EXECUTIVE BOARD
148th session

EB148/PSR/9
5 May 2021

PROVISIONAL SUMMARY RECORD OF THE NINTH MEETING

WHO headquarters, Geneva
Friday, 22 January 2021, at 10:10

Chair: Dr H. VARDHAN (India)

CONTENTS

NINTH MEETING

Friday, 22 January 2021, at 10:10

Chair: Dr H. VARDHAN (India)

PILLAR 1: ONE BILLION MORE PEOPLE BENEFITING FROM UNIVERSAL HEALTH COVERAGE

1. EXPANDING ACCESS TO EFFECTIVE TREATMENTS FOR CANCER AND RARE AND ORPHAN DISEASES, INCLUDING MEDICINES, VACCINES, MEDICAL DEVICES, DIAGNOSTICS, ASSISTIVE PRODUCTS, CELL- AND GENE-BASED THERAPIES AND OTHER HEALTH TECHNOLOGIES; AND IMPROVING THE TRANSPARENCY OF MARKETS FOR MEDICINES, VACCINES, AND OTHER HEALTH PRODUCTS: Item 7 of the agenda (document EB148/9)

The representative of the RUSSIAN FEDERATION said that there was a need to make greater use of generic medicines for cancer treatment and to simplify market access procedures. It was particularly important to ensure the transparency of clinical studies and publish negative results to prevent duplication of research. His Government appreciated WHO's substantial contribution to improving procurement and price transparency, and was using similar approaches for reference pricing of basic medicines included in its State procurement system. Access to the latest generation of medicines and medical technologies could be enhanced through the provision of support to national regulators, and efforts to develop local scientific and technological capacity and technology transfer. The extremely high cost of health products for orphan diseases was a barrier to access, and he outlined some of the actions being taken by his Government to promote access to medicines for patients with orphan diseases and cancer, including children.

The representative of the UNITED ARAB EMIRATES, speaking on behalf of the Member States of the Eastern Mediterranean Region, highlighted the importance of expanded access to medicines and health technologies and affordable pricing for achieving universal health coverage. In many countries of the Region, however, access to screening, detection, diagnosis and treatment of cancer and rare and orphan diseases was challenging. The high cost of treatment, including novel medical products, increased pressure on already strained national health budgets, caused unnecessary financial hardship and could serve as a barrier to access, and she underscored the need for transparency and fair pricing. At its sixty-seventh session, the Regional Committee of the Eastern Mediterranean Region had endorsed a regional strategy, consisting of eight strategic objectives, to improve access to medicines and vaccines by 2030. A proposal to establish mechanisms for improved collaboration and information exchange on prices of medicines and vaccines was being considered in her Region and a number of strategies with direct and indirect effects on prices had been suggested for enhancing efficiency and improving access to medicines.

The representative of CHINA, welcoming the progress made, said that the report should better reflect the substantive cooperation activities across all three levels of WHO. Although some countries had made progress in expanding access to effective treatments for cancer and rare and orphan diseases and in improving transparency of markets, low- and middle-income countries, in particular, continued to face many challenges. Those included: insufficient investment in research and development, poor financial management, lack of regulatory capacity, weak infrastructure and the inappropriate

prescription of health products. He outlined the actions being taken by his Government to improve the supply of antineoplastic drugs and medicines for treating rare diseases. His Government stood ready to share its experience and work with WHO to enhance accessibility to relevant treatments and facilitate fair access to them.

The representative of BOTSWANA, speaking on behalf of the Member States of the African Region, said that the burden of noncommunicable diseases in the Region constituted a major public health challenge and undermined socioeconomic development, and noted that mortality from noncommunicable diseases, including cancer, was projected to increase most rapidly in his Region. Recalling the high prevalence rate of hepatitis B in the population, the unacceptably low number of countries providing the birth dose of the vaccine, and the limited number of countries in the Region with human papillomavirus vaccination programmes, he welcomed the support provided by the Secretariat in implementing and monitoring hepatitis B and human papillomavirus vaccination programmes and in improving procurement practices. The Global strategy to accelerate the elimination of cervical cancer would increase vaccination coverage and promote access to affordable cancer medicines.

He recognized the specific challenges associated with the management of rare and orphan diseases, including the fact that such diseases might be left out of public procurement and reimbursement schemes. He welcomed the Secretariat's collaboration with Rare Diseases International and the Worldwide Network for Blood and Marrow Transportation, and said that the Member States of his Region would be pleased to benefit from such initiatives, as appropriate. He highlighted the fact that many in vitro diagnostic and assistive products were designed only for high-income settings. He welcomed the Secretariat's efforts to raise awareness of the pricing of cancer medicines through the Pharmaceutical Pricing and Reimbursement Information networks and said that the Member States of his Region looked forward to participating in the 2021 Fair Pricing Forum. They remained committed to working with the Secretariat to strengthen capacities in access to health products through transparency, information-sharing and networking.

The representative of the UNITED STATES OF AMERICA said that access to medicines and treatments for rare and orphan diseases, which was a high priority, would benefit from closer regulatory cooperation and capacity-building, particularly in light of the global pandemic of coronavirus disease (COVID-19). Cancer prevention and control were also vital, and she supported expanding access to and worldwide investment in treatment. Transparent and open markets were important, including in promoting the availability and affordability of safe, effective and quality-assured COVID-19 diagnostic tests, vaccines, treatments and devices; continued cooperation on clinical trials and research was also required. Although many resources had been diverted to the pandemic response out of necessity, the Secretariat and Member States should continue their work on the important topics raised in the report in order to build a more equitable world after the pandemic ended. She looked forward to continued engagement, including at the 2021 Fair Pricing Forum, and to the release of WHO's third global report on access to hepatitis C treatment.

The representative of BANGLADESH said that equitable access to safe, effective, quality-assured and affordable vaccines, medicines and medical devices was a global priority, in particular for achieving the health-related Sustainable Development Goals. The absence of treatment for many rare diseases was concerning, as was the fact that certain treatments were limited to high-income countries because of their high price and patent barriers. Furthermore, some diseases that were rare in developed countries but prevalent in developing countries were also labelled as rare diseases, which was unhelpful.

His Government, recognized the need for fair pricing and domestic investment in universal health coverage schemes. Although demand for medical products in Bangladesh was mostly met through local production of generic medicines, treatment for cancer and rare diseases was limited. WHO and other international partners should establish research, innovation and training and development facilities for the management and prevention of noncommunicable diseases. Noting the importance of good

governance, transparency and accountability throughout the supply chain, he requested WHO to build the capacity of Member States to regulate medical devices, in vitro diagnostics and assistive products. He also called on the Secretariat to assist Member States in promoting local production and fair and affordable pricing, and to provide assistance, education, training and necessary equipment for rehabilitation and palliative care for patients with cancer and other rare diseases.

The representative of the REPUBLIC OF KOREA said that, while medicines and vaccines were economic goods, they were also public goods and their pricing had to be transparent in order to achieve universal health coverage. Political commitment remained essential for progress towards transparency of markets for health products, and he trusted that Member States and the Secretariat would continue their efforts to ensure fair pricing. Although definitions of a rare disease varied widely between countries, all patients with such diseases faced difficulties in accessing advanced therapies and health technologies. The absence of a harmonized regulatory framework for cell and gene therapies was a challenge. His Government, which had recently strengthened its national policies and legislation on rare diseases, supported the Secretariat's collaboration with Rare Disease International and the work on developing international nonproprietary names. A robust model of international cooperation should be developed for the sharing of relevant information, experience and best practice in order to guarantee access to innovative health products for patients with rare diseases.

The representative of INDIA, noting that the current agenda item was of particular relevance in the current global health care scenario, said that he concurred with the particular challenges identified in the report. His Government was in the final stages of developing a national rare disease policy and recognized that some cell and gene therapies might have the potential to meet the medical needs of individuals with certain cancers and rare and orphan diseases. He welcomed the Secretariat's support in the implementation and monitoring of hepatitis B and human papillomavirus vaccination programmes and in improving procurement practices, and the guidance for increased access to medical devices. While commending the Organization's tireless efforts, he said that WHO should support the use of flexibilities offered by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) to promote high-quality and sustainable local production, generic competition and access to medicines. It should also provide increased support for international technical collaboration in the regulation of medical devices. His Government would be pleased to cooperate in those efforts.

The representative of TONGA said that, although her country remained free of COVID-19, the pandemic had catalysed the Government's action to achieve universal health coverage. The whole-of-government approach adopted, which included a commitment to accessible, effective and sustainable treatment, medicines and vaccines, sought to strengthen health care delivery and health security, including the response to future outbreaks. While the provision of certain essential services had stalled at the global level since the beginning of the pandemic, her Government had endeavoured to continue building human capacity and redistributed its health resources to support decentralization and the safe continuation of existing services. The strengthening of health care systems and local research was pivotal to economic recovery, security, sustainability and resilience. She thanked the developed countries for their financial commitment to WHO and to ensuring equitable distribution of and access to COVID-19 vaccines in the developing nations, including in the Pacific.

The representative of ARGENTINA, while noting progress made with respect to cancer treatments, called for continued efforts to promote equitable and timely access to quality-assured health products and strengthen research and development. There was a need to redouble efforts to develop a comprehensive cancer treatment approach, including by strengthening vaccination and screening in populations where prevalence remained high. Market supply shortages of certain cancer treatments was a concern, as were the factors that posed barriers to equitable access of products on the WHO Model List of Essential Medicines, including unaffordable prices and fragmented procurement processes. The

lack of transparency and information on production costs remained a challenge and she called for further progress in that regard under resolution WHA72.8 (2019) on improving the transparency of markets for medicines, vaccines and other health products. Her Government was working with WHO to organize the 2021 Fair Pricing Forum, which she hoped would provide an opportunity for all stakeholders to engage in a frank discussion and reach agreement on the need to achieve the fair pricing of medicines, vaccines and other health products.

The representative of INDONESIA said that ensuring access to safe, effective, quality and affordable vaccines, medicines, in vitro diagnostics, medical devices and assistive products was an important factor in strengthening the global health system. Efforts to expand access to effective treatments for cancer and rare and orphan diseases were ongoing in Indonesia, and prices for medicines and medical devices had been publicly accessible since 2013. The Secretariat and Member States should strengthen collaboration to improve transparency and affordability of medicines, vaccines, and high-cost innovative health products, especially essential cancer medicines and patented products, including cell- and gene-based therapies.

The representative of COLOMBIA said that her Government's priorities with respect to cancer and rare and orphan diseases were aligned with those set out in the report. Many public health indicators, including those directly related to cancer, had improved with increasing health insurance coverage and investment in cancer control in her country over the last five years. Furthermore, out-of-pocket expenditure was comparatively low in Colombia, and she outlined some of the progress made by her Government in relation to the international reference price for prescription medication. WHO's efforts to improve the transparency of markets for medicines, vaccines and other health products were welcome and she encouraged continued implementation of the global strategy and plan of action on public health, innovation and intellectual property, and the Roadmap for access to medicines, vaccines, and other health products 2019–2023. Interaction with patient associations and scientific societies in Colombia was facilitating better governance of rare and orphan diseases, and she outlined some of the steps taken by her Government to promote access to relevant treatments and technologies, including cell- and gene-based therapies.

The representative of AUSTRIA said that, although safety concerns were not a major issue in Austria because of strong regulatory capacity and pharmacovigilance, her Government had taken steps to improve transparency and deal with supply shortages. As a member of the Beneluxa Initiative and the host of the Secretariat of the Pharmaceutical Pricing and Reimbursement Information networks, her Government took a special interest in supporting cross-country collaboration. In terms of next steps, WHO should consider the volume data, fragmentation of health systems as a potential barrier, and the value of cross-country collaboration in improving access to medicines and transparency.

The representative of the PHILIPPINES,[1] noting that access to high-cost treatments presented a challenge for the achievement of universal health coverage, said that mechanisms such as health technology assessment, pooled purchasing and price negotiation were used to support implementation of legislation pertaining to cancer control and rare diseases in her country. She welcomed the initiatives undertaken by WHO to strengthen Member States' capacity to address cancer, orphan diseases and other noncommunicable diseases, and outlined measures introduced by her Government in that regard. She supported WHO's initiatives to improve market transparency, and expressed the hope that the scope of the WHO Price Information Exchange for Medicines would be expanded to include high-cost medicines and medical devices of common interest in the South-East Asia Region.

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

The representative of NORWAY[1] said that the high and increasing prices of new medicines constituted a major concern and a challenge to the sustainability of health systems and the provision of universal health coverage, even in high-income countries. Industry's demands for confidential prices made it difficult to justify decisions on new medicines to the public. Transparent pricing of essential testing equipment, treatment and vaccines was essential to end the COVID-19 pandemic. Her Government had supported resolution WHA72.8 (2019) and called for further collaboration with national health authorities, international organizations and other stakeholders to that end.

The representative of ZIMBABWE[1] said that his Government welcomed the earlier announcement by the representative of the United States of America regarding the latter Government's decision to remain in WHO. Turning to the current item of the agenda, he said that it was concerning that critical gaps still remained in access to effective treatments for cancer and rare and orphan diseases. More needed to be done to increase price transparency and clarify the relationship between development costs and pricing, as the ongoing COVID-19 pandemic had shown. The Secretariat should expedite the updating of the WHO guidelines on evaluation of similar biotherapeutic products (2009) to reflect technological advances, in line with resolution WHA67.21 (2014) on access to biotherapeutic products including similar biotherapeutic products and ensuring their quality, safety and efficacy. It should also consider convening an expert panel to establish a technical and scientific regulatory pathway for non-originator vaccines.

The representative of TURKEY,[1] noting the trend in recent years towards value-based health care, said that his Government had initiated various studies on the effectiveness and efficiency of advanced technology treatments for cancer and rare diseases, which benefited from transparency. Treatment processes should be sustainable, and he called for analysis of innovative payment and risk-sharing measures to ensure that health services met urgent needs. Reporting systems should also be established for the treatment of rare diseases, and access to new health technologies should be prioritized, particularly for cancer and rare and orphan diseases. The issue of expanding access to effective treatments was global in nature, which made WHO's leadership necessary. He thanked the WHO Regional Office for Europe and Norway for their efforts on the Oslo Medicines Initiative.

The representative of PORTUGAL[1] welcomed the renewed commitment of the Government of the United States of America to WHO and to multilateral diplomacy. With regard to regular access to health products, he said that significant challenges were associated with access to innovative pharmaceutical products that offered new treatments for cancer, rare and orphan diseases. He commended WHO's important role in international cooperation for the harmonization of standards in regulation and health technology assessment, which promoted greater transparency, and looked forward to the discussions at the 2021 Fair Pricing Forum. Improved patient access to medicines was a programmatic priority for his Government. The international community should build on the momentum for collaboration generated by the pandemic in order to make further progress on ensuring access to safe, effective, quality and affordable essential medicines, which was vital for achieving universal health coverage and the Sustainable Development Goals.

The representative of BRAZIL[1] encouraged the Secretariat to further its analysis to better assist Member States in identifying sustainable ways of providing cutting-edge health care for all in need. To that end, it should make full use of relevant Health Assembly resolutions, including resolution WHA72.8 (2019), the Roadmap for access to medicines, vaccines, and other health products 2019–2023 and the global strategy and plan of action on public health, innovation and intellectual property. Having underscored the close relationship between growing transparency on medicine prices and the ability of Member States to cope with the growing burden on national health systems, he noted some of the steps

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

taken by his Government to promote price transparency, including publishing maximum prices and regulating public medicine pricing policies. The national regulatory authority had developed capacities to assess and monitor technologies, including some cell and gene therapies, and some had received market authorization. His Government stood ready to share its experience with the Secretariat and Member States.

The representative of JAPAN,[1] noting the importance of access to quality, safe and effective medicines and vaccines for achieving universal health coverage, said that it was essential to ensure access to pharmaceuticals and health technologies for cancer and rare and orphan diseases and to offer incentives to develop new therapeutic tools to meet unmet needs. Action to strengthen regulatory capacity and harmonization was essential, and training was provided in Japan for officials of regulatory authorities in Asia and elsewhere. His Government was committed to regional and international regulatory harmonization and recognized the importance of dialogue with all relevant stakeholders. New guidelines, enhanced regulatory capacity and incentives were required for cell and gene therapy products.

The representative of THAILAND[1] said that advancements in medical technology, such as cell- and gene-based therapies, could significantly benefit individuals, but their high prices were a barrier to access. When considering access to essential medicines and treatments, it might be preferable to aim for good treatment for most, rather than the best treatment for a few. The Government of Thailand called on the Secretariat and Member States to accelerate their work on the global strategy and plan of action on public health, innovation and intellectual property, prioritizing research and development on rare and orphan diseases in order to narrow health inequities and promote health for all.

The representative of JAMAICA[1] said that his Government continued to sustain its strong commitment to cancer prevention and treatment, including by pledging to reduce premature deaths due to breast cancer by 25% by 2025. However, with its designation as an upper-middle-income country, Jamaica faced several obstacles, and cell- and gene-based therapies remained inaccessible due to high prices and other barriers. Despite the progress made, much more remained to be done in implementing resolutions WHA70.12 (2017) and WHA72.8 (2019). His Government welcomed the Secretariat's support on hepatitis B and human papillomavirus vaccination programmes and its collaborative work on rare diseases. It would support further efforts to develop affordable solutions for low- and middle-income primary health care settings and called for political commitment, including resource mobilization, to improve transparency and expand access to health products and technologies.

The representative of SPAIN[1] said that her Government was committed to ensuring the accessibility, availability and quality assurance of medicines, promoting innovation and improving health emergency preparedness and response mechanisms. Recognizing the importance of price transparency in that regard, her Government had sponsored resolution WHA72.8 (2019), and called on all Member States to improve transparency to ensure universal health coverage and strengthen public health systems.

The representative of the INTERNATIONAL ATOMIC ENERGY AGENCY said that, in seeking to minimize the double burden of COVID-19 and cancer on patients, it was essential to ensure that work on cancer reached those in need. She drew attention to IAEA's work with WHO and the International Agency for Research on Cancer and its support for key global cancer initiatives, and outlined some of IAEA's activities in cancer control at country level. She said that IAEA looked forward

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

to continuing its collaboration with partners, and to contributing to the WHO-led global efforts towards achieving an integrated approach to cancer control and the Sustainable Development Goals.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIR, said that the report should be amended to include a paragraph on issues of procurement and pricing of the essential medicines for pain and palliative care included in section 2 of the WHO Model List of Essential Medicines, which were in short supply. Member States should heed the INCB, WHO and UNODC statement on access to internationally controlled medicines during the COVID-19 pandemic, and fund initiatives that would enable the Department of Essential Medicines and Health Products of WHO to continue its work with other United Nations organizations.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIR, emphasized the need for sufficient training on access to medicines, including on procurement and funding. The Secretariat and Member States should partner with pharmacists to strengthen regulatory systems and national pharmaceutical pricing policies and to establish a well-coordinated comprehensive infrastructure and improved access to medicines and innovation.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIR, said that the WHO prequalification of biotherapeutic products initiated in 2018 was helping to improve access. The information made available on in vitro diagnostics would be useful to address other noncommunicable diseases such as diabetes. Noting the importance of transparency, he said that it was difficult to identify how the Secretariat was engaged in implementing resolution WHA72.8 (2019), other than through initiatives instigated by WHO regions and existing programmes. The 2021 Fair Pricing Forum could provide an opportunity for specific action on transparency. The pharmaceutical industry should uphold its responsibility to make relevant information available.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIR, said that the disparities in access to the most effective treatments for cancer were severe and called on WHO to propose remedies, with particular regard to the knowledge required for manufacturing biologics and cell therapies. WHO should, in collaboration with WIPO and WTO, provide technical advice on flexibilities in international agreements to create exceptions to patent rights for treatments that could be classified as services. The WHO Global Observatory on Health Research and Development should collect information on the costs associated with clinical trials for new treatments. The WHO Model List of Essential Medicines should include a category for those treatments that would be essential if they were available at affordable prices.

The representative of the INTERNATIONAL ALLIANCE OF PATIENTS' ORGANIZATIONS, speaking at the invitation of the CHAIR, said that access to innovative, safe, effective, quality-assured and affordable treatments was a fundamental human right of every patient. Member States should work in solidarity to leverage the humanitarian spirit developed during the 2003 Human Genome Project to develop affordable solutions for the management of cancer and other noncommunicable and rare diseases in low- and middle-income primary health care settings.

The representative of the MEDICINES PATENT POOL FOUNDATION, speaking at the invitation of the CHAIR, said that mechanisms to ensure sustainable and affordable access to breakthrough cancer treatments in low- and middle-income countries were a long way off. Her organization was working to apply its partnership model based on voluntary licensing with industry to noncommunicable diseases. It had included new essential cancer medicines in its free patent database

MedsPaL and stood ready to provide support in addressing the challenges of the growing cancer burden in low- and middle-income countries.

The representative of the EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY, speaking at the invitation of the CHAIR, welcomed expanded access to effective treatments for cancer and rare and orphan diseases. Drawing attention to three tools available on her organization's website to assist Member States in appropriately selecting and prescribing cancer medicines, she said that her organization would be pleased to use its expertise to contribute to a global network of centres of excellence for rare diseases and to participate in the 2021 Fair Pricing Forum.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIR, said that the global cancer burden could be significantly reduced with timely diagnosis and access to appropriate treatment. Member States should ensure affordability and availability of quality-assured essential medicines and diagnostics based on national need; promote alignment in national lists for essential medicines, diagnostics and technologies; utilize international support to develop effective regulatory systems, procurement strategies and policies for transparent and fair pricing, including the use of flexibilities offered by the TRIPS Agreement; and support policies to increase the uptake of generics, build the capacity of local manufacturers and facilitate technology transfer.

The representative of MEDICUS MUNDI INTERNATIONAL – NETWORK HEALTH FOR ALL, speaking at the invitation of the CHAIR, said that action was required to tackle monopolies on biotherapeutics, streamline regulatory approval for generic medicines and eliminate data exclusivity in order to prevent unjust inequalities in access to treatment. Technology transfer must be accelerated and intellectual property barriers removed, including by using flexibilities offered by the TRIPS Agreement. The lack of transparency on research and development costs and the public financing of research prevented fair pricing, and it was a concern that transparency of pricing was currently prevented by commercial and competition laws in many countries. Member States and research institutions should put public interest conditions into funding for research into cancer and orphan and rare diseases.

The representative of RAD-AID INTERNATIONAL, speaking at the invitation of the CHAIR, highlighted the challenges associated with access to diagnostic imaging and radiation oncology, particularly in low- and middle-income countries. WHO should make access to radiology a priority and develop frameworks and guidance to support procurement and use of those critical tools.

The ASSISTANT DIRECTOR-GENERAL (Medicines and Health Products) thanked participants for their support for WHO's efforts on expanding access, which were guided by resolution WHA72.8 (2019) and the Roadmap for access to medicines, vaccines, and other health products 2019–2023. Access to safe, affordable, quality-assured medicines and health care products was a global concern addressed by many WHO departments in their work. Challenges in regulatory harmonization would increase as technology progressed, particularly in the area of medical devices and assistive technologies, and the Secretariat would look to increase its work in that field. WHO was on the verge of granting prequalification to an additional human papillomavirus vaccine manufacturer, which would help to diversify a very concentrated market. WHO would be pleased to increase its support for policies and recommendations at country level for the hepatitis B birth dose and would shortly be launching an updated report on access to hepatitis C medicines that included intellectual property and in vitro diagnostic issues. Given the limited length of the reports, the Secretariat would be pleased to organize information sessions on specific topics.

Shortages, particularly of medicines for pain and palliative care, were a concern, and she welcomed the positive experience of certain countries in managing price and transparency across the supply chain, and initiatives to promote cross-country collaboration. She looked forward to discussions

at the 2021 Fair Pricing Forum. A decision on equitable access was a political choice by countries and had to be supported by good public health policies and a coordinated approach with other stakeholders, including industry. Balancing the incentives needed for innovation with affordable access and fostering the transfer of technology to generate increased manufacturing capacity constituted key challenges requiring cooperation and dialogue.

The representative of the REGIONAL DIRECTOR FOR EUROPE said that all Member States in the European Region had expressed serious concerns about ever-increasing prices for new medicines entering the market, and restricted access to potentially effective novel medicines, including advanced therapy medicinal products. However, the COVID-19 pandemic had shown that, with commitment and collaboration, critical products could become available as soon as possible. The European Programme of Work 2020–2025 set out a commitment to work with all stakeholders to ensure access to safe, affordable and innovative medicines while leaving investors in the pharmaceutical industry sufficiently incentivized to develop and manufacture them. He trusted that participants would support the Oslo Medicines Initiative developed by the WHO Regional Office for Europe and the Government of Norway, which would present a new vision for collaboration between the public and private sectors to ensure better access to novel, effective medicines. The initiative, which had a strong focus on equity and leaving no one behind, was framed by the themes of solidarity, transparency and sustainability.

The Board noted the report.

2. GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY: Item 8 of the agenda (document EB148/10)

The CHAIR drew attention to the report on the global strategy and plan of action on public health, innovation and intellectual property set out in document EB148/10 and to a draft resolution on strengthening local production of medicines and other health technologies to improve access, proposed by China, Eswatini, Ethiopia, Ghana, Kenya, Namibia, Rwanda, South Africa, Sudan, Togo and Zimbabwe, which read:

> The Executive Board,
>
> Having considered the report on the global strategy and plan of action on public health, innovation and intellectual property,[1]
>
> (PP1) Recalling resolutions WHA60.20 (2007), WHA61.21 (2008), WHA62.16 (2009), WHA63.12 (2010), WHA65.17 (2012), WHA65.19 (2012), WHA66.22 (2013), WHA67.20 (2014), WHA67.21 (2014), WHA67.22 (2014), WHA68.7 (2015), WHA71.8 (2018), and WHA72.8 (2019), all of which encompass aspects of the need to promote access to the quality, safe, effective and affordable medicines and other health technologies;[2]
>
> (PP2) Recalling resolution WHA61.21 (2008), decision WHA71(9) (2018), and document A71/12 (2018), insofar as they address the role of technology transfer and local production of medicines and other health technologies in improving access;
>
> (PP3) Recalling also United Nations General Assembly resolution 74/30 (2020) and resolution WHA73.1 (2020) on the response to the coronavirus disease (COVID-19) pandemic, which call for intensified international cooperation and solidarity to contain, mitigate and

[1] Document EB148/10.

[2] Medicines and other health technologies includes pharmaceuticals, vaccines, biopharmaceuticals, medicals devices.

overcome the pandemic and its consequences through responses that are people-centred and gender-responsive, with full respect for human rights;

(PP4) Recalling also the Human Rights Council resolution 12/24 (2009) on access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health;

(PP5) Recalling further the 2030 Agenda for Sustainable Development and its aim of ensuring that no one is left behind;

[(PP5 bis) Recalling [the WTO Doha; add] Declaration on the TRIPS Agreement and Public Heath ([[WTO; add]; delete] Doha Declaration), adopted on 14 November 2001; add; delete; retain]

[(PP5 bis alt) Recalling the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provides flexibilities for the protection of public health and [the promotion of; add] [promotes; delete] access to medicines for all, in particular for developing countries [and least-developed countries, as affirmed by; add] [, and; delete] the Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that intellectual property protection is important for the development of new medicines. (Source: A/RES/74/20 (OP29) GHFP – previous resolution on TRIPS and public health); add; delete/reserve]

[(PP5 bis alt alt) Reaffirming the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) as amended, and also reaffirming the 2001 WTO Doha Declaration on the TRIPS Agreement and Public Health, which recognizes that the TRIPS Agreement should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, [which recognizes that intellectual property protection is important for the development of new medicines; reserve] [, including considering [as appropriate; add] time limited waivers of some specified provisions related to COVID-19 products and technologies; add; reserve; no objection]; add and replace PP5bis, PP5bis alt and request removal of mention of TRIPS IP in PP8bis, OP1.10, OP2.9; support PP5bis alt alt]

(PP6) Acknowledging Member States' commitment to achieve the Sustainable Development Goals including those that relate to local production of medicines and other health technologies in various ways (e.g. Goals 3, 8 and 9);

[(PP6 bis) Recognizing that some countries face problems in accessing medicines, vaccines and other essential health technologies, [such as [the overwhelming demand; delete/move], low manufacturing capacity, high prices, among others, [condition; delete] [can affect; add] access; add] and that such problems are exacerbated in times of pandemic [and/or overwhelming demand; add] such as COVID-19. [The overwhelming demand, low manufacturing capacity, high prices, among others, [condition; delete] [can affect; add] access; move]; add; reserve; question on source of language]

(PP7) Recalling WHO's roadmap for access to medicines, vaccines and other health products 2019–2023 as part of comprehensive support for access, and strategic local production, while considering regional plans and initiatives such as the Pharmaceutical Manufacturing Plan for Africa;

(PP8) [Considering that there is a need to emphasize; delete] [Emphasizing; add] the possibility of [realizing; delete] [promoting; add] access to [quality-assured; add] [safe, effective and affordable; add] medicines and other health technologies through building capacity for local production, especially in LMICs, [effective technology transfer [on voluntary and mutually agreed terms; add; reserve] and cooperation, [development of patent pools[, and promoting generic competition; add] [in order to promote generic competition,; delete]; delete]; add; delete] [based on; delete] [in line with; add] WHO's road map for access to medicines, vaccines and other health products 2019–2023 as comprehensive support for access;

[(PP8 bis) Recognizing [that; delete] intellectual property protection [has a significative role in the pharmaceutical industry; add; reserve; delete] [is important for the development of new medicines; delete] [while also [recognizing that public health-sensitive intellectual property rules and mechanism can help address the misalignment between profit driven innovation models and public health priorities; add; reserve; delete] [recognizing the need to ensure the financial sustainability of health systems; delete]; delete] [and also recognizes the concerns about its effect on prices; add]; add; reserve; reserve on first part] [delete entire PP8bis]

[(PP8 ter) Mindful of concerns about the current patent system, especially as regards access to medicines in developing countries and reaffirming that public health interests are paramount in both pharmaceutical and health policies; add; reserve; delete PP8ter]

(PP9) Recognizing that integration of local production into overall health systems strengthening can contribute to sustainable access to quality-assured, safe, effective and affordable medicines, help prevent or address medical product shortages, achieving universal health coverage and strengthening national health security;

(PP10) Recognizing also that local production can contribute to other national development goals, such as catalysing local capacity in innovation, strengthening human capital and expertise and building a knowledge-based economy;

(PP11) Recognizing further that the COVID-19 pandemic has highlighted the critical need to prepare for potential disruptions of the supply chain for essential medicines and other health technologies, including through the strengthening of local production;

[(PP11 bis) Recognizing the importance of promoting competition to improve availability and affordability of health technologies consistent with public health policies and needs, inter alia, through the production and introduction of generic versions, in particular of essential medicines, in developing countries; add; reserve]

(PP12) Noting that the local production of medicines and other health technologies can provide for greater [security; question; delete] [sustainability; add] of supply chains, especially in public health emergencies;

(PP13) Noting that the inter-agency statement on promoting local production signed by the six organizations (The Global Fund, UNAIDS, UNCTAD, UNICEF, UNIDO and WHO) calls for a holistic approach, close partnership, inter-ministerial and relevant stakeholder cooperation, and global synergy in promoting quality and sustainable local production of safe, effective, quality and affordable medicines and other health technologies;

(PP14) Recognizing the work of the inter-agency pharmaceutical cooperation group hosted by the WHO and the role of Unitaid and the Medicines Patent Pool to help countries enhance [their local production capacities; delete] [the access to medicines particularly for HIV/AIDS, tuberculosis and malaria, etc.; add], strengthen their regulatory systems and help producers meet pre-qualification standards;

(PP15) Recalling also the launch of the Access to COVID-19 Tools (ACT) Accelerator [and C-TAP; add; delete], which is a global collaboration that seeks to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines;

(PP16) Noting that, with globalization and the variety of country contexts, there is no “one size fits all” approach in promoting local production;

(PP17) Recognizing that conditions in the challenges faced by Member States are suitable for embarking on local production as a strategy to improve access to safe, effective, quality and affordable vaccines, medicines and other health technologies;

(PP18) Recognizing that the small economic size of some Member States’ economies poses a challenge for local production, which could be addressed by regional market integration;

(PP19) Emphasizing the need to ensure the quality, safety, efficacy, effectiveness and affordability of locally-produced medicines and other health technologies including through effective manufacturing and regulatory systems;

(PP20) Recognizing that an effective regulatory system is a necessary component to ensure the quality, safety and effectiveness of medicines and other health technologies; [propose to delete]

[(PP20 bis) Recognizing [the relevance of exercising; delete] [the Doha Declaration, which affirms that; add] the TRIPS [Agreement can and should be interpreted in a manner supportive of WTO members' right to protect public health and promote access to medicines for all, and reaffirms the right of WTO members to use, to the full, the provisions of the TRIPS Agreement, which provides; add] [flexibilities; delete] [flexibility for this purpose; add] [in order to promote research and development as well as local production; delete]; add; reserve] [propose one mention in document in PP5bis alt alt; propose one para in PP and in OP; propose one para in PP; propose mention in OP; delete]

[(PP 20 bis alt) Recognizing the need to promote access to medicines and other health technologies for all, including through the use of the TRIPS flexibilities, recognizing the importance of protection of intellectual property for the development of new medicines as well as the concern[s; add] about its effect on prices; add; delete]

(PP21) Noting that the benefits and sustainability of local production is dependent on a functioning pharmaceutical value chain: from research and development, manufacturing and regulation through to pricing and reimbursement, supply chains and prescribing and dispensing by health workers as well as stewardship to ensure judicious use and prevent inappropriate use;

(PP22) Acknowledging with appreciation the many existing national, regional and global efforts, as well as the achievements made by the Member States, to quality and sustainable local production of safe, effective and affordable medicines and other health technologies to benefit public health needs;

(PP23) Noting that local production can contribute towards achieving the triple billion goals of WHO's Thirteenth General Programme of Work;

(PP24) Noting with concern that Member States still face many challenges in establishing and strengthening sustainable local production of quality-assured, safe, effective and affordable medicines and other health technologies to benefit public health need and health security,

(OP1) URGES Member States, where appropriate, based on the national context:[1]

(OP1.1) to strengthen their leadership, commitment and support in promoting to establish and strengthen quality and sustainable local production of medicines and other health technologies that follows good manufacturing practices;

(OP1.2) to align their national and regional policies and strategies related to local production, and to leverage regional economic integration and coordination platforms to agree upon support for products with sizeable regional demand to expand access to markets and enhance sustainability of local production;

(OP1.3) to develop evidence-based holistic national and regional policies, financing mechanisms, strategies and plans of action, in collaboration with stakeholders, for strengthening the local production of quality-assured medicines and other health technologies;

(OP1.4) to explore the mechanism to establish [a; delete] national/regional pooled fund[s; add] to [ensure; delete and propose "facilitate"; support] sustainable support for the implementation of the national/regional strategies for local production; [question on OP1.4; suggest to integrate into OP1.3; delete OP1.4; retain but can also merge with OP1.3] [reserve/delete; retain]

[1] And, where applicable, regional economic integration organizations.

[(OP1.4 alt) to explore appropriate mechanisms to support the sustainable implementation of the national/regional strategies for local production [, which may include national/regional pooled funds; add; reserve]; add]
(OP1.5) to enhance inter-ministerial policy coherence and to create incentives and an enabling business environment for local production to be quality-assured and sustainable;
(OP1.6) to apply a holistic approach in strengthening local production by considering, for example, promoting research and development, price transparency, regulatory systems strengthening, access to sustainable and affordable financing, development of skilled human resources, access to technology [on voluntary and mutually agreed terms; add; delete] for production and needs-based innovation [and/or in line with international and multi-lateral frameworks; add; delete]; the aggregation of national and regional demand; appropriate incentives for private-sector investment; and [procurement decisions based on quality and not only lowest cost [and following good manufacturing practice; add]; delete], particularly in the context of achieving universal health coverage;
(OP1.7) to engage in global, regional and subregional networks related to promoting quality and sustainable local production of quality, safe, effective and affordable medicines and to further enhance multistakeholder collaboration;
(OP1.8) to further engage in North–South and South–South development cooperation, partnerships and networks to build and improve the transfer [and localization; add] of technology related to health innovation [[on [voluntary and; add] mutually-agreed terms; delete] and/or in line with [international [and multi-lateral; add] frameworks; reserve]; add]
(OP1.9) to promote [sustainable; add] local production of [safe and effective [and evidence-based; add]; add] [knowledge-based; add] traditional medicines as alternative source of medicines especially through research and manufacturing of local herbal medicines [according to national contexts and priorities; add]; [delete OP1.9; retain OP1.9]
[(OP1.10) to [fully; add] use the flexibilities [provided in; delete] [embedded in the TRIPS Agreement and; add] [affirmed by the Doha Declaration [on TRIPS and Public Health; add], which affirms that; add] the TRIPS Agreement [[in order to promote local production; delete], [generic competition; delete; retain] and access to medicines.; delete] [can and should be interpreted in a manner supportive of WTO members' right to protect public health and promote access to medicines for all, and reaffirms the right of WTO members to use, to the full, the provisions of the TRIPS Agreement, which provides flexibility for this purpose; add]; add; reserve]
[(OP1.10 alt) to acknowledge the possibility to use in urgent cases the flexibilities provided in the TRIPS Agreement in order to ensure access to medicines.; propose OP1.10alt or delete OP1.10] [delete OP1.10 and in other OP related to TRIPS; delete OP1.10; propose para mentioned once in document]

(OP2) REQUESTS the Director General:
(OP2.1) to continue to support Member States by strengthening actions related to resolutions WHA61.21, WHA66.22 and WHA67.20;
(OP2.2) to strengthen the WHO's role in providing leadership and direction in promoting the strategic use of quality, accessible and affordable and sustainable local production of medicines and other health technologies, by using a holistic approach and following good manufacturing practices;
(OP2.3) to raise awareness of the importance of sustainable local production of safe, effective, quality and affordable medicines and other health technologies in improving access;

(OP2.4) to continue to support Member States, upon their request, in promoting quality and sustainable local production of active pharmaceutical ingredients, medicines and other health technologies, including, as appropriate, by:

(OP2.4.a) providing technical support to Member States in developing and/or implementing national policies and evidence-based comprehensive strategies and plans of action for local production;

(OP2.4.b) supporting Member States to foster strategic and collaborative partnerships, particularly for research and manufacturing;

(OP2.4.c) building the capacity of Member States towards policy coherence and creating an enabling business environment; [agreed to retain as it is under OP2.4; will propose text; propose to merge with OP2.4a]

(OP2.4.d) building the capacity of governments and other stakeholders to strengthen local production towards quality assurance, regulatory approval and WHO prequalification as appropriate; [text agreed but will propose new text]

(OP2.4.e) strengthening regulatory system and regional regulatory collaboration;

(OP2.4.f) supporting Member States in [facilitating; add] [research and development and; delete; retain] technology transfer [[on voluntary and mutually agreed terms; delete; retain] [and/or in line with international and multi-lateral frameworks; add; delete/reserve, retain] add] for local production of [quality-assured; add] prioritized medicines and other health technologies to [prevent and; add] address shortages and/or specific local public health needs [to continue to support Member States in the exchange and transfer of technology and research findings, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer; add; delete];

(OP2.4.g) exploring a mechanism for collecting and disseminating local production-related market intelligence; [question; retain]

(OP2.5) to encourage greater participation on the part of Member States in existing regional and global initiatives for collaboration and cooperation, in line with WHO principles and guidelines;

(OP2.6) to foster and coordinate with relevant international intergovernmental organizations in promoting local production in a strategic and collaborative approach;

(OP2.7) [to [establish a; delete; retain] [leverage existing; add; delete]; delete] [to leverage existing and, if needed, establish new; add] global platforms to promote need-based transfer of technology [on voluntary and mutually agreed terms; add; delete] [and/or in line with international and multi-lateral frameworks; add; delete] and local production under North–South and South–South cooperation;

(OP2.8) to allocate sufficient resources to carry out activities under this resolution at all three levels of the Organization;

[(OP2.9) to [continue to support the application of; delete] [affirm the right of WTO Members to use; add] TRIPS flexibilities in order to [protect public health and, in particular; add] promote [local production, [generic competition; delete] and; delete] access to medicines [for all; add]; add; reserve] [delete OP2.9; propose mention this type of para once]

[(OP2.9 alt) [to continue to [support; delete] [recognize; add] the application of TRIPS flexibilities in [urgent cases to ensure; add] [order to promote local production, generic competition and; delete] access to medicines; add; reserve]; add]

[(OP 2.9 bis) to continue support transparency of prices and cost of medicines (including the supply chain) in order to promote access and affordability; add]

[(OP2.10) to report [on progress in the implementation of this resolution; add] [back; delete] to the World Health Assembly [yearly from 2023–2027; add] [in 2023; delete], through the Executive Board [and to ensure that strengthening local production is included as part of regular reporting on access to medicines.; add] [, on WHO efforts to support the strategic use of local production of medicines and other health technologies, including the consideration of factors such as quality standards and cost; delete]; add]

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

Resolution:	Strengthening local production of medicines and other health technologies to improve access
A.	**Link to the approved Programme budget 2020–2021**
1.	**Output(s) in the approved Programme budget 2020–2021 to which this draft resolution would contribute if adopted:** 1.3.2. Improved and more equitable access to health products through global market shaping and supporting countries to monitor and ensure efficient and transparent procurement and supply systems 1.3.3. Country and regional regulatory capacity strengthened, and supply of quality-assured and safe health products improved 2.1.2. Capacities for emergency preparedness strengthened in all countries 2.3.3. Essential health services and systems maintained and strengthened in fragile, conflict and vulnerable settings
2.	**Short justification for considering the draft resolution, if there is no link to the results as indicated in the approved Programme budget 2020–2021:** Not applicable.
3.	**Any additional Secretariat work during the biennium 2020–2021 that cannot be covered by the approved Programme budget 2020–2021:** Not applicable.
4.	**Estimated time frame (in years or months) to implement the resolution:** 10 years, from 2021 to 2030.
B.	**Resource implications for the Secretariat for implementation of the resolution**
1.	**Total resource requirements to implement the resolution, in US$ millions:** US$ 69.54 million, for the period 2021–2030.
2.a.	**Estimated resource requirements already planned for in the approved Programme budget 2020–2021, in US$ millions:** US$ 5.16 million.

2.b. Estimated resource requirements in addition to those already planned for in the approved Programme budget 2020–2021, in US$ millions:

Not applicable.

3. Estimated resource requirements to be considered for the proposed programme budget for 2022–2023, in US$ millions:

US$ 13.32 million.

4. Estimated resource requirements to be considered for the proposed programme budgets of future bienniums, in US$ millions:

US$ 51.06 million for the remaining seven years.

5. Level of available resources to fund the implementation of the resolution in the current biennium, in US$ millions

– **Resources available to fund the resolution in the current biennium:**

US$ 0.56 million.

– **Remaining financing gap in the current biennium:**

US$ 4.60 million.

– **Estimated resources, not yet available, if any, which would help to close the financing gap in the current biennium:**

Discussions are ongoing with donors for mobilizing resources as well as for redistribution of underutilized funds within the existing Programme budget.

Table. Breakdown of estimated resource requirements (in US$ millions)

Biennium	Costs	Region						Headquarters	Total
		Africa	The Americas	South-East Asia	Europe	Eastern Mediterranean	Western Pacific		
2020–2021 resources already planned	Staff	0.07	0.12	0.05	0.08	0.04	0.06	1.09	1.51
	Activities	0.00	0.00	0.00	0.00	0.00	0.00	3.65	3.65
	Total	0.07	0.12	0.05	0.08	0.04	0.06	4.74	5.16
2020–2021 additional resources	Staff	–	–	–	–	–	–	–	–
	Activities	–	–	–	–	–	–	–	–
	Total	–	–	–	–	–	–	–	–
2022–2023 resources to be planned	Staff	0.30	0.50	0.21	0.34	0.18	0.26	4.72	6.51
	Activities	0.18	0.18	0.18	0.18	0.18	0.18	5.73	6.81
	Total	0.48	0.68	0.39	0.52	0.36	0.44	10.45	13.32
Future bienniums resources to be planned	Staff	1.08	1.82	0.78	1.23	0.66	0.93	25.78	32.28
	Activities	0.70	0.70	0.70	0.70	0.70	0.70	14.58	18.78
	Total	1.78	2.52	1.48	1.93	1.36	1.63	40.36	51.06

The representative of ARGENTINA welcomed the decision of the Government of the United States of America to remain a Member State of WHO and participate in the COVID-19 Vaccine Global Access (COVAX) Facility. Many of the challenges that had led to the development of the global strategy and plan of action on public health, innovation and intellectual property persisted, in particular regarding access to medicines, and its eight elements remained valid. The 33 priority actions should be fully funded. He reaffirmed the importance of the WHO Global Observatory on Health Research and

Development in generating evidence, and of the role of Member States in determining health research and development priorities, particularly in developing countries. Noting the importance of access to scientific knowledge for building capacity in low- and middle-income countries, he supported the steps to be taken in response to recommendation 7 of the review panel established to conduct an overall programme review of the global strategy and plan of action, and on the recommendations to promote transfer of technology. The WHO prequalification programme was key in facilitating access to expensive technologies in developing countries, and he drew attention to regional mechanisms for addressing procurement issues, including PAHO's Strategic and Revolving Funds. He also underscored the importance of using flexibilities offered by the TRIPS Agreement to increase local production and capacities. He supported the draft resolution.

The representative of CHINA said that she looked forward to the publication of the Secretariat's findings on the Member State questionnaire on implementation progress. The feasibility of the implementation plan 2020–2022 to guide further action on the prioritized recommendations of the review panel was a concern in view of the impact of COVID-19, and the Secretariat should give due regard to human and financial challenges that could affect the priority actions and elaborate on the timeline. The implementation plan should be based on available resources, and consideration might be given to decreasing the number of activities in order to ensure substantive and prompt action. Activities concerning development of and improved access to new vaccines should be aligned with steps to be taken by the Secretariat in response to the recommendations.

The representative of KENYA, speaking on behalf of the Member States of the African Region, said that the challenges of the COVID-19 pandemic had shown the global strategy's main objective of increasing access to medicines and other new health products to be highly relevant and a priority in the global health agenda. Although progress had been made in implementing the global strategy in recent years, more needed to be done to strengthen research, innovation and access to medical products to address priority health challenges, particularly those that disproportionately affected the African Region. The Member States of the Region therefore called for continued resource mobilization efforts to address the recommendations of the review panel. They welcomed the development of the implementation plan 2020–2022, which should be financed from the core budget and included in the programme budget 2022–2023. They supported the draft resolution and called on all Member States to strengthen local production of essential medicines and commodities.

The representative of the UNITED ARAB EMIRATES, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that the planned activities and recommendations would be useful in reviewing progress and setting benchmarks for achieving target 3.8 of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). The Member States of the Region remained committed to supporting the global strategy and plan of action and appreciated the continued technical support provided by the Secretariat to ensure comprehensive, focused and sequential implementation of the planned activities, with particular emphasis on the COVID-19 response.

The representative of BANGLADESH said that the COVID-19 pandemic had demonstrated the importance, value and relevance of implementing the global strategy and plan of action in line with their measurable indicators. Progress on a number of recommendations was necessary in order to combat diseases that disproportionally affected low- and middle-income countries, and he looked forward to receiving a detailed report on implementation progress at the Seventy-fourth World Health Assembly. WHO should ensure that the funds required for the effective implementation of the global strategy and plan of action were available through its core budget. The flexibilities offered by the TRIPS Agreement should be used to ensure that intellectual property rules did not hamper the development of local

production capacity. In addition, developed countries should provide incentives to enterprises for technology transfer to the least developed countries, as provided for in Article 66.2 of that Agreement.

The representative of the UNITED STATES OF AMERICA said that he looked forward to the Secretariat's report on its findings from Member States' responses to the questionnaire. WHO's efforts to make progress on the goals and objectives of the global strategy and plan of action were welcome, particularly in the high-priority areas of regulatory systems strengthening and research capacity-building. It was, however, disappointing that several elements that were not part of the global strategy and plan of action remained in the implementation plan without any clear linkage to their original mandates, and that matter should be addressed. WHO should continue to coordinate with WIPO and WTO on matters relating to international trade and intellectual property. The COVID-19 pandemic had highlighted the importance of strengthening domestic and regional supply chains, including through local production and facilitation of trade in key health products, and the draft resolution provided Member States with many areas of collaboration.

The representative of INDIA said that he fully supported the eight elements of the global strategy and plan of action and welcomed the progress made in implementing the recommendations of the review panel. He acknowledged the efforts of the WHO Global Observatory on Health Research and Development in collaboration with the WHO Global Malaria Programme in devising methodology for prioritizing research and development for malaria. WHO's work on improving research capacity was appreciated, and the Organization should continue to support Member States in generating evidence-based policies and strategic plans to strengthen the role of traditional and complementary medicines in health systems. It should also continue to assist Member States in managing intellectual property issues to enable them to safeguard their public health interests while adhering to their obligations under international trade agreements.

The representative of the RUSSIAN FEDERATION outlined a number of elements necessary to increase access to medicines on the global market, including transparency, voluntary licensing mechanisms, scientific capacity-building, enhanced cooperation, and use of the flexibilities offered by the TRIPS Agreement, including under pandemic conditions. The COVID-19 pandemic had demonstrated the need for a coordinated approach by governments to improve access to innovative and effective medicines, including vaccines and various medical technologies. The draft resolution would provide an additional instrument to assist WHO in its further work.

The representative of ETHIOPIA[1] said that there were huge disparities in access to safe, effective, quality-assured and affordable medicines necessary to achieve universal health coverage in line with target 3.8 of Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages). Moreover, in certain low-resource settings, including Africa, the availability of such medicines was heavily dependent on imports. The COVID-19 pandemic had shown that sustainable local production of quality-assured medicines was a vitally important strategy that could help to ensure reliable access and catalyse knowledge-based economic growth, research and development, while strengthening national regulatory systems to control the influx of substandard medicines. That strategy would also empower Member States and make health systems more resilient in responding to health emergencies.

Although some progress had been made in developing local pharmaceutical industries and promoting local production, many challenges remained. Accordingly, her Government was proposing the draft resolution on strengthening local production of medicines and other health technologies to improve access, which sought to strengthen WHO's role in providing leadership and in continuing to

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

support Member States in promoting sustainable local production. She thanked the Secretariat for facilitating consultation on the text, and noted that general consensus had already been reached on many paragraphs. She expressed her gratitude to the governments that had sponsored the draft resolution, and noted that the Governments of Botswana and Brazil had been added to the list of sponsors. She looked forward to its adoption at the Seventy-fourth session of the World Health Assembly.

The representative of the PHILIPPINES[1] expressed support for the recommendations of the review panel and the elements of the global strategy and plan of action, which remained highly relevant in the context of the COVID-19 pandemic and which would guide future initiatives of Member States on innovation, research and development towards the achievement of other public health goals. Having outlined a number of challenges that her Government faced in tackling the pandemic, she said that the need for global cooperation to build a better system that left no one behind had become clear. Initiatives such as the Solidarity clinical trial and the COVAX Facility, in which her Government was participating, were highly appreciated as a means of ensuring equitable access to COVID-19 medicines and vaccines, especially for low- and middle-income countries.

The representative of JAPAN[1] said that his Government, which highly valued universal health coverage, had contributed to the international collaborative COVID-19 response efforts and was considering making a donation to Unitaid to support collaboration with the Medicines Patent Pool. Intellectual property acted as an incentive for research and development and should be respected and appropriately protected.

The representative of MALAYSIA[1] said that it was important to ensure that people in all countries had access to new medicines and health products. She noted the guiding principles of the implementation plan and the elements of the global strategy and plan of action, which should be applied subject to national law. Furthermore, the Secretariat must recognize existing limitations when seeking to apply the implementation plan before the deadline of 2022.

The representative of THAILAND,[1] noting with concern the slow progress made in implementing the global strategy and plan of action, called on the Secretariat to accelerate efforts and provide a progress report to the Seventy-fourth World Health Assembly as well as a time frame for strategic implementation. Technology transfer, management of intellectual property rights and improved access to medicines, vaccines and medical products were key actions associated with the global strategy and plan of action that were of benefit in the context of the COVID-19 response.

The representative of BRAZIL[1] said that access to affordable, safe, effective and quality-assured medicines, which was essential for sustainable and resilient health systems and should be the cornerstone of efforts to ensure health for all, was assuming even greater importance, particularly in the context of the COVID-19 response and recovery, and the challenges of antimicrobial resistance. Full implementation of the global strategy and plan of action could be achieved with the goodwill and engagement of all stakeholders. He therefore called upon the Secretariat to accelerate action on the implementation plan with the appropriate level of funding and in synergy with the Roadmap for access to medicines, vaccines and other health products 2019–2023 and relevant Health Assembly resolutions.

The representative of INDONESIA[1] said that her Government looked forward to the publication of the findings of the Member State questionnaire, which it hoped would promote further discussion on the implementation of the global strategy and plan of action and help to address barriers to the development of safe, quality and affordable health products. The COVID-19 pandemic had magnified

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

vulnerabilities in global supply chains and had highlighted the strong need to build capacity for local production of medicines, vaccines and medical equipment. Her Government, which was developing its own road map to strengthen local production of health products, supported the draft resolution and would welcome South–South and North–South collaboration to facilitate the transfer of knowledge and technology, particularly to developing countries.

The representative of GABON,[1] emphasizing the importance of local production of medicines, said that his Government would be pleased to sponsor the draft resolution.

The representative of ECUADOR[1] said that the implementation plan 2020–2022 would promote innovation and access to medicines and support needs-driven essential health research and development, including for diseases that disproportionally affected developing countries, and in accordance with the objectives of the 2030 Agenda for Sustainable Development. He welcomed the steps taken by WHO to promote the successful implementation of the global strategy and plan of action and highlighted the importance of sustainable financing in that regard.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIR, noted with satisfaction that all eight elements of the global strategy and plan of action had been deemed valid by the review panel, since the document remained an essential tool for making health innovations available, accessible and affordable to those in need. In the current circumstances, all stakeholders should engage in promoting production in low- and middle-income countries and in increasing transparency, and advantage should be taken of all relevant platforms such as the COVID-19 Technology Access Pool.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIR, said that in order to overcome persistent challenges, WHO should continue providing support to strengthen the capacity of national and regional regulatory systems and, as recommended by the review panel, develop target product profiles for missing antibiotics and in vitro diagnostic tools for priority pathogens and medical devices. WHO should also strengthen the Global Observatory on Health Research and Development.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIR, called on the Secretariat and Member States to give young people opportunities in training, research and development to facilitate the effective use of health technologies, and to organize consultations with youth representatives as part of the decision-making process. He urged Member States to implement an ethical approach to innovation and access to health technologies, particularly in light of the ongoing COVID-19 pandemic.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIR, said that the COVID-19 pandemic had shown that it was possible to accelerate research and development based on health needs with public funding, notwithstanding intellectual property limitations. The initiative to seek a temporary waiver of intellectual property rights for COVID-19 health technologies, which could provide a new approach to managing intellectual property in a pandemic, should be reflected in the implementation plan, and WHO should continue to provide institutional support for the waiver proposal. He expressed concern that the report failed to mention recommendation 4 of the review panel on promoting transparency in, and understanding of, the costs of

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

research and development. He called on Member States to address intellectual property barriers and lack of transparency and improve access to medical tools for COVID-19.

The representative of MEDICINES PATENT POOL FOUNDATION, speaking at the invitation of the CHAIR, said that her organization was committed to contributing to implementation of the global strategy and plan of action, including in the context of recommendation 18 of the review panel. Her organization was working with 21 generic manufacturers in five low- and middle-income countries to promote the production and supply of affordable treatments in those countries and was developing new relationships in other countries. Any manufacturer could apply for a licence, provided that key criteria were met, including stringent quality standards.

The representative of MEDICUS MUNDI INTERNATIONAL – NETWORK HEALTH FOR ALL, speaking at the invitation of the CHAIR, drew attention to a number of shortcomings in the implementation plan. He expressed support for the draft resolution and, highlighting the importance of transparency regarding research, development and production costs, called on WHO to ensure that all entities receiving public funding for research and development made all the associated data publicly available.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIR, said that the WHO Global Observatory on Health Research and Development had yet to play a useful role in the collection and dissemination of information about the economics of research and development. A priority for the Observatory should be the implementation of paragraph 2(4) of resolution WHA72.8 (2019), which concerned the establishment of a web-based tool to share information relevant to the transparency of markets for health products, including information on investments, incentives, and subsidies.

The ASSISTANT DIRECTOR-GENERAL (Medicines and Health Products), thanking the Government of Ethiopia for proposing the draft resolution, said that the COVID-19 pandemic had shown that the production of types of ingredients was concentrated in certain countries and how beneficial it would be to diversify and increase manufacturing capacity in different locations in the world to match the globalized supply chain. She drew attention to the COVID-19 Technology Access Pool, championed by the Government of Costa Rica, as a platform to enhance capacity through the sharing of knowledge and use of all available resources to increase the voluntary licensing of safe, effective and quality-assured technologies to assist in the acute phase of the pandemic. While WHO was engaged in tripartite collaboration with WIPO and WTO on intellectual property issues, it also collaborated with various other United Nations agencies to support Member States. The Secretariat would present its findings on the responses to the questionnaire received from 65 Member States by the end of January 2021. It would continue to report on the implementation plan 2020–2022 and had noted the request for more information, including on the next steps and on the WHO Global Observatory on Health Research and Development. With regard to concerns about financial sustainability, she said that the provision of support for any of the activities outlined in the recommendations would be welcome. The Secretariat was seeking to strengthen the convergence between relevant WHO resolutions to move the equitable access agenda forward and would be pleased to organize information sessions on specific topics.

The DIRECTOR-GENERAL said that rapid and efficient innovation and equitable access to affordable, safe, efficacious and quality medicines and health care products was more critical than ever. The global strategy and plan of action promoted new thinking on innovation and access to medicines, vaccines and diagnostics for all countries, including in response to emergencies, and reinforced new initiatives, such as the Access to COVID-19 Tools (ACT) Accelerator and the WHO COVID-19 Technology Access Pool. The COVID-19 pandemic had provided an opportunity to rethink interaction between health and other policy domains, such as intellectual property and international trade, and to

work collaboratively across all sectors to reinforce and strengthen synergies that advanced scientific progress, innovation and access to medical technologies. WHO was committed to working with Member States, United Nations agencies and other stakeholders to intensify implementation of the recommendations of the review panel.

The pandemic had also shown the importance of strengthening and expanding global manufacturing capacity to meet global demand for priority COVID-19 products in a timely fashion. Local production could play a critical role in achieving equitable access to COVID-19 vaccines, therapeutics, medical devices and equipment, ensuring that health systems would be able to respond to future public health crises and safeguarding health security. Therefore, he thanked the Government of Ethiopia for its initiative in proposing the draft resolution. WHO was committed to working with Member States and partners from the public and private sectors to promote technology transfer and build conducive business, regulatory and technical environments for sustainable local production of quality-assured, safe, effective and affordable medicines and health products.

The CHAIR said that consultations on the draft resolution would continue in the intersessional period with a view to the submission of a final version to the Seventy-fourth World Health Assembly and took it that the Board wished to note the report.

The Board noted the report.

The meeting rose at 12:55.

= = =