PROVISIONAL SUMMARY RECORD OF THE SECOND MEETING

Palais des Nations, Geneva
Tuesday, 22 May 2018, scheduled at 09:15

Chairman: Mr A. SINGHAL (India)
later: Dr S. BROSTRØM (Denmark)

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COMMITTEE A
SECOND MEETING
Tuesday, 22 May 2018, at 09:15

Chairman: Mr A. SINGHAL (India)
later: Dr S. BROSTRØM (Denmark)

STRATEGIC PRIORITY MATTERS: Item 11 of the agenda (continued)

Health, environment and climate change: Item 11.4 of the agenda (documents A71/10, A71/10 Add.1 and A71/11) (continued from the first meeting, section 2)

The representative of the WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, said that, while her organization welcomed WHO’s efforts to prioritize climate change, greater support should be provided to vulnerable small island developing States and further action taken to adopt a wider intersectoral and population-based approach to the issue. Member States, for their part, should uphold their commitments under the Paris Agreement and implement innovative national and international financing mechanisms aimed at building robust health systems.

The representative of MEDICUS MUNDI INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that WHO should play a leadership role in establishing regulations and standards that held to account the main producers of global emissions. While it was important to implement the provisions of the United Nations Framework Convention on Climate Change, further action should be taken to devise new frameworks including on air pollution to tackle the impact of climate change on global health.

The representative of the INTERNATIONAL COUNCIL OF NURSES, speaking at the invitation of the CHAIRMAN, welcomed the linkage made between the unsustainable management of biodiversity and the negative effects on human and animal health. WHO should bear that link in mind when developing health, environment and climate change strategies and policies. The effects of climate change and population ageing had increased the demand for well-educated health care professionals. Greater attention should therefore be paid to the size, composition and skill sets of the health care workforce. She urged WHO to include health care professionals in policy decisions at all levels and in the drafting of a comprehensive global strategy on health, environment and climate change.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, welcomed the formulation of a road map for an enhanced global response to the adverse effects of air pollution. She called on Member States to establish national accountability frameworks aimed at addressing the impact of air pollution on public health and to consider the specific risks to children and other vulnerable groups when monitoring air pollution exposure and establishing thresholds in air quality. Multisectoral engagement would be crucial in preventing air pollution. WHO should raise awareness of the BreatheLife campaign and provide support for national and regional air pollution monitoring, reduction and awareness-raising activities.
The representative of the INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE, speaking at the invitation of the CHAIRMAN, urged Member States to prioritize environmental health issues at the 2018 United Nations High-level Political Forum, promote access to clean and safe household fuels and take a comprehensive approach to mitigating the impact of commercial determinants of noncommunicable diseases.

The representative of WATERAID, speaking at the invitation of the CHAIRMAN, welcomed WHO’s recognition that water, sanitation and hygiene played a vital role in the promotion of healthy populations and the protection of the environment. While she commended the multisectoral approach taken to health, environment and climate change at the global level, greater progress must be made to improve water, sanitation and hygiene levels at the national level, particularly in health care facilities. She therefore urged WHO to coordinate and scale up its actions in that respect.

The representative of the SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, welcomed WHO’s focus on the link between biodiversity and health in its recent reports on health, environment and climate change, and human health and biodiversity. While the report on human health and biodiversity had acknowledged the need for evidence-based policy and comprehensive capacity-building at the national and regional levels, its ambitious targets would only be achieved by adopting a holistic, multisectoral approach. The current Health Assembly and the Convention’s fourteenth meeting of the Conference of the Parties in November 2018 would serve as unique opportunities to reach sound scientific consensus and decide on the best way forward in that regard. The Convention Secretariat remained committed to working with WHO in addressing the challenges facing public health and sustainability and development.

The representative of the SECRETARIAT OF THE WHO FRAMEWORK CONVENTION ON TOBACCO CONTROL, said that tobacco growing and manufacturing negatively affected the environment through deforestation, depletion of soil nutrients, contamination of land and water, reduction in biodiversity and the emission of a significant amount of carbon dioxide into the atmosphere, while tobacco use contributed to the deaths of many of its consumers. She therefore welcomed WHO’s focus on environmental and human health. The Convention Secretariat stood ready to contribute to the fourteenth meeting of the Conference of the Parties of the Convention on Biological Diversity in November 2018 and would include a high-level segment on tobacco control and global climate action at its own eighth Conference of the Parties in October 2018.

The ASSISTANT DIRECTOR-GENERAL (Climate and Other Determinants of Health) expressed appreciation for the positive comments on plans to develop a comprehensive strategy on health, environment and climate change; to develop the action plan for the special initiative on climate change and health in small island developing; and to pursue collaboration with the secretariat of the Convention on Biological Diversity in respect of health, environment and climate change. The Secretariat would also tackle the very heavy burden of noncommunicable diseases by working to reduce air pollution and other environmental risks, and would leverage cross-cluster collaboration to prepare for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases later in the year. The Organization had also applied for accreditation with the Green Climate Fund, with a view to strengthening the cooperation between the two bodies and ensuring that health and climate change proposals made to the Fund benefitted from WHO’s expertise and experience. Regarding Member States’ comments on paragraph 16 of document A71/11, she stressed that Member States should uphold commitments made under other instruments. The Secretariat would monitor the situation closely and would address any unintended negative consequences, as and when they arose.
Concerning the report’s references to sustainable consumption and production, she noted that the Secretariat had merely sought to highlight that large-scale economic and social trends could have profound effects on human health and to underline the importance of sustainable development and production in relation to Sustainable Development Goal 12. She however agreed that WHO should stay within its comparative advantage. The Organization would continue to work closely with its United Nations partners and had recently signed memoranda of understanding with the United Nations Environment Programme, the United Nations Framework Convention on Climate Change and the Convention on Biological Diversity.

The Committee noted the reports.

Addressing the global shortage of, and access to, medicines and vaccines: Item 11.5 of the agenda (documents A71/12 and EB142/2018/REC/1, decision EB142(3))

The representative of QATAR said that his country supported the draft thirteenth general programme of work and remained committed to finding solutions to the global shortage of, and access to, medicines and vaccines. His Government had taken steps to guarantee the affordability and production of medicines by working closely with the private sector and investing in the pharmaceutical industry. It had thereby successfully maintained transparency in the national pharmaceutical production and supply chains.

The representative of BAHRAIN said that governance, local production, contingency planning, and technology transfer between organizations and stakeholders would play a vital role in ensuring access to affordable medicines and vaccines. She therefore urged the Secretariat to review the WHO Model Lists of Essential Medicines and to support Member States in their efforts to provide access to those medicines, particularly in emergencies. She supported the draft decision contained in decision EB142(3).

The representative of BULGARIA, speaking on behalf of the European Union and its Member States, said that the candidate countries Turkey, Montenegro, Serbia and Albania, and the country of the stabilisation and association process and potential candidate Bosnia and Herzegovina, aligned themselves with her statement. She welcomed the WHO’s analysis of the whole pharmaceutical value chain and its recognition of the vital role played by national medicines regulatory systems. Local pharmaceutical production and supply chains required good governance and adequate regulatory and workforce capacity in order to meet international standards and conform to quality assurance requirements. To overcome barriers to access, the Organization must respond to the ongoing rapid transformations in biomedical research, development and innovation. Action should be taken to address the prohibitive prices of some innovative medicines and tackle the high costs associated with research and development. Efforts to finance, promote and strengthen research were also needed, particularly in respect to the development of affordable and effective solutions for diseases predominantly affecting developing countries. The inclusion of an Executive Board agenda item to discuss the global shortage of, and access to, medicines and vaccines represented a positive step. The Organization had an essential role to play in leading multisectoral action and providing relevant technical guidance on the issue so that Member States could successfully tackle the obstacles restricting access to medicines. She expressed her support for the draft decision.

The representative of BANGLADESH, speaking on behalf of the Member States of the South-East Asia Region, expressed support for the definitions of shortages and the supply and demand of medicines and vaccines contained in the report. It was imperative to reach consensus on those definitions and collate information on supply and demand at the global level in order to minimize the risk of medicine and vaccine shortages. A number of Member States in the Region had expertise and
experience in producing quality medicines and vaccines at affordable costs and could fill the gaps left by shortages at the global level if they received the appropriate support. Those countries with limited production facilities would require WHO assistance to improve access to quality medicines and vaccines. He stressed that public funding of research and development would also be imperative to success. The full cost of research and development must not influence the end price since that could lead to high prices for consumers and create shortages. A reliance on value-based pricing would have a similar detrimental effect on access to medicines and vaccines. He therefore urged the Secretariat to promote the recommendations of the United Nations High-level Panel on Access to Medicines and provide Member States with the technical support required to ensure transparency, good governance and accountability throughout the supply chain. Efforts must also be made to ensure coherence between the road map outlining the programming of WHO’s work on access to medicines and vaccines for the period 2019–2023 and the implementation of the recommendations of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.

The representative of the FEDERATED STATES OF MICRONESIA welcomed WHO’s efforts to draw attention to the acute shortage of medicines and vaccines. It was incumbent upon Member States to ensure that medicines and vaccines were safe and effective and to combat discourse implying that such medical products represented a threat to the existence of the global health community. His country greatly appreciated the assistance it had received from donor partners to access medicines and vaccines, and fully supported the efforts made by UNICEF to make human papillomavirus and bacille Calmette–Guérin birth dose vaccines readily available in Pacific Island Countries. He similarly welcomed the Australian Government’s initiative to perform medicinal efficacy testing for those Pacific Island Countries that lacked the capacity to do so. He supported the draft decision.

The representative of MALAYSIA commended WHO efforts to ensure access to safe, effective, quality and affordable essential medicines and vaccines. The Organization should continue to support Member States in the promotion of price transparency, the establishment of platforms for sharing procurement price information and the development of joint procurement frameworks. It should also support capacity-building efforts with a view to establishing fairer pricing models and ensuring better price negotiations. Her Government supported the initiative to strengthen trilateral collaboration between WHO, WIPO and WTO to address the challenges of access to medicines and vaccines at the country level. It also agreed that the Medicines Patent Pool should be expanded to include all antimicrobial and patented medicines on the WHO Model List of Essential Medicines and called for the initiative to be extended to middle-income countries. She supported the draft decision.

The representative of MADAGASCAR said that strong political resolve would be required at all levels to guarantee access to medicines and vaccines, especially in terms of pricing policies and investment in universal coverage systems. Efforts to integrate anti-corruption strategies into medicine and vaccination policies would also be crucial in that respect. He requested WHO technical assistance so that his country could bolster its national immunization programme and strengthen access to medicines and vaccines.

The representative of JAMAICA said that her Government had recently launched an online vaccine management application, which had vastly improved the accuracy of vaccine orders and stock management. WHO should support such efforts to assess medicine and vaccine shortages and introduce a global medicine shortage notification system that would provide further information on the root causes of medicine shortages. Her Government supported the draft decision and supported the proposal to focus on the actions with the greatest potential impact.

The representative of ETHIOPIA said that his Government firmly believed that building capacity for local manufacturing was a viable solution to addressing the global shortage of medicines.
and vaccines. He therefore urged the Secretariat to provide technical and capacity-building assistance to Member States so that they could devise national vaccine manufacturing plans and adopt effective manufacturing practices.

The representative of ZAMBIA, speaking on behalf of the Member States of the African Region, supported the focus on areas that would lead to achievable and sustainable improvements in access to medicines and vaccines. She suggested that a pharmaceutical framework should be established that would allow for pooled procurement and would offer the benefits of economies of scale. Policies and regulations that encouraged fair pricing and domestic investment should be encouraged to that end. Political will would be essential to guaranteeing the affordability and availability of medical products. She called upon the Secretariat to support the African Union’s efforts to establish the African Medicines Agency as substandard and falsified medical products posed a serious risk to Member States of the Region, particularly those countries with regulatory systems that required strengthening. She welcomed the focus on capacity-building for the implementation of intellectual property laws in line with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The Africa Region however had not yet been able to fully utilize the flexibilities offered by the TRIPS Agreement to facilitate access to medicines since most diagnostic and assistive technologies remained under patent and were expensive. While she welcomed the report’s emphasis on the importance of research, she stressed that areas of research showing the most promise should be given priority. In future, balanced consideration should be paid to both access to, and shortages of, medicines and vaccines since linking the two issues could skew discussions. She supported the draft decision.

The representative of ECUADOR said it was imperative that public health interests prevailed over economic and commercial considerations. WHO’s work on access to medicines represented a powerful tool in addressing the barriers to the enjoyment of the right to health. In order to leverage the progress made in the different Regions to guarantee that right, the content of the WHO Regional Committee for the Americas resolution CD55.R12 on Access and Rational Use of Strategic and High-cost Medicines and Other Health Technologies should be included in the proposed road map.

The representative of SENEGAL said that recent vaccine stock outs had hindered her country’s eradication of polio and management of a yellow fever outbreak. She therefore called on WHO to support the production of quality generic medicines and vaccines at a subregional level and encourage manufacturers to produce sufficient stock of all vaccines, especially for yellow fever, polio and meningococcal meningitis.

The representative of PORTUGAL said that access to quality, safe and affordable medicines should be viewed through a human rights lens and the costs associated with the research and development of new medicines and vaccines should be fairly reflected in the price of the end product. He therefore supported WHO efforts to encourage collaborative processes for procurement and to devise policies that promoted transparency throughout the value chain. He was also pleased to note that the Organization had reviewed its activities in line with the recommendations contained in the report of the United Nations Secretary-General’s High-level Panel on Access to Medicines.

The representative of CHINA, expressing support for the draft decision, said that political will, multilateral cooperation and capacity-building would be essential to improve access to medicines and vaccines. The issues concerning regulatory weaknesses, new drug development, pricing policies, and inappropriate use of medicines indicated problems at the managerial and technological levels that must be addressed. In developing the road map, WHO should leverage its managerial and technical expertise, and his Government stood ready to assist in those efforts. He supported the expansion of the
Medicines Patent Pool, the pooling of procurement at the national, regional and global levels, and the establishment of a global medicine shortage notification system.

The representative of TANZANIA said that, in order to ensure access to medicines and vaccines, WHO should prioritize and invest in areas in which it had the comparative advantage over other organizations. Noting the importance of the need for a robust regulatory framework, he outlined the action his Government had undertaken to ensure the availability of quality, effective and safe medicines, namely increasing the budget for essential vaccines and medicines from US$ 13.5 million in 2015–2016 to US$ 113 million in 2017–2018 and implementing a five-year plan to combat substandard and counterfeit medicines. His Government would welcome the support of the Secretariat in its efforts to strengthen local pharmaceutical production capacities and reduce the country’s high dependency on imported products. He supported the draft decision.

The representative of AUSTRALIA supported the comprehensive health-systems approach contained in the report and the recognition that equitable and reliable access to safe, efficacious and quality medicines would be vital to achieving universal health coverage and the health-related Sustainable Development Goals. He noted that there were many factors that had an impact on access to medicines and that efforts to address access needed to account for the complexities of all contributing elements. He also welcomed the strong focus on improving access to medicines in the draft thirteenth general programme of work and called for continued collaboration with international agencies to support that work. He fully supported the draft decision and looked forward to engaging in the development of the road map report.

The representative of PANAMA said that an absence of local production, high prices caused by monopoly producers who refused to register their products and a lack of drug safety contributed to the shortage of, and lack of access to, medicines and vaccines in her country. Panama also lacked some of the medicines on the WHO Model Lists of Essential Medicines, making it difficult to comply with certain recommendations. She supported the list of priority actions contained in the report and recognized the importance of including patented and palliative care medicines in the WHO Model Lists of Essential Medicines. WHO should continue to strengthen and expand its prequalification programme to ensure a high-quality, safe and effective supply of medical products. Without guaranteed access to medicines and vaccines, the adoption of health care standards and allocation of national resources to universal health coverage programmes would be futile.

The representative of BELGIUM said that the lack of regulatory harmonization that had led to poor quality medicines bought with development aid funds circulating in the global market and entering countries with weaker regulatory systems posed a threat to patients and public health. To rectify that situation, the scope of the WHO prequalification programme should be extended to include many of the products on the WHO Model Lists of Essential Medicines. That approach should also be reflected in the proposed road map outlining the programming of WHO’s work on access to medicines and vaccines for the period of 2019–2023. Furthermore, Member States and private donors should establish their own quality assurance policies to reduce the risk of purchasing poor quality medicines with development aid funds.

The representative of TURKEY said that international cooperation must be strengthened to guarantee access to essential medicines and vaccines. Her Government had launched a pharmaceutical track and trace system to guarantee quality and safety and manage demand and supply. It had also conducted training sessions on access to medicines and vaccines at the national and intercountry level. She thanked the Organization for its normative and regulatory work to address the shortage of, and access to, medicines and vaccines, and for its efforts to tackle antimicrobial resistance. She supported the draft decision.
The representative of BARBADOS said that she supported the draft decision and commended the Organization's increased focus on the challenges resulting from shortages and stock outs of medicines and vaccines. The Secretariat must further support Member States in their efforts to promote access to medicines, vaccines and other health technologies, especially vulnerable small island developing States. The flexibilities provided by the TRIPS Agreement should be used to strengthen competition and promote the transparency of prices and research and development costs. Given Barbados’ limited production capacity and the global shift towards quality generics, she was concerned that her country's limited purchasing power would prevent it from sourcing quality pharmaceuticals in a timely manner. She therefore urged the Director-General to work with the Caribbean Community to explore more effective methods of pooled procurement.

The representative of INDONESIA said that political commitment and effective regulation at the national, regional and global levels would be essential to ensuring the affordability and availability of safe, effective and quality medical products. He supported the development of a global medicine shortage notification system, but emphasized that it was crucial to solve the problem of the global shortage itself. Indonesia had recently been recognized as a centre of excellence for vaccinations and biotechnology by the Organization of Islamic Cooperation and had been offering training on vaccine development to that organization and other interested States. He supported the draft decision.

The representative of ANTIGUA AND BARBUDA, recognizing the integral role of access to medicines and vaccines in the achievement of universal health coverage and the Sustainable Development Goals, fully supported the draft decision. The pooled procurement system of the Organisation of Eastern Caribbean States and the PAHO Revolving Fund had increased the affordability of medicines and vaccines. However, access to medicines outside those systems remained hampered by high prices, and the unreliability and uncertainty of generics had led to low-quality counterfeit medicines entering the market. Further support from WHO and PAHO to improve the Caribbean Regulatory System would therefore be greatly appreciated.

The representative of SAUDI ARABIA said that the draft decision failed to mention the shortage and unavailability of medicines and vaccines in emergencies, which was a very significant issue. Recognizing the importance of access to medicines and vaccines for the attainment of universal health coverage, he called on the Secretariat to advocate greater sharing of best practices in procurement and supply-chain management among Member States. The Organization should also review the WHO Model Lists of Essential Medicines in order to identify the products or active pharmaceutical ingredients at risk of shortage because of limited manufacturer interest, and should offer financial incentives to boost the production of medicines and vaccines in low supply. He recommended that WHO should establish a crisis management mechanism for medicine and vaccine shortages, involving all Member States, and supported the idea of a global medicine shortage notification system. He called for communication and cooperation with representatives of global industries and professional associations to draw up standards on best practices in that area.

The representative of COLOMBIA said that comprehensive actions should be taken to facilitate access to medicines and vaccines, including by making use of the flexibilities provided by the TRIPS Agreement, generating competition through biogenerics, and ensuring transparency in research costs. She welcomed the recognition contained in the report of the importance of implementing resolution WHA67.21, which required the Secretariat to update the 2009 directives on the evaluation of similar biotherapeutic products, specifically the requirements that hindered competition by obliging producers of biogenerics to repeat extensive and costly clinical tests in order to gain health registration. Updating the directives was an important step in promoting standards that enhanced competition, without compromising quality, safety and efficacy. She therefore supported the draft decision.
The representative of THAILAND said that improving access to medicine depended on prioritizing access to essential medicines and using strategic purchasing to ensure affordability, all of which relied on transparency, participation and the good governance of universal health coverage. Fast progress could be made, and at little cost, by improving access to medicines for rare diseases. Noting that Thailand had supplied Nigeria with botulinum antitoxin at WHO’s request, she said that stockpiling of rare drugs was only possible under the universal health coverage strategic purchasing system and that Thailand was working with SEARO to establish a sustainable regional depot. In that context, she urged the Organization to move swiftly to create a sustainable global depot for rare diseases. She supported the draft decision.

The representative of MEXICO said that, in addition to being a Sustainable Development Goal, ensuring access to quality, safe and efficacious medicines and vaccines was a cross-cutting strategic action essential to the other goals of the 2030 Agenda including the attainment of universal health coverage. The shortage of medicines and vaccines affected supply chains and threatened vulnerable populations and strategic achievements in public health. It was therefore imperative to develop public pharmaceutical policies and to guarantee access to quality, safe and efficacious medicines and vaccines by promoting the development of national industries that operated at the highest standards and reduced prices through competition. That approach would also help to combat the entry into the market of low-quality and counterfeit medical products. Calling for an intersectoral approach to be included in the road map, he expressed support for the draft decision and urged Member States to strengthen their efforts in that regard, particularly in terms of ensuring access to medicines and vaccines for the most vulnerable countries and populations.

The representative of the RUSSIAN FEDERATION, noting that effective resource management played a key role in ensuring access to medicines, said that a medicines strategy based on WHO recommendations had been operating successfully in his country since 2013. Such initiatives should be taken into account when drafting the road map requested in the draft decision. Given the importance of the development and local production of medicines for neglected diseases, a methodical approach was needed to manage mechanisms for registering and controlling such medicines at the national level, under the aegis of the Organization. The road map should include measures to ensure that the WHO global plan of action on antimicrobial resistance was effectively implemented, including through monitoring antibiotic use and furthering international cooperation in the area of access to medicines to fight priority pathogens. Support should be given to the Member State mechanism on substandard and falsified medical products to improve the effectiveness of its work at the national and global level. With the Committee of the Parties to the Council of Europe Convention on the Counterfeiting of Medical Products and Similar Crimes involving Threats to Public Health (Medicrime Convention) soon to be set up, it was also important to consider cooperation with other international organizations in that regard.

The representative of the NETHERLANDS expressed concern at the worryingly slow progress made towards improving access to medicines and vaccines at the national, regional and global levels. It had become clear that bold steps would be needed to achieve target 3.8 of the Sustainable Development Goals. The obstacles to access were diverse and complex. The Secretariat must therefore provide comprehensive guidance and support to Member States, including in the areas of intellectual property and the appropriate use of medicines. The sharing of data and experiences between countries on relevant data, such as innovation pipelines, pricing, market forces and patents, would be vital to attaining target 3.8 of the Sustainable Development Goals. Compulsory licensing also had an important role to play. The first WHO Fair Pricing Forum had been very instructive in that regard and there had been calls for a follow-up meeting. His country would continue its efforts with low-income countries to mitigate the effects of “TRIPS-plus” provisions in free trade agreements and remained committed to contributing to the development of the road map for access to medicines. His
Government would continue to take firm action against high medicines prices and would collaborate with other Member States to ensure the global availability and affordability of medicines.

Dr Brostrøm took the Chair.

The representative of IRAQ said that WHO should prioritize the development of essential medicines and vaccines, such as those used in the treatment and prevention of tuberculosis, drug-resistant tuberculosis and cancer, and ensure their sustainability and affordability in all countries, irrespective of income-related factors. Doing so would involve ensuring that the manufacturers of medicines and vaccines did not form cartels. In addition, WHO should encourage the manufacture of medicines and vaccines at the national level, focusing on intra- and interregional collaboration and the attainment of the Sustainable Development Goals.

The representative of the BAHAMAS said that he was pleased to see that the important issue of the global shortage of, and access to, medicines and vaccines would be included on the agenda of the 144th session of the Executive Board. The impact of hurricanes, such as the hurricanes Irma and Maria, and other weather-related phenomena on pharmaceutical supply chains, manufacture and storage was often omitted from discussions. In addition, recent publications highlighting pharmaceutical successes made clear use of biased evidence, which had been particularly evident in studies funded by the pharmaceuticals industry. WHO should be vigilant and monitor the work of non-State actors since manipulated scientific studies posed a threat to all Member States.

The representative of the PLURINATIONAL STATE OF BOLIVIA said that the development of medicines for certain diseases that affected his country, such as Chagas disease, Dengue and Zika virus disease, was limited because their development was subject to market forces and the market for them remained small. His Government had taken several steps to overcome medicine and vaccine shortages, including through the adoption of legislation regulating the procurement, cost and purchase of essential medicines on the local market. National measures would be ineffective, however, if the international community failed to improve access to medicines at an affordable cost. The road map proposed in the draft decision, which his Government supported, should focus on transparent pricing and viable alternatives to the market-based pharmaceutical system, with a view to increasing access to medicines. The road map should incorporate the recommendations of the United Nations Secretary-General’s High-level Panel on Access to Medicines in that respect.

The representative of GERMANY said that, although the ability to patent pharmaceutical products and intellectual property helped to foster innovation, additional measures in the areas of health-system strengthening, quality control and supply-chain management would be required to address the issue of the global shortage of, and access to, medicines and vaccines. Member States should allocate the greatest amount of funds possible to quality health care and appropriate structures, and should adopt a holistic approach to the issue of insufficient access to medicines and vaccines, rather than focusing on individual factors. Her Government had done much in recent years to ensure access to medicines for all, including fostering research and development, promoting local pharmaceutical production and supporting procurement mechanisms, such as the GAVI Alliance. She supported the preparation of a road map, as set out in the draft decision.

The representative of INDIA said that his Government had taken account of the recommendations of the United Nations Secretary-General’s High-level Panel on Access to Medicines by hosting the first World Conference on Access to Medical Products and International Laws for Trade and Health in November 2017 in New Delhi. The second edition of the Conference would be held in 2018. The global shortage of, and access to, medicines and vaccines were two separate issues. Considering both issues under one agenda item drew attention away from the latter. In addition, when
used in isolation, the term “fair pricing” cast the issue of access to medicines and vaccines in the light of profitability, which should be avoided. Greater global cooperation was necessary to establish mechanisms capable of delinking the cost of research and development from end prices, thus promoting access to good health for all. He urged WHO to set up a special fund to promote the research and development of medicines and vaccines for diseases that mainly affected developing and least developed countries.

The representative of BRAZIL said it was meaningful that the issue of the global shortage of, and access to, medicines and vaccines was one of the first substantive items considered by the Seventy-first World Health Assembly, in view of the importance of the availability and affordability of medicines, vaccines and other medical products to all other items on the agenda. Her Government supported the draft decision and hoped that the road map proposed therein would promote a broader discussion on access to medicines and vaccines, encompassing every aspect of the value chain and without losing sight of central themes, such as affordability, transparency, delinking of prices and the reduction of out-of-pocket payments.

The representative of PAKISTAN said that the extent of medicine and vaccine shortages and stock outs should be considered by experts, taking supply and demand into account. Baseline assessments of the severity and nature of shortages at the local level should be conducted. Shortages should be addressed through the establishment of a global medicine shortage notification system, which would provide information on how to detect and understand the causes of national and global shortages. Member States would therefore be able to use that source of information to forecast and avert stock outs in a timely manner. In that regard, his Government urged Members States to implement effective notification systems and apply best practices in procurement, distribution and contract management. A reliable supply chain and further research into the development of medicines and vaccines for communicable and noncommunicable diseases were paramount to ensuring access to safe, effective and quality medicines and attaining universal health coverage. The challenges facing Member States were diverse and complex and were exacerbated by insufficient information and reporting on the safety, quality and availability of medicines and vaccines, which could be addressed only through the collaboration of all stakeholders, the application of best practices and human resource capacity-building at the national level. The Secretariat should continue to help Member States to implement good governance strategies, to strengthen their regulatory and workforce capacities and their monitoring systems, and to increase collaboration between stakeholders.

The representative of BOTSWANA said that his Government had been working to increase national immunization coverage and to secure vaccines at affordable prices. However, the country had been adversely affected by the shortage of some vaccines, such as inactivated poliovirus vaccine and human papillomavirus vaccine. Fostering political will was therefore essential to securing more resources to tackle such shortages. His Government had taken steps to implement the Addis Declaration on Immunization, extend the scope of its policy on immunization and medicines, and revise national legislation on medicines and related substances. It had sought, wherever possible, to strike a balance between ensuring availability, accessibility and affordability on the one hand and preventing overregulation that could represent a barrier to access on the other.

The representative of NAMIBIA said that inefficiencies in the supply chain hampered the timely and adequate supply of medicines and vaccines more than lack of resources. The Secretariat should therefore help Member States to improve the efficiency and effectiveness of their supply-chain management, for example, by supporting outsourcing through the establishment of good governance mechanisms and best practices. In addition, the Secretariat should provide technical support for the establishment of the African Medicines Agency. A good regulatory system was a powerful instrument with which to assure the high quality of medicines and vaccines. Although almost all Member States
of the African Region had medicines regulatory authorities, most were unable to fulfil their mandate. The Secretariat should therefore strengthen its programmatic work in that area.

The representative of GHANA said that her Government had taken action to strengthen every step of the pharmaceutical value chain, including through the promotion of needs-based research, development and innovation and the review of manufacturing pricing and policies. Fostering political will would be essential to ensuring adequate access to medicines at the national and regional levels. The implementation of effective regulation and policy would also be necessary, particularly pricing and financial policy that encouraged fair, domestic investment in universal coverage schemes that reduced out-of-pocket payments. The Medicines Patent Pool should be expanded to include all medicines on the WHO Model Lists of Essential Medicines. Framework contracts should be instituted for essential medicines and Member States’ governments should reduce taxes on medicines. National pricing committees should be set up to regulate the price of medicines and vaccines, supported by national finance and trade ministries. Key data relating to medicines and vaccines should also be collected at the national level, including availability, price, expenditure and usage, which could be used in evidence-based policy-making.

The representative of VIET NAM said that his Government appreciated the benefits of the WHO prequalification programme for medicines and vaccines, which facilitated access to quality, safe and effective medicines and vaccines globally, especially in developing countries like Viet Nam. His Government stood ready to share its experiences and country information with WHO and the international community, with a view to establishing a shared database containing information on the supply of essential medicines and vaccines.

The representative of KENYA said that his Government had adopted measures to facilitate access to medicines and vaccines, including the adoption of new health legislation in 2017. However, challenges remained in the form of delays in procurement and the high cost of some medicines, especially medicines for noncommunicable diseases. WHO should increase its support for further regional and inter-organizational collaboration on best regulatory practices. Furthermore, the Secretariat should offer technical assistance on how to prioritize medical products via the Global Observatory on Health Research and Development; should continue to provide support on the development, regulation, pricing, distribution, selection and prescription of medicines and vaccines; and should make guidance available on the strategic procurement of highly priced vaccines and possible procurement channels for provision in local pharmacies.

The representative of JAPAN said that, in order to attain universal health coverage, it was important to establish robust health systems and invest in the research and development, manufacture and delivery of medicines and vaccines. She supported the draft decision. However, the set of actions listed in paragraphs 7, 9 and 11 of document A71/12 differed in terms of their resource requirements and feasibility. The Secretariat should therefore review the mandate and current resources of WHO to determine to what extent the actions proposed could be implemented, which could subsequently be reviewed when considering the proposed programme budget for 2020–2021.

The representative of JORDAN said that the influx of Syrian refugees into his country had affected the availability of medicines and vaccines at the national level. He therefore called on WHO and UNESCO to make affordable medicines and vaccines available so that his Government could offer the appropriate health services to refugees and Jordanian citizens.

The representative of HONDURAS said that his Government had made significant progress in strengthening the pharmaceutical supply chain and improving the distribution of medicines and vaccines by reviewing and updating the national list of essential medicines, increasing the portion of
the national budget set aside for the purchase of medicines and using new procurement mechanisms, such as those proposed by PAHO and WHO. New antigens had been introduced into the national immunization programme, including rotavirus, human papillomavirus and inactivated poliovirus vaccines, all of which had been produced locally. His Government was considering passing a new national medicines act by transposing the Medicines Policy of Central America and the Dominican Republic, of which it was already a signatory, into national law.

The representative of SWITZERLAND, supporting the draft decision, said that many factors hindered access to quality medicines, including financial and geographical accessibility and issues concerning market authorization. All aspects of supply and demand should therefore be addressed to ensure access to safe and effective medicines. The expansion of the Medicines Patent Pool to include other medicines from the WHO Model Lists of Essential Medicines should be studied further since it had the potential to improve access to a wider range of quality medical products for low- to middle-income countries. She encouraged WHO to maintain its broad vision in the formulation of the road map outlining the programming of work on access to medicines and vaccines for the period 2019–2023, which should include aspects of demand, such as improving public knowledge on health matters. Her country was willing to assist the Organization in that respect.

The representative of CANADA, expressing support for the draft decision, said that it remained unclear whether the activities and roles set out in the report formed part of WHO’s ongoing work or whether they constituted an increase in the scale of the Organization’s mandate. In the latter case, such actions might fall under the remit of other multilateral organizations or be better implemented through inter-organizational collaboration with international bodies such as WTO or WIPO. She would like to know, ahead of consultations on the formulation of the road map, which activities identified in the report corresponded to which previous Health Assembly and/or Regional Committee decision or resolution.

The representative of the REPUBLIC OF KOREA said that the issue of the global shortage of, and access to, medicines and vaccines required a multidimensional approach taking into account areas such as procurement and supply-chain management. In view of the limited resources available, WHO’s prioritization of activities to improve access to medicines and vaccines based on a cost-effective analysis was commendable. Since the globalization of the pharmaceutical industry made it difficult for Member States to respond effectively to the issue of access to medicines at the national level, increased cooperation and information exchange at the regional and global level would be crucial to success. She therefore urged the Secretariat to share data on shortages and supplies of medicines and vaccines at the national, regional and global levels, and expand its role in strengthening partnerships among the relevant international organizations.

The representative of the DOMINICAN REPUBLIC said that, in order to further strengthen access to medicines and vaccines, action must be taken to address the issues surrounding pricing, the impact of new technologies, and the presence of substandard and falsified medical products. An evaluation of the impact of antimicrobial resistance should be conducted as part of that work. While the regulation of medicines and initiatives against falsified products had been strengthened at the national level, the Organization should make greater effort at the global level to encourage flexible, voluntary contributions aimed at countering the inappropriate use of medicines and corruption in the pharmaceutical sector. Strengthening cooperation with stakeholders such as WIPO and WTO would be vital in that regard. It was also imperative to encourage the use of national data on medicines and vaccines for better evidence-based decision-making and to devise collaborative approaches for strategic procurement, particularly in respect of national immunization programmes.
The representative of AUSTRIA, expressing support for the draft decision, said that, in order to develop effective solutions to shortages of medicines and vaccines, due consideration must be given to all stages of the pharmaceutical value chain. Public investment in research and development would be crucial to promoting innovation. National health authorities must play a greater role in setting priority areas for pharmaceutical research and governments should take a needs-based approach to funding research. The Secretariat, for its part, should take regional specificities into account when providing guidance on sustainable priority setting in publicly-financed research and development projects.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that the road map should focus on the importance of preventing antimicrobial resistance and promoting antimicrobial stewardship. Addressing antimicrobial resistance would require coordinated action across the Organization and strengthened trilateral collaboration between WHO, WIPO and WTO. She supported the draft decision.

The representative of the UNITED STATES OF AMERICA, while supporting the draft decision, expressed disappointment that the report contained proposals relating to intellectual property and international trade which had not been agreed upon by Member States and which extended beyond the Organization’s remit. Suggestions that the Secretariat should engage in political advocacy were outside the Organization’s normative core mission. The report of the United Nations Secretary-General’s High-level Panel on Access to Medicines did not represent an appropriate starting point for the formulation of the road map given that the panel had not been convened at the request of Member States and the report failed to address access to medicines in a holistic manner. The report’s recommended courses of action would, in fact, have unintended harmful consequences on the global innovation system. She urged the Secretariat in the drafting of the road map report to take account of the disproportionate high burden of costs associated with medicine development borne by a small number of countries, including her own. Efforts must be made to counter the threats to intellectual property and ensure that pricing policies reflected the true value of medicines and future development of new medical products. Compulsory licensing was not fair to those who had invested in innovation. The road map must reflect that fact.

The representative of TRINIDAD AND TOBAGO said that access to medicines and vaccines could be facilitated by strengthening medicine and vaccine procurement processes and improving stock management. Her country, for instance, had put in place accurate forecasting mechanisms designed to avoid shortages and stock outs. Additional funding would be vital to implement the broad scope of the actions identified in the report. Political will at the national level would therefore be essential for securing the resources required for sustainable access to safe, effective and quality medicines.

The representative of COMOROS, expressing support for the draft decision, said that access to safe, effective and quality medicines required a comprehensive health systems approach that addressed all stages of the pharmaceutical value chain. She outlined various measures that had been taken in her country in that regard, including the establishment of a national medicines regulatory authority and the amendment of the pharmaceutical code.

The representative of GREECE expressed support for the draft decision. WHO’s work in developing standards and guidance for all stages of the pharmaceutical value chain was commendable. Structural measures, such as the adoption of a tendering process for off-patent medicines and the introduction of mandatory licensing for patented medicines, should form the basis of all policies concerning access to safe and effective medicines.
The representative of ALGERIA said that, in order to achieve universal health coverage, efforts must be made to promote development and innovation and delink medicine prices from research and development costs. It was essential to increase transparency throughout the value chain by optimizing the WHO Vaccine Product, Price and Procurement Web Platform; by lifting barriers to intellectual property; strengthening public awareness of new health products; and by implementing the priority recommendations of the report of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. Certain upper middle-income countries did not introduce health products at the same rate as low- and middle-income countries, which ultimately hindered the implementation of the global vaccine action plan. WHO should take steps to address that situation, in cooperation with the GAVI Alliance.

The representative of CHILE said that the road map should include provisions to strengthen mechanisms aimed at promoting transparency and facilitating access to information regarding medicines. He urged the Secretariat to provide Member States with support in terms of price negotiations. Action should be taken to encourage needs-based biomedical research and formulate mechanisms to build governments’ negotiating capacities with industry that could subsequently be adapted to national regulatory frameworks. He supported the draft decision.

The representative of the ISLAMIC REPUBLIC OF IRAN said that strong political will would be required to resolve the challenges concerning access to medicines and vaccines. The road map would play a vital role in addressing the issues relating to shortages and stock outs of medicines and should focus on ensuring access to medicines and vaccines in emergencies and crises in particular. Efforts should also be made to ensure the supply of medicines to the general population by shielding the pharmaceutical industry from political pressures and unilaterally imposed sanctions. The monitoring and management of the supply of medicines and vaccines should also be improved. WHO efforts to strengthen national regulatory authorities and technical advisory groups would be imperative in that regard. Barriers to research and development for medicines and vaccines should be removed, particularly during disease outbreaks. The Organization should promote technology transfer among Member States and make the necessary guidance and assistance on the WHO prequalification programme available, where appropriate. His country intended to launch a programme in the Eastern Mediterranean Region equivalent to the ASEAN vaccine security and self-reliance initiative for improving vaccine security.

The representative of BHUTAN, expressing support for the draft decision, said that his country remained vulnerable to medicine supply and quality issues given its lack of local production capacities. It also failed to benefit from larger economies of scale due to the small size of its population and the fact that it was not a signatory to the TRIPS Agreement. He therefore called on WHO to continue building the local production capacity of small countries in positions of vulnerability, with a view to addressing shortages and improving access to medicines. Pooling mechanisms should also be promoted in an effort to improve access and affordability.

The representative of SOUTH AFRICA said that robust health systems required effective supply-chain management. Shortages and stock outs of medicines presented a threat to patient safety and hindered progress towards universal health coverage. His country had devised a national strategy to improve the availability of medicines and vaccines, which focused on strengthening all stages of the supply chain and involved partnerships with consumer goods industries to guarantee the availability of health products at the point of sale. That type of approach should be explored by the Organization at the global level. The use of mobile technology had proven to be an effective tool in the management of medicine supply chains, especially in low-income countries. He expressed concern at the prohibitively high costs of life-saving medicines and urged the Secretariat to engage in consultations with the pharmaceutical industry to introduce tiered pricing. In view of the fact that biological
products remained unaffordable for most developing countries, the Organization should also consider the prequalification of key biosimilars with a view to reducing morbidity and mortality rates in those countries. He called on the Secretariat to publish a list of medicines that the pharmaceutical industry was no longer interested in producing so that other manufacturers could produce such medicines.

The representative of the PHILIPPINES said that her country had faced shortages and stock outs of certain medicines due to poor needs forecasting and disruptions in manufacturer supply. Action had been taken to address those shortcomings and establish a system for reporting medical shortages. She therefore welcomed the proposal to develop collaborative approaches for strategic procurement and fully supported the adoption of a global approach towards access to medicines and vaccines.

The representative of NIGER said that her Government had participated in subregional initiatives organized by the West African Health Organization to evaluate and upgrade national production facilities, with a view to building the country’s capacity to produce safe, effective medicines. WHO’s technical assistance would also be welcome in that regard.

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

The meeting rose at 12:35.