, HIV/AIDS and tuberculosis. The situation was exacerbated by regulatory gaps and poor technical capacity in many countries. Access to safe, efficacious and affordable essential medicines of good quality was one of the most cost-effective aspects of modern health care and an important indicator of progress towards the health-related Millennium Development Goals; in contrast, lack of access could jeopardize the credibility of health care systems. Effective national and international cooperation was needed to combat the transnational criminal networks involved in counterfeiting. The establishment of the West African Drug Regulatory Authority Network, the appointment of independent analysts to re-certify drugs for export to Nigeria, and Nigeria's sustained campaign for an international convention against drug counterfeiting were changing the attitudes of regulators, the pharmaceutical industry and customs and crime-fighting organizations.

Dr SLAMET RIYADI YUWONO (Indonesia), speaking on behalf of the Member States of the South-East Asia Region, applauded the Organization's efforts to ensure the quality, safety and efficacy of medical products and promote access to affordable, safe and efficacious medicines of good quality. WHO should continue to support capacity-building and the strengthening of national and regional drug regulatory infrastructures, especially in developing and least developed countries. The

Organization also had a crucial role to play with regard to SSFFC medical products from a public health perspective, with the exception of trade and intellectual property issues. The draft resolution merited support, as did the proposed Member States mechanism, which should be transparent and inclusive and include expertise in national regulation of medical products.

Dr SHOHANI (Iraq) said that prevention and control of SSFFC medical products was an important aspect of food and health security. Iraq had set up an effective, law-based national system for the control of medical products that included selection procedures and a monitoring mechanism. Drug samples were analysed at national laboratories, and drugs were marketed only after tests based on international scientific criteria had proved their efficacy and ensured that they met quality standards. Drugs were purchased from approved providers and the process was continuously monitored. WHO had an important role to play in regularly compiling and circulating information on spurious products and companies. He endorsed the draft resolution.

Mr McIFF (United States of America) said that his delegation had participated in the Working Group and supported the draft resolution. It welcomed the proposed Member State mechanism and was committed to its success. SSFFC medical products were both a domestic and an international concern and represented a considerable share of the drugs used to treat serious diseases in some countries. Better surveillance and pharmacovigilance were required in order to collect the data needed to assess and manage all aspects of the problem. Drug counterfeiting and diversion, cargo theft and intentional adulteration were flourishing because of recent global changes. Greater cooperation between regulation and enforcement experts was needed to ensure proper manufacturing and distribution practices and deter criminal activity. The pharmaceutical industry had shifted manufacturing and supply sourcing operations into new geographical areas in recent years, resulting in a more complex supply chain that was providing new entry points for contaminated, adulterated and other substandard products. National regulatory systems and cross-border cooperation must therefore be strengthened. WHO was well positioned to lead the effort using a data-driven approach based on sound scientific evidence. He thanked the Government of Argentina for its offer to host the first meeting of the proposed Member State mechanism in November 2012 and supported the call for preparatory meetings in Geneva to ensure its success.

Dr BRENNEN (Bahamas) said that while the Bahamas did not have a large drug manufacturing sector, SSFFC medical products were traded into and out of the country. The situation was exacerbated by parallel importation without appropriate documentation, and weak regulatory capacity. The Working Group had recommended the creation of national networks with international links and national programmes to prevent counterfeiting, which would include training plans and indicators. At the same time, greater support would be needed from the international community to ensure that standards in manufacturing countries were the same as those in importing countries. Small island developing countries found it difficult to set up the requisite drug testing facilities in each territory, and support was needed to promote harmonization of legislative and regulatory frameworks and to build pharmacovigilance capacity. The Bahamas would welcome cooperative agreements to take that process forward. Convinced that the programmes endorsed by the Working Group would benefit countries in their combat against SSFFC medical products, he endorsed its report and the draft resolution pertaining to it. He urged the Secretariat to take into account the particular challenges faced by small island States such as his own.

Mr AGHAZADEH KHOEI (Islamic Republic of Iran) commended the Working Group's efforts and endorsed the goals, objectives and terms of reference of the proposed Member State mechanism. He urged the Director-General to expedite its establishment and to provide it with the necessary operational support. The new mechanism should be the sole official international mechanism for preventing and controlling the production of medical products that were compromised in terms of

quality and safety and should enhance collaboration between Member States and the Secretariat. WHO should continue building the capacity of national drug regulatory authorities and health systems. Nevertheless, the lack of sufficient funding for WHO's work concerning the quality, safety and efficacy of medicines was a serious concern.

Mr SILLO (United Republic of Tanzania) reported that his country had taken a number of steps to strengthen its national drug regulatory systems. Its quality control laboratory, run by the national food and drugs authority and prequalified by WHO in 2011, played a critical role in testing suspected SSFFC medical products in the African Region. National efforts were complemented by the East African Community Medicines Registration Harmonization Project, launched in March 2012 with the aim of harmonizing medicines registration with recognized policies and standards. He commended WHO's efforts to prevent and control SSFFC medical products which, despite the progress made, remained a major public health concern. His own country, for example, had recently discovered that quinine tablets containing metronidazole rather than quinine sulfate were being used to manage severe and life-threatening malaria in unsuspecting impoverished patients. Endorsing the draft resolution, he urged the Secretariat to convene the first meeting of the proposed Member State mechanism as soon as possible to ensure rapid implementation of the resolution, in which regional and subregional groups would have a critical role to play.

Ms POLL (Costa Rica) said that SSFFC medical products could have serious consequences for patients; every effort must therefore be made to prevent their production, distribution and consumption. Fortunately, her country had managed to counter serious threats in that area: efforts to introduce SSFFC products had been detected and their distribution prevented. Health authorities in Costa Rica were currently cooperating with other sectors and with international organizations such as INTERPOL to improve the country's prevention and control system, under which criminal penalties could be applied. She supported WHO's coordinating role in promoting national measures to ensure the availability of safe and efficacious medical products of good quality, and endorsed the proposed Member State mechanism. The international community, working with WHO, must set up mechanisms to identify the criminal organizations responsible for trade in SSFFC medical products. Training in that regard would be needed to establish effective cooperation networks among Member States.

Mr BEN AMMAR (Tunisia), speaking on behalf of the Member States of the Eastern Mediterranean Region, agreed that SSFFC medical products represented a danger to all countries, particularly when they could be obtained through public and private health systems and in pharmacies. Even registered distributors were sometimes found to be involved in the distribution of SSFFC medical products, and they were now being encouraged to cooperate in efforts to determine the source. The growing international trade in medical products, especially through the Internet, was facilitating the entry into the market of compromised products. The Region needed greater resources to meet the challenges it faced, which included absence of appropriate legislation, lack of cooperation between legislative bodies and law enforcement and customs officials, and reduced national representation at international meetings. Furthermore, priority should be given to: mobilizing sufficient resources to fund WHO field activities; identifying differences between procedures used for manufacturing and marketing SSFFC medical products and those for legal drugs; and adopting a unified Member State position on combating related criminal activities. He endorsed the proposals to establish a Member State mechanism and to set up a subcommittee of the WHO Expert Committee on Specifications for Pharmaceutical Preparations to give technical advice on SSFFC medical products.

Dr TSECHKOVSKY (Russian Federation), endorsing the draft resolution, said that his country had had first-hand experience with SSFFC medical products and attached great importance to the establishment of appropriate international cooperation to combat the threat they posed, especially in

view of the global nature of the production and distribution process. Studies were needed to determine the extent to which SSFFC products were available since they were capable of undermining the authority of public health systems. The 2011 Medicrime Convention,[1] which was the first pan-European instrument on counterfeiting of medical products, gave priority to protecting public health and stressed the importance of international cooperation, information exchange and coordination of activities. The global monitoring and integrated notification system established under the aegis of WHO should increase the effectiveness of measures to combat trafficking in SSFFC products and create new prevention opportunities.

Dr ST. JOHN (Barbados), endorsing the draft resolution, said that efforts must be made to ensure that the definition of counterfeit medical products did not cause generic competition to shrink, since that would result in higher prices and reduced access to medicines. She urged the Director-General to continue supporting national drug regulatory and inspection authorities in order to ensure their capacity to prevent licensing and entry of SSFFC products and, if necessary, to remove them from the market. Other challenges included bridging the Organization's funding gap for its work in prevention and control of SSFFC products; providing additional resources for the pharmacovigilance training launched by WHO in the Caribbean region in 2006; expanding the WHO drug prequalification programme to new products; and ensuring continued WHO support for national efforts to monitor good manufacturing practices in drug producing countries. The Pan American Network for Drug Regulatory Harmonization was a potential source of support but tapping it would require language training for the region's English-speaking countries. She hoped that the joint WHO/European Union renewed Partnership on Pharmaceutical Policies would be launched soon since Barbados still had work to complete under that programme. She asked WHO to facilitate training on Internet pharmacy regulation in all Member States. The Caribbean Pharmaceutical Policy, approved by CARICOM in April 2011, should be supported.

Mr DESIRAJU (India) said that for the past two years, Member States had been seeking innovative solutions to combat the growing international trade in SSFFC medical products. The draft resolution and, in particular, the proposal to establish a Member State mechanism, was welcome in that regard. Once the mechanism had been set up, WHO should dissociate its activities from those of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT). Cooperation between the Member State mechanism and other partners would be beneficial but the mechanism's first task was to review the definitions, which still needed clarification. Further information from the Secretariat in that regard would be appreciated.

(For continuation of the discussion, see the summary record of the fifth meeting.)

The meeting rose at 17:30.

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[1] The Council of Europe Convention on counterfeiting of medical products and similar crimes involving threats to public health, signed in Moscow in October 2011.