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SIXTY-NINTH WORLD HEALTH ASSEMBLY

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COMMITTEE B

PROVISIONAL SUMMARY RECORD OF THE FIFTH MEETING

Palais des Nations, Geneva
Friday, 27 May 2016, scheduled at 14:30

Chairman: Dr M. KIFLE (Ethiopia)
later: Dr PHUSIT PRAKONGSAI (Thailand)

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FIFTH MEETING

Friday, 27 May 2016, at 14:35

Chairman: Dr M. KIFLE (Ethiopia)
later: Dr PHUSIT PRAKONGSAI (Thailand)

HEALTH SYSTEMS: Item 16 of the agenda (continued) [transferred from Committee A][1]

Follow-up to the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination – Report of the open-ended meeting of Member States: Item 16.2 of the agenda (document A69/40) (continued)

The representative of SWITZERLAND said that it was regrettable that more progress had not been made towards establishing a suitable system for funding and coordinating health research and development. She welcomed the establishment of the Global Observatory on Health Research and Development, the development of a conceptual framework for the pooled fund for voluntary contributions, and the fact that funding had been secured for some of the demonstration projects. However, the pool of contributors was limited, funding had not been secured for all demonstration projects and the Global Observatory continued to lack the funding it required. In order to make further progress, it was necessary to focus on the principle of shared responsibility, with greater involvement of middle- and low-income countries. She welcomed the contributions made by Brazil, India and South Africa to the pooled fund, but pointed out that Switzerland's contribution of US$ 1.5 million in matching funds remained unused.

The research and development agenda could not afford to fail, especially since it was an integral part of the 2030 Agenda for Sustainable Development. Thus, it was essential to continue developing and to secure sustainable funding for the Global Observatory, establish a priority-setting procedure for health research and development, draw up a new plan for the implementation of the voluntary pooled funding mechanism, and mobilize additional funding for demonstration projects. Political will on the part of all would be needed to achieve those objectives. Member States must take action to ensure that people suffering from neglected tropical diseases would, at last, have access to needed medicines.

The representative of SOUTH AFRICA expressed satisfaction with the progress reported. The coordination mechanism would enhance policy coherence in research and development work, and would contribute to achieving Sustainable Development Goal 3 on healthy lives for all. The Global Observatory had an important role to play in monitoring and providing needed information. However, care must be taken to ensure that work on other aspects of the strategic workplan agreed under resolution WHA66.22 (2013) was not neglected or delayed while the Global Observatory was being consolidated. It was disappointing that funding had been allocated for only three demonstration projects; there should be a clear and transparent method of allocating resources. The funding gap required urgent attention.

He supported the inclusion of funding for health research and development in the financing dialogue. A voluntary financing mechanism was unlikely to be sustainable and could hamper progress. The voluntary financing system should be reviewed after a trial period and, if it had proved ineffective, a mandatory approach should be considered. Greater commitment from Member States

[1] See the summary record of the General Committee, first meeting, section 2.

and partners was needed to finance the full implementation of the important work on research and development. He supported the draft resolution.

The representative of the DEMOCRATIC REPUBLIC OF THE CONGO, welcoming the Expert Working Group's recommendations put forward in its report, said that research could contribute to a wide range of issues relating to the achievement of universal health coverage. Given the scarcity of resources, it was essential for countries to establish partnerships with research institutions to identify priority areas where research was needed to provide evidence to inform health policy-making.

The representative of IRAQ said that resources for research and development should be allocated from the biennial budget at regional and country levels.

The observer of CHINESE TAIPEI wholeheartedly supported the plan to strengthen international health research and development capacity and invest in research on diseases disproportionately affecting developing countries. The improvement of monitoring mechanisms and coordination would be important steps towards ensuring sustainable funding for that purpose. Chinese Taipei was prepared to increase investment in health research and development for developing countries and to share its research technologies, including its capacity to develop and produce a wide range of vaccines and medicines. It was currently focusing on the development of new tools and technologies for the control of dengue. Chinese Taipei wished to play an active role in building a more resilient global health system with a view to achieving universal health coverage.

The representative of MÉDECINS SANS FRONTIÈRES, speaking at the invitation of the CHAIRMAN, said that the decision of the United Nations Secretary-General to launch a High-Level Panel on Access to Medicines had highlighted the failings of the research and development system. Access to medicines was a global challenge and a structural problem that could not be addressed by countries acting alone; global coordination and agreement were needed. Research and development must be needs-driven and evidence-based and its cost must be de-linked from market prices. Ensuring affordable, efficient and equitable access to medicines should be seen as a shared responsibility. Decisive action was needed, particularly on the part of governments. The broken research and development system was a problem that governments had created and one that, ultimately, only they could solve. She urged Member States to commit to organizing an intergovernmental conference on research and development before the Seventieth World Health Assembly in 2017 with the aim of ensuring policy coherence.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that de-linking research and development costs from drug prices could promote greater openness and exchange of knowledge and ensure that research and development investments were more cost-effective and responsive to the needs of patients and of society. If the current global research and development financing system, which depended on monopolies and high prices, was to be replaced, new ways of funding research and development must be found and global agreements on funding reached. However, it was difficult to persuade governments to fund research and development. WHO should convene a meeting to identify incentives for inducing Member States to fund medical research and development as a public good. The Global Observatory should be adequately funded and should collect and publish data on research and development costs, as well as the terms of licences for publicly funded research and development.

The representative of MEDICUS MUNDI INTERNATIONAL (INTERNATIONAL ORGANIZATION FOR COOPERATION IN HEALTH CARE), speaking at the invitation of the CHAIRMAN, said that a sustainable research and development system must be guided by the

principles of effectiveness, efficiency and equity and grounded in the concepts of de-linkage and knowledge-sharing. The Global Observatory's work should form part of a broader framework, encompassing not only neglected tropical diseases, but also antimicrobial resistance and noncommunicable diseases. Policy coherence and effective coordination should be ensured among all WHO-led research and development initiatives, including the proposed research blueprint for emerging pathogens and the global action plan on antimicrobial resistance. He urged Member States to send a clear message by acknowledging that the current monopoly-based system was unsustainable and limited access to medicines for those in need and to take decisive action. The world could not afford 10 more years of idle discussions.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS, speaking at the invitation of the CHAIRMAN, said that it was necessary to focus on practical and politically feasible proposals. Protection of intellectual property rights remained central to the development of new medicines. Nevertheless, new models, such as product development partnerships and patent pooling, had yielded positive outcomes in patients' access to medicines. Such collaborative approaches had led to real progress in tackling HIV, malaria and neglected tropical diseases. Future solutions should be designed to meet specific problems; a one-size-fits-all approach would not work. Overcoming barriers to access should be achieved through a holistic approach, encompassing not only research and development models, but also financing, investment in infrastructure and enhancement of workforce capacity.

The representative of the DRUGS FOR NEGLECTED DISEASES INITIATIVE, speaking at the invitation of the CHAIRMAN, said that the current discussion offered an opportunity to consider four actions for redressing the failures of the current system for financing medical innovation and for putting in place a sustainable and efficient innovation system. To that end, Member States should consider requesting the Secretariat to establish a priority-setting mechanism; ensure that the Global Observatory was sustainably funded and covered all important areas of public health; ensure that pooled funds covered all areas of need, focused on agreed priorities and applied the principles advocated by the Consultative Expert Working Group, including de-linkage; and develop an overarching framework covering all research and development stakeholders and all areas of public health importance. It should also be asked to organize an intergovernmental conference on policy coherence in the field of research and development.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) acknowledged the undoubted progress since 2013, but lack of funding, especially for the implementation of the demonstration projects, remained a major obstacle. Responding to specific points raised in the discussion, she said that the aim of the Global Antibiotic Research and Development Partnership was to develop new antibiotic treatments, promote responsible use of antibiotics and ensure access to those medicines for all. The Partnership's incubation project was a joint undertaking of WHO and the Drugs for Neglected Diseases initiative, which aimed to achieve some of the objectives of WHO's global action plan on antimicrobial resistance. In December 2015, the Board of Directors of the Drugs for Neglected Diseases initiative had agreed to host the Partnership for a start-up phase of two years and to provide the necessary scientific environment and infrastructure to ensure an effective incubation period. During that period, the project would come under the current governance structure of the Drugs for Neglected Diseases initiative; no decision had been made as yet about future governance arrangements. WHO would provide technical input on the identification of global health needs, financing strategies, target product profiles, the identification of research and development portfolios, the governance structure of a future entity, and access and conservation strategies for new antimicrobial medicines.

Important roles for WHO in the field of research and development included convening stakeholders, taking the lead in analysing research gaps – the responsibility of the new Global

Observatory, and making recommendations on priorities through the proposed coordination mechanism. The Secretariat was willing to assume responsibility for those roles. Supporting research and development for Type II and Type III diseases, and for the specific needs of developing countries with regard to Type I diseases, was the shared responsibility of all countries, rich and poor. That mandate had been reinforced by the commitment made by all countries to meeting the Sustainable Development Goals. She called upon all Member States to support the important work under way, especially the demonstration projects. Although the financial shortfall of just over US$ 70 million seemed huge, it was a mere drop in the ocean of global investment in research and development.

The CHAIRMAN said that consideration of the draft resolution on the item would be deferred until the drafting group had completed its work.

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

Dr Phusit Prakongsai took the Chair.

Substandard/spurious/falsely-labelled/falsified/counterfeit medical products: Item 16.3 of the agenda (document A69/41)

The representative of NIGERIA, speaking on behalf of the Member States of the African Region, said that the circulation of substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products had increased to such an extent that it severely threatened public health in the African Region. Significant steps had been taken by the Region to tackle SSFFC medical products, including the establishment of a regional plan of action, the establishment of the Medicines Anti-Counterfeit Committee of the Economic Community of West African States, and the introduction of the WHO global surveillance and monitoring system in more than 33 Member States.

In total, 46% of all reported cases of SSFFC medical products were from the African Region, consisting mainly or antimalarial, antiparasitic, antibiotic and emergency contraceptive medical products, some of which had been falsely labelled as WHO-prequalified products. To counter the negative impact of SSFFC medical products on public health and socioeconomic development, there was a need to build capacity to ensure oversight and regulation; put in place single points of contact and build national capacity, including in the use of information and communication technology to track and trace those products; build effective collaboration in oversight within and between Member States to ensure the security of the supply chain; and strengthen the capacity of regulatory authorities and national quality control laboratories. Support was also needed to enable countries to meet their requirements in relation to medical products and to strengthen national ownership of control mechanisms. The Secretariat should ensure sufficient funding for the Member State mechanism.

The representative of the BOLIVARIAN REPUBLIC OF VENZUELA, speaking on behalf of the Members of the Union of South American Nations, said that the Member State mechanism had yielded significant results, including valuable guidance on track and trace models and recommendations for detecting and dealing with actions, activities and behaviours that could give rise to SSFFC medical products. The mechanism's work should be supported by the Secretariat, and transparency and a focus on public health should be ensured. The latter was of crucial importance in the context of WHO's interaction with non-State actors and the emergence of external initiatives that sought to link the debate on SSFFC medical products with third parties whose interests were not always consistent with public health interests. The work of the mechanism must remain within WHO in order to ensure a continued focus on public health. He urged the Secretariat and Member States to redouble their efforts to ensure the allocation of sufficient resources to enable the mechanism to continue to operate.

The representative of IRAQ highlighted WHO's role in the sponsorship of companies producing drugs and medical products and the need for regular reporting thereon. WHO should support capacity-building in Member States for registration of medicines, vaccines and other medical products. Capacity-building was also needed to enhance monitoring and evaluation of medical products and the capacity of quality control laboratory personnel. With the support of WHO, knowledge should be exchanged at the intra- and inter-regional levels. Community health education on the issue was also vital.

The representative of INDIA said that the recent establishment of the global focal point network on SSFFC medical products would facilitate the timely exchange of information among national medical regulatory authorities. In addition, the finalized draft document on track and trace technologies (document A69/41, Appendix 2) would assist Member States in selecting the appropriate technology for the national context. He welcomed the decision to establish a working group of experts on refining the working definitions of SSFFC medical products, which would bring much needed clarity and a shared understanding, which in turn would increase the transparency of the activities of the WHO global surveillance and monitoring project. It would also provide needed guidance to other United Nations bodies working in the area of SSFFC medical products.

The document on the actions, activities and behaviours that fell outside the mandate of the Member State mechanism, for which India was responsible, had not yet been finalized. The issue of transit, in particular, required further discussion, particularly given the recent trend to include provisions relating to in-transit scrutiny in regional regulations and trade agreements, which might conflate the issue of trademark infringements with that of SSFFC medical products and thereby hinder access to legitimate generic medicines. Regulatory capacity should be strengthened in order to enforce appropriate quality control; at the same, measures should be taken to improve access to affordable, high-quality medicines. He welcomed the proposed study to increase the understanding of the links between the prevalence of SSFFC medical products and lack of access to affordable medicines.

The representative of INDONESIA, welcoming the effort to refine the definitions used in the work on SSFFC medical products, said that, in order to eradicate such products, a multistakeholder approach was essential, as was effective risk communication and awareness-raising. A robust system to identify such products had been introduced at the national level and a single point of contact had been established. A clear identification of the activities that fell within and outside the mandate of the Member State mechanism was needed to minimize the risk of inefficient use of resources.

The representative of the REPUBLIC OF KOREA said that, in order to halt the distribution of illegal medical products, Member States needed to cooperate closely and reach consensus on a clear definition of SSFFC medical products and on the best ways to regulate them. Monitoring systems, including quality control mechanisms and "track and trace" processes, should be established at the local level. Her country had implemented a range of measures to tackle SSFFC medical products, such as the introduction of strict measures to prevent the entry of illegal medical products, promotion of the safe use of medical products and collaboration with industry to encourage self-regulation. It was participating actively in international collaborative efforts to eradicate SSFFC medical products.

The representative of the PHILIPPINES, referring to her Government's active involvement in discussions on the WHO MedNet platform, said that a forum for information-sharing and dialogue among national regulatory authorities would enhance efforts to combat SSFFC medical products. The recommendations to be developed by the proposed working group on effective risk communication and awareness-raising campaigns would enhance existing national advocacy activities. Efforts to tackle SSFFC medical products must focus on demand as well as supply. The proposed study on the public health and socioeconomic impact of SSFFC medical products would be a useful tool to provide an accurate picture of the scope and extent of the problem and to guide future efforts.

The representative of the UNITED REPUBLIC OF TANZANIA, welcoming the creation of a focal point network for consultation and the exchange of information and the publication of the draft document on track and trace technologies, called on the Secretariat and the Member State mechanism to expedite the completion of that work. His Government had taken steps to strengthen the national medicines regulatory system and had played a leading role in the implementation of the East African Community Medicines Regulatory Harmonization Programme. A national plan of action to combat SSFFC medical products would be finalized in 2016. He urged the Secretariat and the mechanism to fast-track the finalization of the framework/guidelines on developing a national plan for preventing, detecting and responding to SSFFC medical products, and called for additional funding to sustain the work of the mechanism and the Secretariat on the issue.

The representative of KENYA commended the efforts of the Secretariat and the Member State mechanism in tackling SSFFC medical products and encouraged Member States to continue supporting those efforts. He welcomed the establishment of the global focal point network for the exchange of information and consultation and urged Member States to consider adopting the existing set of global identification and serialization standards.

The representative of SRI LANKA said that the establishment of global and regional networks connecting customs and border protection officials would serve to enhance collaboration and information-sharing and help to prevent smuggling and other illegal activities. An effective global drug-testing laboratory network should also be established. Educating the public on the issue of SSFFC medical products was also important.

The representative of ETHIOPIA said that a range of intervention strategies had been implemented in his country based on the findings of a recent national study conducted in collaboration with WHO on the status of SSFFC medical products, including the revision and strengthening of regulatory legislation, the reinforcement of import and export procedures and increased cross-border collaboration. Nevertheless, challenges remained. Acknowledging the efforts of the Director-General and the Member State mechanism, he called for priority to be accorded to enhancing technologies for detecting SSFFC medical products. His Government remained committed to the work of the mechanism.

The representative of THAILAND said that the global focal point network would provide a vital link with the WHO global surveillance and monitoring system for SSFFC medical products. Lack of clear definitions had hindered the work on such products, and she therefore encouraged the Secretariat and the Member State mechanism to accord priority to refining the working definitions. Member States should submit timely feedback for the review of the mechanism to be conducted in 2017, pursuant to resolution WHA65.19 (2012).

The representative of NIGER said that her Government had launched an extensive campaign to raise public awareness of SSFFC medical products. In order to eradicate such products, WHO should support countries in establishing a multisectoral approach with multistakeholder involvement, including ministries of trade and law enforcement and customs authorities.

The representative of SENEGAL noted that his country was a member of the Member State mechanism and actively participating in the working group tasked with developing and leveraging existing recommendations for effective risk communication and for awareness campaigns on SSFFC medical products and related actions, activities and behaviours. His Government had established a national committee to tackle such products and illegal pharmacy practices and was developing a national awareness-raising programme. He called on the Secretariat to make available increased resources to enable all countries to more effectively combat the scourge of SSFFC medical products.

The representative of CHINA underlined the need for a standardized approach to the value chain, in addition to early detection and control of SSFFC medical products. Technical exchanges on detection and risk assessment should be encouraged and the work on refining the definitions of SSFFC medical products should be completed as soon as possible. His Government was developing guidelines to combat such products based on experience and best practices. China stood ready to continue working with other Member States to tackle the problem of SSFFC medical products and encouraged increased international cooperation.

The representative of SOUTH AFRICA supported the proposals to develop guidelines for national plans for preventing, detecting and responding to the threats posed by SSFFC medical products, which would harmonize the procedures to be adopted. The guidelines might also be incorporated into national legislation. She also supported the establishment of a global focal point network which, by facilitating information-sharing among Member States, would allow the extent of the problem to be understood and interventions to be designed. The information on track and trace models was welcome. Implementing such systems was complex and costly, however, and low-cost options should be explored. Member States and manufacturing companies would need to agree on a common system that could be easily used by all. Member States should, as a matter of priority, submit training materials to be incorporated into the guidelines under development and appoint focal points for information-sharing.

The representative of ARGENTINA said that it was not clear whether the terms of reference for the global focal point network contained in Appendix 1 of the Member State mechanism's report were definitive or were intended to serve as a starting point for discussion. The proposed study on the public health and socioeconomic impacts of SSFFC medical products would require a robust methodological framework. The Member State mechanism should continue working to reach consensus on key issues, such as the transit of SSFFC medical products, which could have an impact on the international circulation of generic active ingredients. She supported the Member State mechanism's decision to allow the Secretariat to observe on a provisional basis meetings of the global steering committee for quality assurance for health products. As requested by the mechanism, the Secretariat should provide a report on the global steering committee, including documents and information on its nature, legal status, governance and participants.

The representative of BURUNDI said that, although the development of generic pharmaceuticals had improved access to and reduced the price of medicines, the parallel rise in false and counterfeit products had caused a rise in deaths and iatrogenic illnesses. In Burundi, concrete measures had been taken to tackle the problem, including independent laboratory testing of medicines purchased with public funds; the publication of a quality assurance manual for essential medicines; a system to ensure the quality of medicines for malaria, HIV and tuberculosis; and random sampling and testing of medicines at the point of distribution.

The representative of TUNISIA said that the global focal point network would facilitate information exchange and improve monitoring of SSFFC medical products. Countries should establish national mechanisms and laws to prevent the distribution of such products. Her country had launched a programme to monitor the production of a wide range of medical products and was also monitoring the provision of medicines at dispensary level.

The representative of MALAYSIA said that her country used security labels to help to identify SSFFC medical products and planned to introduce a track and trace system. She hoped that the Secretariat would help to coordinate further dialogue on such systems so that Member States could find a common platform and make better use of information technology to counter SSFFC medical products.

The representative of MOROCCO said that his Government had taken several measures to ensure access to high-quality medicines, including the establishment of a price control system and the introduction of regulations facilitating the registration of generic medicines. Morocco had ratified the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health in 2016.

The representative of COSTA RICA, referring to the proposed terms of reference for the global focal point network contained in Appendix 1 of the Member State mechanism's report, proposed several modifications to the provisions regarding the designation of focal points. Subparagraph 7(b) should encourage Member States always to designate a deputy focal point who could perform the functions of the focal point in the event that the latter was not available. The two officials should be appointed by the highest authority within the institution that was to house the focal point. Subparagraph 7(f) should indicate that the nominated national focal point must be trained on the use of the WHO global surveillance and monitoring system. Likewise, subparagraph 7(i) should state that focal points must be trained in the use of an electronic platform to be created and administered by the WHO Secretariat. The current text read "should be trained" in both cases, but focal points should be required to have such training.

The representative of the RUSSIAN FEDERATION said that her Government supported the establishment of intergovernmental policy and the exchange of information on SSFFC medical products. It was important to support the future development of the monitoring and surveillance system as a structural component of national plans to monitor pharmaceutical products and detect SSFFC medical products and other measures to minimize the risks posed by such products to public health. The Russian Federation was, on the basis of WHO recommendations, planning to introduce a track and trace system.

The observer of CHINESE TAIPEI said that attempts to prevent the circulation of SSFFC medical products could not rely solely on the power of health authorities; other government departments must also be involved. Chinese Taipei had enhanced its inspection system and planned to introduce a traceability system. It was also conducting outreach activities to inform the public about SSFFC medical products and safety of medicines. Through a series of integrated efforts, the problem of SSFFC medical products had been significantly reduced in Chinese Taipei.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, welcomed the development of track and trace models and viewed with interest the development of initiatives aimed at authenticating medicines at the point of dispensing or purchase. Such tools, especially when developed in collaboration with health professionals, could help to improve vigilance and enhance confidence in medicines. WHO's medical product alerts could serve as important tools for health professionals. A similar initiative for medical and dental devices would be welcome. To address the lack of awareness of the risks associated with obtaining medicines through unsafe, illegal or non-legitimate sources, the World Health Professions Alliance was developing interactive educational videos, which would be available in mid-2016.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that SSFFC medical products could undermine trust in health systems and compromise physicians' ability to build strong therapeutic alliances with their patients. Action to tackle the problem should not only target the supply side of the issue, but also involve stakeholders on the demand side. She called on governments to promote professional education on SSFFC medical products for health workers, many of whom lacked knowledge on the issue, and to develop an effective public outreach and education campaign to inform consumers about the health risks of such products.

The representative of MEDICUS MUNDI INTERNATIONAL (INTERNATIONAL ORGANIZATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, said that the broad term "counterfeit" inappropriately conflated the public health problem of spurious and substandard medicines with asserted breaches of intellectual property rights. The confusion of efficacious and affordable generic medicines with substandard products had led Member States to adopt measures that reduced access to vital medicines. The term "SSFFC" had been in use for six years, although it was supposed to have been temporary. Lack of a clear definition was hindering evidence-based policy-making. She urged the Secretariat to publish the complete datasets and methodology applied in the recently commissioned socioeconomic impact study on SSFFC medical products in order to ensure transparency. She also urged it to reflect critically on whether its participation in the global steering committee for quality assurance of health products might run counter to its efforts to ensure impartial approaches to SSFFC medical products.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, said that the Fight the Fakes initiative, in which her organization was a partner, offered support to Member States in increasing awareness and understanding of, and protecting patients from, fake medicines. Coordination among all actors was vital to tackle the risk posed by SSFFC medical products to public health. She welcomed the efforts of the Member State mechanism in exchanging best practices and experiences at the national, regional and global levels. Her organization was ready to contribute to those efforts and share expertise.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation), expressing gratitude to the members of the Member State mechanism for their hard work, said that strong participation by technical experts from national regulatory authorities from all regions in the various working groups was needed. The Secretariat would continue to expand the global surveillance and monitoring system for SSFFC medical products. To date, 115 national regulatory authorities had been trained in the use of the system, and more than 1100 SSFFC medical products had been reported in the first three years. Further regional workshops were planned to train more personnel in the use of the system. The system would provide technical support and practical tools while gradually accumulating a body of evidence which could be used to improve vigilance and focus investment.

Responding to specific points, she said that the Secretariat recognized the need to maintain transparency and exclude commercial interests. It looked forward to working with technical experts from all Member States to improve and refine definitions. The final draft of the socioeconomic study would be submitted to the Member State mechanism by the end of 2016. Work was under way to improve capacity in laboratory facilities. Communication, awareness-raising and collaboration were the first steps in combatting the global problem of SSFFC medical products. She looked forward to the results of the review of the Member State mechanism, which would be reported to the Seventieth World Health Assembly in May 2017.She thanked Member States that had contributed funding and in-kind support to the mechanism and affirmed the Secretariat's commitment to engaging in dialogue with Member States on how to ensure adequate future funding.

The Committee noted the report.

Addressing the global shortages of medicines, and the safety and accessibility of children's medication: Item 16.4 of the agenda (document A69/42)

The CHAIRMAN said that two draft resolutions had been proposed for consideration under the agenda item. The first, on promoting innovation and access to quality, safe, efficacious and affordable medicines for children, had been proposed by the delegations of China, Malaysia, Pakistan and Thailand and read:

The Sixty-ninth World Health Assembly,

PP1 Having considered the report on addressing the global shortages of medicines, and the safety and accessibility of children's medication;[1]

PP2 Recalling resolution WHA60.20 (2007) on better medicines for children and WHA67.22 (2014) on access to essential medicines, which identified actions for Member States and the Director-General in support of better access for children to essential medicines;

PP3 Recalling also resolution WHA67.20 (2014) on regulatory system strengthening for medical products and its relevance for promoting safety, accessibility and affordability of medicines for children;

PP4 Concerned about the lack of access to quality, safe, effective and affordable medicines for children in appropriate dosage forms and problems with rational use of children's medicines in many countries, and that, globally, children under age five still do not have secure access to medicines that treat pneumonia, tuberculosis, diarrhoeal diseases, HIV infection, AIDS and malaria, as well as medicines for many other infectious diseases, noncommunicable diseases and rare diseases;

PP5 Concerned about the lack of research and development on age appropriate dosage forms most suitable for children as well as for new medicines for diseases that affect children, that are appropriate for use in all environments, including areas lacking access to clean water;

PP6 Aware that an important factor linked to morbidity and mortality of children is the lack of safe, effective, affordable and quality-assured medicines for children, and in some circumstances, lack of packaging in child-proof containers;

PP7 Noting that despite sustained efforts over a number of decades by Member States, the WHO Secretariat and partners, many countries are still facing multiple challenges in ensuring the availability, affordability, quality assurance and rational use of children's medicines;

PP8 Acknowledging Goal 3 of the 2030 Agenda for Sustainable Development, "Ensure healthy lives and promote well-being for all at all ages" particularly noting the targets related to access to medicines, and its interlinked goals and targets;

PP9 Noting that the WHO World Health Report 2010 identified the promotion of generic medicines as a key action that could be taken to improve access by making medicines more affordable and recognizing the importance of accelerating generic availability and uptake following the expiration of patents;

PP10 Recalling the Convention on the Rights of the Child in which States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illnesses and rehabilitation of health,

(OP1) URGES Member States:[2]

(1) to accelerate implementation of the actions laid out in resolution WHA60.20 on better medicines for children and WHA67.20 on regulatory system strengthening for medical products;[3]

(2) to learn from successful experiences with medicines policies for children in other countries and formulate and implement appropriate national measures including legislation as appropriate, and pharmaceutical policies in support of access to quality, safe, effective and affordable medicines for children;

[1] Document EB138/41.

[2] And, regional economic integration organizations, as appropriate.

[3] Taking into account the context of federated states.

(3) to take all necessary measures, including legislation as appropriate for establishment of national plans and organizational structures and capacity to enhance such measures in the framework of national pharmaceutical policies as appropriate, to improve children's health;

(4) to ensure that national health policies and plans incorporate consideration of the needs of children based on the national situation, with clear objectives for increasing access to children's medicines;

(5) to establish transparent and evidence-based processes for the designing and updating of their national essential medicines list or its equivalent to include medicines for children, according to each country's health needs and priorities, taking into account the WHO model list of essential medicines, including the WHO model list of essential medicines for children, and its transparent and evidence-based process which considers public health relevance, evidence on efficacy and safety and comparative cost–effectiveness;

(6) to implement actions agreed under Sustainable Development Goal 3, with a focus on children, which states: Support the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health and, in particular, provide access to medicines for all;

(7) to undertake analysis of their pharmaceutical supply systems, including through the use of the WHO standardized surveys, to identify inefficiencies in the cost and pricing structures of medicines and sources of mark-ups on the prices of medicines, and to seek to reduce the price of children's medicines by promoting greater availability and use of generics, and identifying strategies to reduce prices including mark-ups on medicines, in order to increase availability and affordability of medicines for children;

(8) to strengthen research and development of appropriate medicines for diseases that affect children, to ensure that high quality clinical trials for these medicines are conducted in an ethical manner and to collaborate in order to facilitate innovative research and development on, formulation of, and timely regulatory approval of, provision of adequate and prompt information on, and rational use of, medicines for children, including generic medicines;

(9) to facilitate clinical trials of medicines for children based on sound ethics, needs, principles of patient protection, [and to promote clinical trial registration in registries recognized by the WHO international clinical trials registration platform (ICTRP)] and to make information on those trials publically available, including publication of summary and complete data of completed trials in accordance with national and regional legislative frameworks as appropriate;

(10) to strengthen national regulatory systems including pharmacovigilance and post-market surveillance and to promote quality, ethical clinical trials of medicines for children and the accessibility and availability of quality, safe, effective and affordable medicines for children;

(11) to enhance the health workforce education and training in rational use of medicines for children, including generic medicines, and to enhance the health education of the public, to ensure acceptance and understanding of rational use of medicines for children;

(OP2) REQUESTS the Director-General:

(1) to accelerate implementation of the actions laid out in resolutions WHA60.20 on better medicines for children, WHA67.22 on access to essential medicines and WHA67.20 on regulatory system strengthening for medical products;

(2) to further develop and maintain within the Model List of Essential Medicines, the list of Essential Medicines for Children (EMLc) using evidence-based clinical guidelines in coordination with all relevant WHO programmes;

(3) to consider appropriate representation of paediatric experts on the WHO Expert Committee on Selection and Use of Essential Medicines;

(4) to support Member States in taking appropriate measures through provision of training and strengthening regulatory capacity according to national and regional circumstances, and in promoting communication and coordination between countries on paediatric clinical trial design, ethical approval and product formulation, including through regulatory networks;

(5) to continue to collaborate with governments,[1] other organizations of the United Nations system, including WTO and WIPO, donor agencies, nongovernmental organizations and the pharmaceutical industry in order to encourage fair trade in safe and effective medicines for children and adequate financing for securing better access to medicines for children;

(6) to support Member States in implementing, as appropriate, upon request, standards for ethical and appropriate clinical trials of medicines in children, and to facilitate communication and coordination among Member States[1] to promote the sharing of paediatric clinical trial information;

(7) to support analysis and better understanding of costs of research and development for medicines of children, including for rare diseases in children;

(8) to support countries in implementing relevant policies in line with the 2030 Agenda for Sustainable Development including Goal 3 and related access to medicine targets, and to provide necessary technical assistance in this regard upon request;

(9) to report to the Seventy-first World Health Assembly on progress in the implementation of this resolution.

The financial and administrative implications for the Secretariat of adoption of the draft resolution were as follows:

Resolution: Promoting innovation and access to quality, safe, efficacious and affordable medicines for children
A. Link to the general programme of work and the programme budget
1. Please indicate to which impact and outcome in the Twelfth General Programme of Work, 2014–2019 and which output in the Programme budget 2016–2017 this draft resolution will contribute if adopted. Twelfth General Programme of Work: outcomes 3 and 4.3.1.

[1] And, regional economic integration organizations, as appropriate.

2. If there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017, please provide a justification for giving consideration to the draft resolution.

Not applicable.

3. What is the proposed timeline for implementation of this resolution?

From the fourth quarter of 2016 until the end of 2019.

If the timeline stretches to future programme budgets, please ensure that further information is provided in the costing section.

B. Budgetary implications of implementation of the resolution

1. Current biennium: estimated budgetary requirements, in US$ million

Level	Staff	Activities	Total
Country offices	0.83	0.13	0.96
Regional offices	0.83	0.27	1.10
Headquarters	1.12	0.98	2.10
Total	**2.78**	**1.38**	**4.16**

1(a) Is the estimated budget requirement in respect of implementation of the resolution fully included within the current programme budget? (Yes/No)

Yes.

1(b) Financing implications for the budget in the current biennium:

– How much is financed in the current biennium?

– What are the gaps?

US$ 4.16 million.

– What action is proposed to close these gaps?

The gap will be addressed through the coordinated resource mobilization efforts for possible financing by voluntary contribution.

2. Next biennium: estimated budgetary requirements, in US$ million

Level	Staff	Activities	Total
Country offices	0.83	0.123	0.96
Regional offices	0.83	0.27	1.10
Headquarters	1.12	0.98	2.10
Total	**2.78**	**1.38**	**4.16**

2(a) Financing implications for the budget in the next biennium:

– How much is currently financed in the next biennium?

– What are the financing gaps?

US$ 4.16 million.

– What action is proposed to close these gaps?

The gap will be addressed through the coordinated resource mobilization efforts for possible financing by voluntary contribution.

The second draft resolution, on addressing the global shortage of medicines, had been proposed by the delegations of Kenya, South Africa and the United States of America and read:

The Sixty-ninth World Health Assembly,

PP1 Having considered the report on global shortages of medicines and the safety and accessibility of children's medicines;

PP2 Recommends to the Sixty-ninth World Health Assembly the adoption of the following resolution;

PP3 Recalling the World Health Assembly resolutions WHA67.22 on access to essential medicines, WHA60.20 on better medicines for children, WHA67.20 on Regulatory system strengthening WHA67.21 access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy, WHA61.21 on global strategy and plan of action on public health, innovation and intellectual property, WHA65.19 on substandard/spurious/falsely-labelled/falsified/counterfeit (SSFFC) medical products, WHA65.17 on vaccines, WHA68.7 and WHA67.25 on antimicrobial resistance as well as resolutions WHA64.9 sustainable health financing structures and universal coverage, and also, recalling the Resolution A/HRC/RES/12/24 from the Human Rights Council on access to medicines;

PP4 Noting with particular concern that for millions of people, the right to the enjoyment of the highest attainable standard of physical and mental health, including access to medicines, remains a distant goal, that especially for children and those living in poverty, the likelihood of achieving this goal is becoming increasingly remote [reference (A67/81)];

PP5 Recognizing that the continuous supply of quality, safe, effective medicines is one of the building blocks of every well-functioning health system, which requires a reliable supply chain: and noting reports of global medicines shortages and stock-outs that also infringe on patients right to health; undermine public health prevention and treatment goals; and threaten governments' ability to scale up services towards achieving universal health coverage;

PP6 Recalling the Agenda 2030 for Sustainable Development, which includes, inter alia, the commitment to achieve universal health coverage, financial risk protection, access to primary health-care services and access to safe, effective, quality and affordable medicines and vaccines for all by 2030;

PP7 Acknowledging that Agenda 2030, supports the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, (A/RES/70/1 target 3.*b)*;

PP8 Noting that the challenges related to medicine shortages and stock-outs are widespread, affecting medicine manufacturers, procurement agencies and countries at every economic level, and they appear to be escalating in severity, and the factors that affect the non-

availability of medicines can be categorized into three areas: problems with the manufacture of the medicine, challenges with the procurement of medicines and problems with the supply chain which result in medicines being unavailable when patients access care; therefore interventions to address weaknesses in all three areas are critical to ensure that medicines are available at the point of care;

PP9 Aware that the shortage of medicines is a global problem, the causes and implications of which vary from one country to another and that there is insufficient information to determine the magnitude and specific characteristics of the problem;

PP10 Noting also that the implications of these shortages in the case of infectious diseases goes beyond the individual patient and impacts public health as a shortage/stock--out of antibiotics, antituberculosis drugs, antiretrovirals or vaccines may result in the spread of infection beyond the individual patient;

PP11 Considering that there is a need for improved international collaboration on the management of shortages of medicines given that medicines shortages may increase risks of SSFFC medical products entering the supply chain;

PP12 Concerned about the challenges that shortages of medicines pose to Member States, in relation to ensuring universal access to healthcare, research and development, rational use of medicines, and that the financial sustainability of health systems can be affected by technological pressure caused by high-cost medicines; and aware that urgent patient-centred action is needed by the international community, Member States and relevant actors in health systems,

1. URGES Member States:[1]

(OP1) to develop strategies that may be used to forecast, avert or reduce shortages, adapted to national priorities and contexts, including:

(a) to implement effective notification systems that allow remedial intervention to circumvent medicine shortages;

(b) to ensure that best practices for medicines procurement, distribution and contract management processes are in place to mitigate the risk of shortages;

(c) to develop systems that are capable of monitoring medicine supply, demand, availability and alerting procurement departments to possible medicine availability problems;

(d) to strengthen institutional capacity to ensure sound financial management of procurement systems, to prevent funding shortfalls for medicines;

(e) to promote, review and strengthen programmes, public policies, regulatory frameworks, systems and authorities that promote access to medicines and align policy frameworks to be responsive to medicines that are at risk of being unavailable at the point of care, through the appropriate regulatory strategies;

(f) to urge Member States to focus on health rights of everyone especially vulnerable groups and to ensure these groups have timely access to medicines in shortage;

(g) to seek to make medicines more affordable through the implementation of various strategies to manage prices such as price negotiations/regulation, voluntary/compulsory licences in order to decrease prices of medicines in shortage;

[1] And, regional economic integration organizations, as appropriate.

(OP2) calls upon manufacturers (active pharmaceutical ingredient and formulation), wholesalers, global, and regional procurement agencies and other relevant stakeholders to contribute to global efforts to address the challenges of medicines shortages, including through participation in notification systems;

(OP3) to advance gradually regional and international integration of national notification systems including but not limited to sharing of best practices, training for human capacity building where necessary with a view of establishing an international notification system for essential medicine shortages and stock-outs;

2. REQUESTS the Director-General:

(1) to support Member States in addressing the global challenges of medicines shortages by developing a global medicine shortage notification system; which may include information to better detect and understand the causes of medicines shortages;

(2) to propose global best practices for the notification and management of shortages, including data standards, database management and regulatory/legislative strategies including the full use of TRIPS to minimize the impact of shortages;

(3) to develop an assessment of the magnitude and nature of the problem of shortages of medicines, including factors such as: market supply system failures and pressures, manufacturing and distribution challenges, and recommended solutions, to address the most important factors identified;

(4) to identify medicines that are at particular risk of being in short supply and develop strategies to ensure their availability at an affordable price in collaboration with global partners;

(5) to prioritize, the development of new or updated procurement and supply chain guidelines, to support the effective functioning of health systems and minimize the risk of shortages;

(6) to work with global partners to strengthen systems for supply chain management;

(7) to support Member States in the implementation of surveillance systems that will monitor and report supply and demand of medicines, using standardized formats throughout the supply chain, to predict needs and shortages, and that also reduce the risk of SSFFC entering the supply chain;

(8) to continue to support the Member State mechanism on SSFFC medical products;

(9) to report on progress and outcome of the implementation of this resolution to the Seventy-first World Health Assembly.

The financial and administrative implications for the Secretariat of adoption of the draft resolution were as follows:

Resolution: Addressing the global shortages of medicines
A. Link to the general programme of work and the programme budget
1. Please indicate to which impact and outcome in the Twelfth General Programme of Work, 2014–2019 and which output in the Programme budget 2016–2017 this draft resolution will contribute if adopted. Twelfth General Programme of Work: Outcomes 3 and 4.3.1.

2. If there is no link to the results as indicated in the Twelfth General Programme of Work, 2014–2019 and the Programme budget 2016–2017, please provide a justification for giving consideration to the draft resolution.

Not applicable.

3. What is the proposed timeline for implementation of this resolution?

From the fourth quarter of 2016 until the end of 2019.

If the timeline stretches to future programme budgets, please ensure that further information is provided in the costing section.

B. Budgetary implications of implementation of the resolution

1. Current biennium: estimated budgetary requirements, in US$ million

Level	Staff	Activities	Total
Country offices	0.20	0.46	0.66
Regional offices	0.16	0.43	0.59
Headquarters	0.55	2.51	3.06
Total	**0.91**	**3.40**	**4.31**

1(a) Is the estimated budget requirement in respect of implementation of the resolution fully included within the current programme budget? (Yes/No)

Yes.

1(b) Financing implications for the budget in the current biennium:

– How much is financed in the current biennium?

0

– What are the gaps?

US$ 4.31 million.

– What action is proposed to close these gaps?

The gap will be addressed through the coordinated resource mobilization efforts for possible financing by voluntary contribution.

2. Next biennium: estimated budgetary requirements, in US$ million

Level	Staff	Activities	Total
Country offices	0.20	0.46	0.66
Regional offices	0.16	0.43	0.59
Headquarters	0.55	1.51	2.06
Total	**0.91**	**2.40**	**3.31**

2(a) Financing implications for the budget in the next biennium:

– How much is currently financed in the next biennium?

– What are the financing gaps?

US$ 3.31 million.

– **What action is proposed to close these gaps?**

The gap will be addressed through the coordinated resource mobilization efforts for possible financing by voluntary contribution.

The representative of CHINA said that, after additional consultations, consensus had been reached on subparagraph 1(9) of the first draft resolution . The bracketed text, which read "and to promote clinical trial registration in registries recognized by WHO international clinical trials registration platform" should be replaced by "and to promote clinical trial registration in any registry that provides data to the WHO international clinical trials registration platform".

The representative of SRI LANKA, noting that the safety and accessibility of medicines was a major challenge in his country, said that a global approach was needed to prevent global shortages and ensure the safety and accessibility of children's medications. It was necessary to establish a pricing mechanism and a centralized negotiating system that would prevent shortages of essential medicines. Drug registration authorities should give priority to controlling monopolies and oligopolies in the sector.

The representative of NORWAY said that shortages of essential medicines and access to high quality products for children continued to be key priorities for Norwegian development assistance. Her Government had worked to improve access to live-saving commodities by ensuring affordable prices, addressing supply chain and regulatory bottlenecks, and incentivizing local manufacturing. Addressing shortages would require intersectoral partnerships and transparent sharing of information. Monitoring and notification systems were needed to promote early detection of shortages and the identification of joint rapid responses, which would improve national forecasting. Information-sharing on the use of children's medications also needed strengthening. The harmonization of regulations and procurement practices could lead to efficiencies and should be promoted. Ensuring adequate paediatric formulations and vaccines and medicines for epidemic outbreaks would require joint effort with the private sector. She supported both draft resolutions.

The representative of INDONESIA said her Government had a special scheme in place to ensure access to medicines; however, it could not do so effectively when global shortages occurred. She agreed that options to prevent and manage global stock-outs should involve drug regulators, health care professionals, ministries of finance, pharmaceutical manufacturers and other related agencies and institutions. She urged the Secretariat to move forward with developing a globalized notification system and response mechanism to prevent and manage shortages and stock-outs. It was to be hoped that the first draft resolution would lead to substantive improvement and pragmatic action to enhance the safety and accessibility of children's medication.

The representative of IRAQ said that WHO had a role to play in supervising pharmaceutical companies in order to ensure an equitable and needs-based distribution of medicines and vaccines. Specific medicines, such as paediatric medication and medicines for cancer and other noncommunicable diseases should be supervised and sponsored by WHO to ensure their availability. The Secretariat should also promote capacity-building for personnel and institutions in relation to medicines policy, procurement management and drug registration. Vulnerable groups such as mothers and children should be given priority in the provision of essential medicines and vaccines.

The representative of FINLAND said that increased research and development was needed on diseases specifically affecting children for which no paediatric medication was available. It was important to develop formulations that could be used where there was no cold chain or access to clean water. Clinical trials in children must adhere strictly to the highest ethical standards at all times.

Increased transparency with respect to the results of clinical trials was crucial to enhance collective knowledge and reduce unnecessary testing. He called on the Secretariat to provide guidance in that regard. Where relevant, applications for the inclusion of medicines on the WHO Model List of Essential Medicines should be required to include data on paediatric use. An expert group should be set up to assess such applications. The experts could also advise the Secretariat on gaps in access to paediatric medicines that required urgent attention. He supported the draft resolution on promoting innovation and access to medicines for children and, in particular, endorsed the request that the Director-General should increase the number of specialists in paediatric medicine on the WHO Expert Committee on Selection and Use of Essential Medicines.

The representative of ARGENTINA said that any strategy that used higher prices as an incentive to pharmaceutical companies and as a means of reducing the risk of shortages of essential medicines could prove counterproductive, as some medicines could become unaffordable. Shortages could lead to inappropriate use of medicines, putting patient safety at risk. States should strengthen their capacity to assess the cost-effectiveness of high-cost technologies.

The representative of the UNITED REPUBLIC OF TANZANIA said that his country had faced the challenges outlined in the report and fully supported the options for action proposed therein, especially in relation to medicines for children. He supported the adoption of both draft resolutions.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA, speaking on behalf of the Members of the Union of South American Nations, said that ensuring equitable access to medicines was a prerequisite for the achievement of universal health coverage. Shortage and stock-outs of medicines was a global problem requiring attention by the Health Assembly, which should take action to address, with the Secretariat's support, barriers to access, especially for children, who should not be deprived of access to medicines owing to shortages of paediatric formulations. The Member States of the Union of South American Nations had agreed in 2014 to strengthen regional monitoring mechanisms in order to generate information and early alerts with a view to preventing shortages. He urged the Secretariat and Member States to promote the development and use of best practices for preventing and managing shortages and to work together to improve equitable access to medicines.

The representative of TUNISIA supported the proposals put forward in the report to prevent and manage shortages of essential medicines. It particularly welcomed the idea of establishing a global list of essential medicines in short supply or susceptible to shortages. WHO should consider establishing international agreements with pharmaceutical companies in order to ensure the availability of essential medicines. Her country had worked closely with WHO to formulate legislation and put in place mechanisms to ensure the availability of safe, high quality and effective medicines and now produced half of its pharmaceutical requirements. In addition, Tunisia had set up a national observatory to monitor and ensure adequate supplies of essential medicines.

The representative of JAPAN said that it was important to collect and evaluate scientific data on the effectiveness and safety of medicines for children and to provide that information to health care providers. His Government had adopted various measures to promote the clinical development of children's medications and would be happy to share its experience with others. He urged other Member States also to share best practices in procurement and supply management. Although shortages of essential medicines were often regarded as a problem of countries with limited resources, all countries faced shortages. He therefore encouraged the Secretariat to develop concrete measures that were applicable to all countries, regardless of level of economic development. He welcomed the two draft resolutions.

The representative of GABON, speaking on behalf of the Member States of the African Region, said that shortages of essential medicines were caused by various factors, including difficulties in obtaining raw materials, high prices, fragmentation of markets and lack of local producers. Access to paediatric medicines, in particular, was hindered by lack of regulatory mechanisms to ensure the quality of medicines and poor representation of children in clinical trials. Those challenges could best be met through the use of online information systems, improved coordination among producers and approval and local production of generic medicines. Better international coordination and the creation of a global evaluation system and a global supply management mechanism would facilitate early detection of and rapid response to shortages. Attention to pricing practices was also needed. Member States in the Region fully supported the strategies developed following the adoption of resolution WHA60.20 (2007) on better medicines for children, including the Paediatric Medicines Regulators Network, and considered it important to mobilize resources to ensure the sustainability of those efforts. They also supported the two draft resolutions.

The representative of the REPUBLIC OF KOREA said that, in order for an international notification system to operate effectively, the terms "stock-outs" and "shortages" should be clearly defined; the former meant that a medicine was no longer in stock, and the latter meant that there was not enough to meet demand. A global information-sharing mechanism should be created to enable Member States to report shortages of essential medicines in a timely manner. Global and regional working groups should be established in order to enhance cooperation between countries and ensure a stable supply chain. Her country wished to be added to the list of sponsors of the draft resolution addressing the global shortage of medicines.

The representative of ETHIOPIA welcomed the Secretariat's work, including the WHO Model List of Essential Medicines for Children and the development of global standards for the formulation of paediatric medicines. His Government had adopted various strategies to facilitate the registration of medicines suitable for children, including streamlined review of documentation on WHO prequalified medicines and permitting clinical trials for paediatric medicines in special circumstances. It was committed to working in partnership with the pharmaceutical industry to encourage the reformulation of paediatric medicines for regulatory submission and with the Paediatric Medicines Regulators Network to develop legislation relating to medicines for children.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND, endorsing the draft resolution on medicines for children, said that a more coordinated approach that tackled persistent drivers of shortages and stock-outs was needed. Her Government had worked with partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the GAVI Alliance and UNITAID to increase access to medicines, including paediatric antiretroviral medicines, and to explore innovative approaches to intellectual property issues, such as patent pooling and market-shaping programmes.

Referring to the progress report on access to essential medicines (document A69/43, part G). she said that WHO should continue to take a coordinated systems approach, integrating efforts with overall health system strengthening and ensuring data-sharing across all initiatives relating to access to medicines. She encouraged Member States to ensure adequate funding for that work.

The representative of ITALY urged more action to ensure the availability of adequate supplies of medicines for persons with chronic and infectious diseases, in particular tuberculosis and HIV disease. Ensuring children's access to medicines for tuberculosis prevention and control was especially important. The Secretariat should promote global and local partnerships of governments, pharmaceutical companies, regulators and civil society organizations with a view to establishing monitoring, evaluation and accountability systems and joint procurement schemes. Steps should also be taken to overcome market barriers and provide appropriate technical support to countries on

registration of medicines. Without rapid uptake of new formulations, there was a risk that their production would cease. He therefore called for additional investment in research on paediatric formulations. His country wished to be added to the list of sponsors of the draft resolution on medicines for children.

The representative of COSTA RICA, noting the importance of reaching an international agreement to ensure continuity in the manufacture and supply of essential medicines, said that a means should be found of ensuring international access to the results of studies and clinical trials on paediatric medicines, especially for medicines designed to treat complex and rare diseases in children.

The representative of SENEGAL said that a global regulatory system would help to ensure the availability of essential medicines. Ideally, each medicine should be available from at least three producers. Supply coordination systems and streamlining of procurement and marketing authorization procedures for essential medicines could help to ensure a constant supply of medicines. The WHO Model List of Essential Medicines for Children should be more widely publicized, particularly among low-income countries, and it should be ensured that each country had a mechanism to enable it to procure paediatric medicines without major constraints. He supported the draft resolution on medicines for children.

The representative of PANAMA said that her Government had taken measures nationally to tackle shortages of essential medicines, including the introduction of domestic legislation to assure the quality and safety of medicines and the strengthening of the National Medicines Commission. Pooled-procurement mechanisms, such as those available through PAHO and UNICEF, provided a useful means of improving the availability and affordability of essential paediatric medicines. She supported both draft resolutions.

The representative of THAILAND, expressing support for the draft resolution on medicines for children, emphasized the importance of disseminating the results of clinical trials in order to promote transparency and avoid duplicating studies and wasting resources. She supported the draft resolution on global shortages of medicines, but if permitted would like to propose some amendments to strengthen it.

The representative of SOUTH AFRICA said that solving the complex problem of medicines shortages and stock-outs would require in-depth understanding; there was no single solution. The unavailability of first-line medicines for the treatment of infectious diseases could result in widespread use of second-line medicines intended for restricted use, contributing to antimicrobial resistance, with significant consequences for public health. He supported the proposals put forward in the draft resolution on medicines shortages, particularly global collaborative responses, an international notification system and in-country surveillance systems. He proposed that a revised version of the draft resolution on shortages of medicines, incorporating several suggested amendments, be circulated in due course.

The representative of COLOMBIA said that his Government had been adopting innovative measures to ensure access to medicines, including strengthened technology assessment processes and price regulation. Access to and availability of efficacious, safe and affordable medicines was a prerequisite for the enjoyment of the right to health. His country wished to be added to the list of sponsors of the draft resolution on medicines for children.

The observer of CHINESE TAIPEI said that Chinese Taipei had a health insurance system that covered the cost of more than 15 000 medicines, an online platform for reporting of shortages of

medicines, and a strategic plan for preventing and mitigating those shortages. More than 80% of shortages had been mitigated as a result. Incentives such as increased reimbursement and lower prices for new paediatric formulations and dosage forms had helped to encourage the introduction of innovative medicines for children.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, welcomed the timely report, as existing shortages were worsening and new shortages were occurring; in Venezuela, for example, 75% of medicines were unavailable. A coordinated international approach involving all stakeholders was needed to ensure continuity in the supply of medicines. It was gratifying to see reflected in the report a series of recommendations that had been agreed by a broad range of stakeholders at an event her organization had hosted in Canada in 2013. Pharmacists were committed to finding solutions to ensure timely access to medicines.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA said that it was regrettable that, in the context of the Health Assembly, irresponsible references were being made to figures relating to the situation in his country. The source of the figure cited was unknown. Moreover, although there were stock-outs of medicines in his country, they were by no means as severe as had been suggested, and the problem was confined to specific types of medicines for the treatment of certain types of diseases, a problem that was linked to what was known as the "economic war" in his country. His Government was committed to ensuring access to medicines for the entire population and had put in place an essential medicines policy and a pharmacy network. Anybody who had difficulties finding medicines could call a free national hotline.

The representative of MÉDECINS SANS FRONTIÈRES, speaking at the invitation of the CHAIRMAN, said that the problem of shortages and stock-outs of medicines needed long-term structural solutions, including measures to address market failures, monopolies and supply-chain weaknesses. Uncoordinated changes in treatment guidelines could increase the risk of stock-outs. Common definitions of shortages and stock-outs were necessary, as were indicators to measure the number of patients who received the right amount of the correct medicine. Patient should be involved in reporting whether medicines arrived. That information would assist in forecasting and help to prevent shortages.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that the current research and development system was incapable of providing effective solutions to medicines shortages. Patents no longer encouraged innovation or the development of new medicines, and alternative models were therefore needed. Innovative incentives for research and development at every stage of the process were imperative to address inequalities in access to medicines throughout the world. WHO should speak out against international trade agreements currently under negotiation that had the potential to negatively impact access to medicines.

The representative of the GLOBAL HEALTH COUNCIL, speaking at the invitation of the CHAIRMAN, supported the new requirement to include paediatric data in applications for inclusion of medicines relevant to children in the WHO Model List of Essential Medicines. All applications for the inclusion of new medicines or for changes to or deletions from that List should also be evaluated for the WHO Model List of Essential Medicines for Children. The continued lack of paediatric formulations of antiretroviral medicines led to irregular treatment adherence and high rates of treatment failure. The development of fixed-dose combinations and other paediatric formulations was urgently needed. As many noncommunicable diseases could not be diagnosed or managed without basic medical technologies, she encouraged coordinated efforts to include essential medicines and

basic technologies for noncommunicable diseases in work designed to tackle shortages and stock-outs of medical supplies.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, said that real-time reporting systems that informed all relevant stakeholders of disruptions in medical supplies would enable pharmacists to make informed clinical decisions. Through medication substitution, cost-effective procurement and equitable medication allocation pharmacists could mitigate the potential harm to patients caused by gaps in supply. She encouraged Member States that had not yet implemented real-time systems to do so without delay and called on WHO as a whole to take account of pharmacy practice when considering solutions to the problem of medicines shortages.

The representative of the WORLD HEART FEDERATION, speaking at the invitation of the CHAIRMAN, particularly welcomed the reference in the report to shortages of benzathine penicillin G, a medicine that was crucial to the prevention of rheumatic heart disease, a preventable disease that began in childhood. High-quality supplies of benzathine penicillin G could be secured by collating and sharing national data on the need for it, enhancing manufacturing capacity by working with the pharmaceutical industry and encouraging countries with a high burden of rheumatic heart disease to include benzathine penicillin G in their national essential medicines list. Action was also needed to improve the availability of some essential medicines for cardiovascular disease, including cheap, generic, widely-manufactured products such as aspirin.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, welcomed the inclusion of 46 cancer medicines in the 2015 update of the WHO Model List of Essential Medicines. Shortages of essential medicines to treat cancer resulted in children with curable cancers dying unnecessarily in many parts of the world. She approved the focus in the report on strengthening regulatory infrastructures in order to tackle weak distribution chains, poor storage and counterfeit medicines. Efforts to stabilize demand and identify incentives for manufacturers to enter the children's medicines market were also to be encouraged. She also welcomed the emphasis on overall health system strengthening in the two draft resolutions.

The representative of HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that essential medicines could be made accessible and affordable by removal of barriers to their import and of mark-ups on generic medicines, in particular those for noncommunicable diseases The global market for many paediatric medicines was characterized by low and inconsistent demand, erratic production and volatile prices, which led to poor access to essential medicines and the preventable deaths of thousands of children each year. Member States should consider developing regional pooled financing and procurement mechanisms, such as PAHO's Revolving Fund. Such mechanisms would aggregate demand, resources and procurement power and help to stabilize production, prices and quality of medicines.

The ASSISTANT DIRECTOR-GENERAL (Health Systems and Innovation) recalled that shortages and stock-outs of medicines had been increasing throughout the world, affecting all Member States, for complex reasons. The commitment expressed in the draft resolution on shortages of medicines to timely, joint action was important. The Secretariat acknowledged the need to strengthen international cooperation with all stakeholders and to support information-sharing. Monitoring the availability of medicines across regions would be especially important, as would the development of a list of key medicines that were in short supply. Terms and definitions must also be standardized.

With regard to medicines for children, the Secretariat commended the efforts of Member States to accelerate the actions laid out in resolution WHA60.20 (2007) on better medicines for children and resolution WHA67.22 (2014) on access to essential medicines. The Secretariat would intensify its

support to Member States for those efforts. The international community needed to do more to improve access to medicines for children, including action to ensure fair and affordable prices. She had taken note of the comments on the need: to increase expertise in the work on the WHO Model List of Essential Medicines for Children; to promote global standards on the formulation of medicines for children; and to ensure the availability of medicines for children with tuberculosis. She acknowledged the importance of supporting the optimization of procurement mechanisms for children's medicines, including through existing global mechanisms.

The Committee noted the report.

The CHAIRMAN invited the Committee to consider the draft resolution on promoting innovation and access to quality, safe, efficacious and affordable medicines for children.

The representative of CHINA said that, as agreed, the bracketed text in paragraph 1(9) would be amended to read: "and to promote clinical trial registration in any registry that provides data to the WHO international clinical trials registration platform (ICTRP)". A footnote would also be added after "registry", reading: "including internationally-recognized open registries such as clinicaltrials.gov, among others, and national registries".

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

The CHAIRMAN proposed that consideration of the draft resolution on addressing the global shortage of medicines should be deferred to allow for further consultations.

It was so agreed.

(For continuation of the discussion and approval of the draft resolution, see the summary record of the seventh meeting, section 4.)

The meeting rose at 17:40.

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[1] Transmitted to the Health Assembly in the Committee's third report and adopted as resolution WHA69.20.