EXECUTIVE BOARD
148th session

EB148/PSR/12
5 May 2021

PROVISIONAL SUMMARY RECORD OF THE TWELFTH MEETING

WHO headquarters, Geneva
Saturday, 23 January 2021, scheduled at 14:00

Chair: Dr H. VARDHAN (India)

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TWELFTH MEETING

Saturday, 23 January 2021, at 14:05

Chair: Dr H. VARDHAN (India)

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

1. SUBSTANDARD AND FALSIFIED MEDICAL PRODUCTS: Item 10 of the agenda (document EB148/12)

STANDARDIZATION OF MEDICAL DEVICES NOMENCLATURE: ITEM 11 OF THE AGENDA (DOCUMENT EB148/13)

The representative of AUSTRIA, speaking on behalf of the European Union and its Member States, welcomed the reports and the continuation of WHO's work on substandard and falsified medical products and the standardization of medical devices nomenclature.

The representative of the RUSSIAN FEDERATION said that he appreciated the Organization's support of the Member State mechanism on substandard and falsified medical products. It was important to ensure access to information on the mechanism by publishing it online, continue exchanging information on the subject and strengthen coordinated action by Member States to tackle the availability of substandard and falsified medical products. He welcomed the development of a procedural document to help Member States navigate the mechanism. While he supported the notion of standardization of medical devices nomenclature, he expressed doubt as to the appropriateness of harmonization with the European Medical Devices Nomenclature, since work on that nomenclature had not been finalized. Rather, the Global Medical Device Nomenclature should be employed, as it was widely available and utilized at the international level.

The representative of AUSTRALIA said that she did not support the establishment of another medical device nomenclature. The Global Medical Device Nomenclature met WHO's list of requirements for governance, classification and access to information, was available in 20 languages and was widely used. A lack of harmonization of the proposed international classification, coding and nomenclature with the Global Medical Device Nomenclature would create further inconsistency in the identification of medical devices. The limited transparency of the comparative analysis and insufficient engagement with regulators and the medical device industry had restricted WHO's understanding of the impact of a new nomenclature. Noting the proposal regarding the European Medical Devices Nomenclature that was under development, she expressed concern that global nomenclature standardization would be challenging for those required to adopt the new nomenclature, as various jurisdictions would continue to use established systems. She encouraged the Secretariat to consider the risks of increased complexity, confusion and patient costs and to continue discussing the way forward with Member States.

The representative of INDIA expressed support for the work of the Member State mechanism on substandard and falsified medical products. He opposed any improper use of the mechanism to impede the availability of authorized, quality and affordable generic drugs based on erroneous interpretations or definitions of substandard and falsified medical products. He did not support the use of the term

"counterfeit" in relation to medicines, since it was associated with intellectual property rights and could be used to prevent the export of quality and affordable generic medical products to countries in need. The mechanism should ensure the availability of quality generic medical products and guard against vested interests that might block their manufacture, marketing and export.

The representative of KENYA, speaking on behalf of the Member States of the African Region, acknowledged the progress made by the Member State mechanism. Efforts were being made to curtail the circulation of substandard and falsified medical products in her Region, and regulatory capacity would improve with the entry into force of the African Continental Free Trade Area. Adequate financing and support were needed for the implementation of activities under the Member State mechanism. She supported the establishment of a dedicated working group for initiatives to raise the profile of the mechanism. Recognizing the urgent need for an international classification, coding and nomenclature for medical devices and noting the preference in the report for the National Classification of Devices adopted by the European Commission, she recommended that, prior to starting work, WHO should convene a forum for national regulatory authorities responsible for medical devices in order to present the assessment of the available systems and consult on the preferred system. Member States should be actively involved in finalizing the standardization of medical devices nomenclature.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND welcomed the report on substandard and falsified medical products. Regarding the standardization of medical devices nomenclature, she said that, in the light of the rapidly-changing market and the diverse and complex needs of all stakeholders, Member States had requested the Secretariat to work closely with the International Medical Devices Regulators Forum on the technical requirements for medical device nomenclature and how to fulfil them, and she would welcome confirmation of that ongoing work. She asked the Secretariat to provide further information on the reasons behind the finding of inconsistency between certain nomenclature systems and principles set out by WHO. Greater transparency in that respect would enable Member States to compare the shortcomings and consider possible solutions. An opportunity for further engagement on the matter would be welcome.

The representative of ISRAEL said that he supported the work of the Member State mechanism and encouraged Member States to participate in its activities. He welcomed the Secretariat's work on the pharmacy school curriculum on substandard and falsified medical products, and stood ready to share his country's experience in that area. More information would be appreciated on the work of the working group on the distribution or supply of substandard and falsified medical products via the internet, particularly on how Member States could contribute to its work. He would welcome a procedural document to assist Member States in understanding the intergovernmental process.

The representative of the UNITED STATES OF AMERICA said that the Member State mechanism should prioritize activities to address substandard and falsified medical products distributed through informal markets, and WHO should strengthen coordination with other bodies to address the supply chain for medical products. Given the delays caused by the coronavirus disease (COVID-19) pandemic, the Secretariat should use virtual means to drive progress on the pilot programme for risk-based post-market surveillance in the United Republic of Tanzania. He encouraged all Member States to engage with the Secretariat to support and use the mechanism.

With regard to the standardization of medical devices nomenclature, he expressed his continued concern about WHO's efforts to host and make available an existing nomenclature system, and the possible adoption of the European Medical Devices Nomenclature. It was regrettable that the Secretariat had not held a briefing on that matter in late 2020. The decision-making process for the proposal to adopt the European Medical Devices Nomenclature had lacked the full involvement of appropriate stakeholders, including medical device manufacturers, and could lead to greater complexities, cost and

confusion in the medical technology and health-care sectors. He was also concerned that the European Medical Devices Nomenclature was not harmonized with the Global Medical Device Nomenclature, which was already utilized, free of charge, by many national medical device regulators. Further information would be appreciated on the Secretariat's conclusion that the Global Medical Device Nomenclature did not meet WHO's principles for an international classification system, as well as on the specific principle stating that information should be freely available and considered a global public good. It was critical to ensure that the chosen system was harmonized and interoperable with the Global Medical Device Nomenclature and other relevant systems to prevent further inconsistencies in the identification of medical devices and obstacles to patient access. He urged WHO to continue cooperating with the International Medical Device Regulators Forum to develop a harmonized approach.

The representative of COLOMBIA commended the Organization for the progress made and support offered to Member States relating to the standardization of medical devices nomenclature. Advances were being made in her country in that regard, for which WHO's support was essential. A report should be prepared compiling experiences relating to medical devices nomenclature, which would give countries quick and free access to information on best practices, with a view to standardization.

The representative of the REPUBLIC OF KOREA said that increased demand and supply chain disruption caused by the COVID-19 pandemic had led to a sudden increase in substandard and falsified medical products, particularly in the context of e-commerce. Measures were taken in her country to combat the problem, but the threat to health was global. The standardization of medical devices nomenclature would afford various benefits to countries whose current systems had not proven successful. The Secretariat should keep Member States abreast of its progress in that area, including progress on a transition period, and share detailed information on its plans for managing and supporting the international nomenclature for medical devices.

The representative of OMAN, speaking on behalf of the Member States of the Eastern Mediterranean Region, said that adequate control was needed over the supply chain, particularly given the increased proliferation of substandard and falsified medical products generated by the COVID-19 pandemic. Stringent measures must be established to mitigate the risk of falsified COVID-19 vaccines, alongside communication campaigns to maintain public trust and encourage vaccination through regulated channels. The Member State mechanism should consider the supply and use of generic medical products with potential to support the prevention and control of substandard and falsified medical products. She requested WHO's continued support to facilitate an exchange of experiences regarding substandard and falsified medical products; provide technical support to identify gaps in national legislation and regulatory structures; build capacity for prevention, detection and response; and strengthen coordination between the mechanism and Member States.

The representative of INDONESIA, expressing support for the activities of the Member State mechanism, said that, given the importance of a quality reporting method, a mobile application to detect the use of substandard and falsified medical products among health workers had been piloted in her country, the results of which would be published by WHO. She called on Member States to participate fully in global efforts to combat substandard and falsified medical products and ensure better-quality health care. While global standardization of medical devices nomenclature systems was important, the diversity of systems already in place posed an obstacle to that endeavour. Global standardization should be based on scientific findings and international standards, taking into account the diverse regulatory systems and manufacturing conditions in all Member States to enable global application.

The representative of GERMANY highlighted that the establishment of a global system of medical devices nomenclature was a normative core function of WHO that could not be outsourced to a private body outside of WHO's control. Any such system should be: designed and governed by

regulators for regulators, rather than by private bodies dominated by industry for industry; stable, unlike the existing private system, and changes should be fully transparent and traceable; available for use by all public health systems in WHO Member States; and available to all Member States, not only rich countries. Small innovative companies in smaller or poorer countries could not afford the registration fee charged by the private system to register devices. Such a system should be transparent and overseen by Member States rather than by a private body, and should be multilingual. He therefore strongly supported WHO's current handling of the matter and its continuing work, without hindrance from other areas.

The representative of BRAZIL[1] encouraged all Member States and the Secretariat to continue supporting the Member State mechanism. The causes of the manufacturing and distribution of substandard and falsified medical products needed to be addressed, especially high prices and shortages, and particularly in health emergency settings. While a standardized medical devices nomenclature was important, the Secretariat's efforts in that area overlapped with established nomenclature systems. Over 100 countries, including his own, had licensed the Global Medical Device Nomenclature, which had offered free access to users since 2019. In that light, there was no need for WHO to develop or endorse any alternative system for the standardization of medical devices nomenclature.

The representative of THAILAND[1] supported the WHO Global Surveillance and Monitoring System for substandard and falsified medical products. It was important to ensure appropriate investment throughout pharmaceutical supply chains, formulate policy recommendations based on situation analysis, and continue reporting to the Global Surveillance and Monitoring System. Given the potential impact of substandard and falsified medical products on action to tackle the COVID-19 pandemic, the recommendation to expand the Global Focal Point Network was welcome. Recognizing the importance of an international nomenclature of medical devices, he supported WHO's leading role in the establishment of such a system.

The representative of CANADA[1] said that, while she supported WHO's overarching objective of standardization of a global nomenclature for medical devices, the establishment of the proposed international classification, coding and nomenclature as an additional system could create complexities, costs and confusion in the medical device and health-care sectors. Limited transparency and the limited involvement of regulators, medical device manufacturers and industry stakeholders in the comparative analysis were causes of concern, as was the impact of a new nomenclature on technical barriers to trade. It was not clear whether those concerns, which had been raised at previous meetings of the International Medical Devices Regulators Forum, had been taken into account. Further clarification would be appreciated on the comparative analysis performed, the shortcomings of other systems that had led to the current proposal and how compatibility challenges would be addressed. The Secretariat should continue discussions with Member States on the issue and engage with the International Medical Devices Regulators Forum to minimize the impact of a duplicate nomenclature system.

The representative of ZAMBIA[1] said that the problem of substandard and falsified medical products was more pervasive in places where access to affordable, quality, safe and effective medical products was restricted, and the technical capacity to ensure good practices in manufacturing, quality control and distribution was limited. No single country had sufficient resources to effectively regulate the whole supply chain system, and he therefore fully supported WHO's global mechanism on substandard and falsified medical products. He urged the Secretariat to work with relevant stakeholders at the national and regional levels to strengthen regulation of their respective markets.

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The representative of TURKEY[1] said that global cooperation was crucial to ensure timely information-sharing on substandard and falsified medical products and it was therefore important to expand and maintain the Global Focal Point Network among national regulatory authorities. The development of an online "good practices" bookshelf would help to address the online supply of substandard and falsified medical products. Additionally, the growing global circulation of medical devices due to the COVID-19 pandemic had underlined the need for a Member State mechanism for medical devices. She urged WHO to initiate a process to establish such a mechanism.

The representative of AUSTRIA, speaking on behalf of the European Union and its Member States, said that he supported the suggestion by the representative of Kenya, on behalf of the Member States of the African Region, that a Member State briefing should be held on standardization of medical devices nomenclature. He reiterated his support of WHO's work on that matter and encouraged the Secretariat to make the proposed medical device nomenclature available as soon as possible.

The representative of the INTERNATIONAL FEDERATION FOR MEDICAL AND BIOLOGICAL ENGINEERING, speaking at the invitation of the CHAIR, said that he supported the Organization's proposal to host the European Medical Devices Nomenclature, once it had been finalized by the European Union. Members of his organization needed an accessible nomenclature for the sound management and maintenance of medical devices. His organization and its experts stood ready to join WHO in its efforts towards the standardization of medical devices nomenclature.

The DEPUTY DIRECTOR-GENERAL, thanking Member States for their valuable guidance, said that the proliferation of substandard or falsified medical products was an urgent global health challenge since it harmed patients, damaged trust in health systems, wasted precious resources and led to antimicrobial resistance. She applauded the work accomplished through the Member State mechanism, to which she reaffirmed WHO's strong commitment. The Organization was also committed to working with Member States to ensure the availability of a harmonized international nomenclature of medical devices. The guidance of Member States on both issues would be fully utilized to move forward. Guidance on the nomenclature was particularly important, and she welcomed the proposal to hold a briefing for Member States.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines and Health Products) said that support for the Member State mechanism was heartening. The WHO Global Surveillance and Monitoring System had identified approximately 50 substandard or falsified products related to COVID-19, including vaccines and in vitro diagnostics. While the operations identified were small, they served to alert procurement agencies to the need to be wary of such products advertised on the internet. Increased movement had also been detected on the darknet, which was an issue for WHO to explore with the help of the mechanism. She welcomed the encouragement for the Organization to engage with regional bodies, as well as the call for greater engagement in the mechanism. She thanked all participants in the mechanism for their work over the previous year.

She welcomed the collaborative spirit at the core of the debate on the standardization of medical devices nomenclature. Since there were thousands of different types of medical device, ranging from stethoscopes to X-ray machines, it was important to establish quality control. National regulatory authorities and procurement agencies at the country level needed to be able to follow clear policies based on international agreement. The Organization's proposal had prompted an international discussion because, despite a gradual increase, over half of the Member States still did not have a nomenclature for medical devices and, to date, the market consisted mainly of proprietary nomenclatures that few countries could actually afford. The Global Medical Device Nomenclature had fees attached in some

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cases, posed copyright issues and did not comply with certain principles of governance and transparency, rendering its global use complicated. In that light, discussion of how WHO might take a stronger leading role in the matter was welcome. She would take forward the suggestion that the Secretariat should hold a briefing on the topic, which would also present an opportunity to provide further information on the shortcomings of the different systems, as requested by some Member States. The advantages of the system being proposed should also be highlighted. WHO had met with the International Medical Devices Regulators Forum and other regulatory bodies to discuss the matter on several occasions. She recalled that similar positions had been taken during the discussions prior to the establishment of an essential medicines list, which ultimately served as a public health good. There were no quick fixes for such a complex issue.

The Board noted the reports.

2. IMMUNIZATION AGENDA 2030: Item 12 of the agenda (document EB148/14)

The representative of AUSTRIA, speaking on behalf of the European Union and its Member States, said that the candidate countries North Macedonia, Montenegro, Albania, the country of the stabilization and association process and potential candidate Bosnia and Herzegovina, as well as Ukraine, the Republic of Moldova and Armenia aligned themselves with his statement. The Immunization Agenda 2030 would guide work on immunization over the next decade and should be focused on and led by countries, with appropriate support from global health actors. Immunization against COVID-19 was central to ending the pandemic and adjustments to the Agenda should be considered in that light. He encouraged the Secretariat to propose mechanisms to ensure equitable access to vaccines against pandemic pathogens, potentially building on the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Despite unprecedented scientific innovation related to the COVID-19 vaccine, misinformation about vaccines was spreading. He therefore encouraged WHO to continue countering such information and provide evidence-based, reliable information to Member States and the public. It was vital to expand immunization against COVID-19 by ensuring equitable access to high-quality, safe, effective vaccines for all. He called on Member States to support WHO and the COVID-19 Vaccine Global Access (COVAX) Facility to ensure equal access and leave no one behind. Transparent follow-up should be provided for all vaccination campaigns, in order to address any gaps.

The representative of CHINA said that rates of mortality due to vaccine-preventable diseases were falling thanks to global vaccination programmes, which should be offered to all. The use of technology had accelerated work on vaccination against preventable diseases in her country, and most preventable diseases had therefore been eliminated. WHO should continue to offer technical support to countries with low rates of vaccination.

The representative of BANGLADESH said that it was important to consider how immunization programmes for other diseases would be maintained during the COVID-19 pandemic. Given that low-income countries faced challenges in expanding immunization nationally, adequate resources should be mobilized in addition to domestic funding, including for Immunization Agenda 2030 strategic priority objective 1.4 on supply chains and vaccine management in primary health care. Further details in that regard would be appreciated. The strategic priority objectives and proposed global indicators did not focus on equitable affordability and availability of vaccines; appropriate mechanisms for reducing prices and promoting registration by vaccine manufacturers would help to ensure access to medicines for low- and middle-income countries. The Agenda's objectives and indicators should also address potential

global shortages of vaccines and an expansion of productive capacities alongside supply chain constraints.

The representative of the REPUBLIC OF KOREA, expressing support for the Immunization Agenda 2030, said that the current discussion was timely, particularly given the challenges many countries faced in implementing immunization programmes, which had been exacerbated due to the impact of the COVID-19 pandemic. She supported efforts to finalize a framework for monitoring and evaluation, which should lead to the strengthening of health systems and the implementation of universal health coverage.

The representative of BURKINA FASO, speaking on behalf of the Member States of the African Region, said that it was vital that stakeholders at all levels worked together to ensure access to vaccines to save lives and leave no one behind, particularly during the COVID-19 pandemic. As research and development posed a challenge to the production and distribution of vaccines globally, it was essential that States should share knowledge and skills, irrespective of their level of development. He called for research and development relating to neglected tropical diseases and noncommunicable diseases to be strengthened with a view to introducing vaccines to combat such diseases. Lessons learned from the implementation of the global vaccine action plan should be incorporated into the Immunization Agenda 2030. National ownership and prioritization of the Agenda in policy would contribute to achieving its objectives. He appealed to all stakeholders to facilitate implementation of the strategic objectives, and on technical and financial partners to make resources available to that end.

The representative of the UNITED KINGDOM OF GREAT BRITAIN AND NORTHERN IRELAND said that she strongly supported implementation of the Immunization Agenda 2030. Establishing effective disease surveillance would be critical to identifying those who did not have access to life-saving immunization and ensuring equity. Her Government had pledged £1.65 billion to Gavi, the Vaccine Alliance, over the following five years to support its mission to save lives; the work of Gavi would also bolster the resilience of health-care systems to tackle COVID-19 in the poorest countries. In the pandemic and post-pandemic period, strong primary health care systems must be established as the critical foundation to forecast, plan, monitor and deliver vaccines, alongside building public trust in vaccine services. Measures taken in her country included introducing a strategy on immunization programmes and tackling misinformation about vaccines by working with social media companies. She applauded WHO for leading a strong, collaborative process with all stakeholders and encouraged all Member States to continue working together to ensure vaccines for all.

The representative of AUSTRALIA said that it was vital that the proposed monitoring and evaluation framework and indicators for the Immunization Agenda 2030 were consistent across global, regional and country strategies to effectively measure progress and promote accountability. She requested further details of how the proposed partnership council would operate and its financial implications; the Access to COVID-19 Tools (ACT) Accelerator Facilitation Council provided a good model in that regard. More information would be appreciated on how WHO would support robust cold chain storage and supply mechanisms for effective delivery of vaccine doses globally, including COVID-19 vaccines. She welcomed recognition of the need for targeted vaccination communication strategies to combat vaccine hesitancy and misinformation, which was increasingly important due to the roll-out of COVID-19 vaccines. She would appreciate further information on the plan to reflect disease-specific initiatives under the Agenda.

The representative of INDIA said that it was essential to accelerate progress and ensure a smooth transition from the global vaccine action plan. Describing the measures taken on immunization in his country over the previous decade, he highlighted the development of strategies and guidelines to address

gaps that had emerged in routine immunization, including during the COVID-19 pandemic, and the use of domestic funding for immunization programmes.

The representative of the RUSSIAN FEDERATION expressed support for the development of the ownership and accountability mechanism and monitoring and evaluation framework for the Immunization Agenda 2030, and for the results-oriented impact goals and proposed indicators and targets. The value of the proposed indicators and their calculation methods and deadlines at the global and regional levels should be finalized, and targets should be attached to every goal. The technical strategies developed, including the Measles and rubella strategic framework 2021–2030 and the global strategy on comprehensive vaccine-preventable disease surveillance, would inform policy-making at the national level. Her Government had adopted a national strategy on immunization for the period up to 2035, and Russian scientists had developed a number of innovative medical products to tackle COVID-19, including three vaccines. Cooperation with other countries was boosting access to those vaccines, primarily by localizing their manufacture.

The representative of ARGENTINA said that the contributions of the private sector and civil society to the strategic frameworks under the Immunization Agenda 2030 were fundamental. The need to work with all stakeholders to address gaps in health systems had been highlighted by the COVID-19 pandemic. Access to high-quality COVID-19 vaccines should be secured as quickly as possible – particularly for target populations – under target 4.3 on new vaccines to protect more people. Coverage rates under the general immunization programme in her country had been affected by the pandemic. Immunization programmes should be strengthened based on the principles of fairness and equity, particularly given the likely social and economic consequences of the pandemic. Compliance with the targets under the Agenda should be continuously evaluated to remedy the shortcomings and mitigate the damage of the pandemic for populations.

The representative of GERMANY, thanking the Secretariat for the report, noted that the COVID-19 pandemic had underlined the importance of extensive immunization to prepare for pandemic threats. However, protection against other infectious diseases must not be overshadowed by the current pandemic. Strengthening immunization against various diseases should remain a priority for the global community, as universal health coverage could only be attained through worldwide immunization. He therefore reiterated his commitment to the Immunization Agenda 2030.

The representative of the UNITED STATES OF AMERICA said that the Secretariat and Member States must continue efforts to promote trust in vaccines in general, as well as confidence in vaccines against COVID-19 as critical countermeasures to overcome the pandemic. His Government supported multilateralism in the international response to COVID-19, including by supporting access to the ACT-Accelerator and joining the COVAX Facility, and would take an active role in driving the response and supporting global vaccine distribution, and research and development in that area. National essential vaccine services should be maintained, especially during the pandemic, to prevent overwhelming health systems. Immunization programmes should be linked to outbreak preparedness and response capacities to decrease the risk of outbreaks of vaccine-preventable diseases, in addition to supporting the research and development of vaccines against persistent public health threats and emerging infectious diseases. It was regrettable that various factors had prevented the finalization in 2020 of the draft resolution on strengthening global immunization efforts to leave no one behind; he expressed interest in working with Members State and the Secretariat to consider some of the issues tackled in that resolution as part of discussions on implementation of the Immunization Agenda 2030, ahead of the Seventy-fourth World Health Assembly.

The representative of COLOMBIA, describing the immunization programme in her country, said that the objectives of the Immunization Agenda 2030 had been incorporated into national plans for the

control and eradication of vaccine-preventable diseases. The proposed measures relating to technical cooperation, monitoring of immunization initiatives, epidemiological surveillance, research and vaccine-preventable disease control were particularly relevant for her country. The Organization should continue to promote quick, safe and equitable access to COVID-19 vaccines and provide for emergency licences that would boost timely access to them.

The representative of BOTSWANA, outlining historic markers in the development of the immunization programme in her country, said that a robust immunization programme was in place. Pharmacovigilance systems had been established, for which increased support was needed, and challenges persisted in sustaining equitable immunization coverage. Cooperation with development partners, civil society organizations and the private sector would enable the country to achieve the objectives of the Immunization Agenda 2030, the implementation of which would also require support from the Secretariat.

The representative of the PHILIPPINES[1] said that she supported the global vision of accelerating progress towards immunization targets. Measures had been adopted in her country to achieve the goal of reducing mortality and morbidity from vaccine-preventable diseases, including policies on immunization against COVID-19 and for immunization during the pandemic. Support at the regional level for efforts to ensure that no one was left behind in immunization programmes was appreciated. She requested stronger support from the Secretariat for the implementation of mechanisms for cross-border collaboration and resource mobilization to reach marginalized populations, including refugees and undocumented populations, and achieve the impact goals of the Immunization Agenda 2030. She would welcome further support from the Secretariat in strengthening alliances and forging multisectoral partnerships for the effective integration of immunization programmes.

The representative of JAPAN[1] welcomed the Secretariat's technical guidance for the implementation of the Immunization Agenda 2030 and the focus on immunization as a central function of wider primary health care and universal health coverage. His Government wished to offer support, in collaboration with WHO, to the Pacific island States of the Western Pacific Region that were facing challenges in vaccine supply; and would contribute more than US$ 130 million to the Gavi COVAX Advance Market Commitment to ensure equitable vaccine access, distribution and administration in those areas. He looked forward to further action by WHO and its partners to maintain and improve immunization programmes.

The representative of the DOMINICAN REPUBLIC,[1] expressing support for the report, outlined various measures in place in her country to combat vaccine-preventable diseases, including COVID-19, such as capacity-building relating to the COVAX Facility. She welcomed the continued membership of WHO of the United States of America, its interest in participating in the COVAX Facility and the ACT-Accelerator, and its wish to work with WHO under the principles of multilateralism and solidarity, which were all valuable efforts in addressing the pandemic.

The representative of BRAZIL[1] welcomed progress made on the operational elements of the Immunization Agenda 2030, which would contribute to vaccination coverage and foster equitable access to vaccines. Member States should identify efficient ways of promoting broader pools of vaccine developers and manufacturers, which would lead to more resilient supply chains and immunization programmes. To achieve the goals of the Agenda, governments should establish strategic actions for transition from the global vaccine action plan, with a view to implementing information systems and organizing supply chain networks, in accordance with country-specific needs. Close dialogue and

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consultations would ensure that national contexts and priorities were taken into account in the implementation of the ownership and accountability mechanism, and the monitoring and evaluation framework.

The representative of SPAIN[1] said that she supported the Immunization Agenda 2030. Outlining measures taken at the national level to immunize the population against COVID-19, she said that her Government participated in international initiatives, such as the COVAX Facility, to support the availability of vaccines globally. It had adopted a national solidarity plan aimed at ensuring that vulnerable groups, such as refugees, had access to immunization, for which support from all partners was needed. Equitable access, solidarity, strengthening of health-care systems and multilateral cooperation were essential principles in overcoming COVID-19.

The representative of NORWAY[1] welcomed the proposed frameworks and the tailoring of various measures to country contexts. It was important to use existing structures, such as the WHO regional committees, and to coordinate contributions from development partners, including the private sector and civil society organizations, among the partners themselves and with such structures. As many countries lacked adequate surveillance systems, she urged the implementation of systems that would enable the use of new technology. Although operationalization of the Immunization Agenda 2030 would be challenging, the systems established during the pandemic should serve as examples to be used in other immunization programmes.

The representative of MALAYSIA[1] said that the development of technical guidance under the Immunization Agenda 2030 was timely and relevant and would strengthen vaccine-preventable disease control activities. She welcomed the approach set out in the report that was tailored to country contexts to ensure ownership and accountability at the national level. Collaboration and partnerships were important for the successful implementation of the Agenda. In addition to effective communication and advocacy, technical support from WHO and other partners, including civil society organizations, would enable the timely and effective implementation of the Agenda.

The representative of THAILAND[1] said that populations affected by conflict, disaster and epidemics should be included in the global targets, and priority should be given to high-risk and neglected populations in immunization programmes. She urged Member States to include vaccination programmes in family health care, and to strengthen monitoring to ensure vaccination coverage and identify neglected populations. WHO could contribute to building public trust by addressing misinformation on vaccination programmes, which remained a serious problem in many countries.

The representative of PAKISTAN,[1] describing the impact of COVID-19 on immunization programmes in his country, said that most of the children who had initially missed their essential immunizations had been reached through enhanced interventions. With a view to achieving the goals of the Immunization Agenda 2030, the electronic immunization registry would be expanded across the country to track "zero-dose" children. All stakeholders and international partners should work together towards the successful implementation of the Agenda and to ensure that no child was left behind.

The observer of PALESTINE said that immunization was critical to efficient primary health systems. Vaccines against COVID-19 were inaccessible or unavailable in several low-income and developing countries, especially areas of conflict. It was important to support the COVAX Facility and

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the ACT-Accelerator to ensure the equitable and transparent distribution of vaccines against COVID-19. Multilateral partnerships and activities were essential to tackling the COVID-19 pandemic.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIR, called on all stakeholders to ensure implementation of the Immunization Agenda 2030 to accelerate progress towards universal health coverage. She emphasized the role that young people played in the holistic and interprofessional approach needed to implement the Agenda and called on Member States to involve young people in areas such as research and advocacy. Promoting early availability and affordability of vaccines for all countries was necessary to work towards equitable distribution of vaccines and deliver on the promise to leave no one behind.

The representative of THE TASK FORCE FOR GLOBAL HEALTH, INC., speaking at the invitation of the CHAIR, said that his organization would work in partnership with the United States Centers for Disease Control and Prevention to implement the Immunization Agenda 2030 and strengthen the capacity and performance of immunization programmes at all levels. The new Global Immunization Strategic Framework of the Centers for Disease Control and Prevention would contribute to the achievement of the goals and objectives of the Agenda, using an approach informed by data and based on partnership and focused investment. His organization would work to support the Agenda's implementation, with an emphasis on the role of strong immunization systems in advancing global health security.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIR, said that her organization had issued a vaccine hesitancy toolkit to help members advocate immunization at the local level. She urged the Secretariat and Member States to integrate pharmacists into national immunization plans and provide training and legal authorization to administer vaccines. Involving pharmacists in vaccination campaigns increased coverage while guaranteeing patient safety. She called on Member States to work with young people to develop plans to tackle vaccine hesitancy.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIR, said that immunization was a critical component of global efforts to combat cancers attributable to infection. The disruption of immunization services in schools caused by the COVID-19 pandemic had negatively affected the global goal to eliminate cervical cancer. National ownership of immunization strategies was essential to optimize technical support from civil society organizations at all levels. To accelerate action on immunization, she called on Member States to develop national targets and baselines for core vaccinations, including hepatitis B and human papillomavirus vaccines; report regularly on progress, challenges and lessons learned – including through WHO regional committees and technical advisory groups; develop strategies to bring all immunization programmes up to date with the support of partners; and build public confidence in immunization.

The DEPUTY DIRECTOR-GENERAL said that immunization had never before been so important to human well-being and the economy. WHO's immediate task was the equitable roll-out of vaccines against COVID-19. The broader Immunization Agenda 2030 was crucial, however, and its adoption by the Seventy-third World Health Assembly represented a milestone, as it set out a vision of a world where everyone, everywhere, at every age, fully benefited from vaccines to improve health and well-being. The Agenda positioned immunization as a key component of primary health care on the road towards universal health coverage and the Sustainable Development Goals. The need to coordinate an integrated immunization agenda with primary health care was crucial as the Operational framework for primary health care was also being rolled out. As underlined by many Member States, the Agenda was

a global strategy that responded to each country's needs following an extensive global consultation and was owned by all stakeholders. At the start of the new decade, the Organization was moving towards the implementation of the Immunization Agenda 2030 at a time when the introduction of vaccines against COVID-19 was bringing hope to the world, but when many national immunization programmes were facing challenges in sustaining routine immunizations and other essential health services against the backdrop of the pandemic. She appreciated guidance from Member States on the main elements to operationalize the Agenda: the accountability mechanism; the partnership council; and advocacy and communication and research and development.

The DIRECTOR (Immunization, Vaccines and Biologicals), responding to participants' comments, said that she appreciated Member States' interest in the proposed partnership council. Work was being carried out regarding its financing and operation, and lessons were being incorporated from the COVAX Facility and the ACT-Accelerator Facilitation Council. Partners would make contributions to the partnership council to limit the amount of financing required for its operation. More specific information on the monitoring and evaluation targets at the global, regional and country levels would be provided prior to the Seventy-fourth World Health Assembly. The monitoring and evaluation framework had been developed in cooperation with the monitoring and evaluation framework for Gavi's new five-year strategy to ensure the alignment of all targets and outcomes, particularly for countries that were also supported by that Gavi strategy. The tailored approach enabled countries to define some of their own targets with a view to contributing to the global targets.

One of the strategic priorities of the Immunization Agenda 2030 was focused on vaccine supply and sustainability. Transparency concerning countries' procurement of vaccines and real production capacity would become increasingly important as advances were made in WHO's technical and advocacy work; WHO's reports on monitoring and access to immunization would help provide transparency. In the run-up to the Seventy-fourth World Health Assembly, more detailed information would be provided on equitable access to vaccines against the pandemic pathogens and on the impact of the COVID-19 pandemic on essential health services. Although further language on financing would be incorporated into the report, technical annexes had been established for each of the strategic priorities that provided more detail on some of the technical financial issues. The report was a living document, which would be continuously adapted.

The DIRECTOR-GENERAL said that at no other time in history had the importance of vaccines for a thriving global economy and the well-being of the world's people been so apparent. An urgent priority for 2021 was the roll-out of COVID-19 vaccines to curb the pandemic. It would be remiss to exclude the critical and innovative work relating to COVID-19 vaccines from the broader agenda of routine immunizations, effective health systems and platforms to protect populations from vaccine-preventable diseases. It was important to take the opportunity to put the ambitious vision and strategy of the Immunization Agenda 2030 to work around the globe. He counted on Member States to deliver equal access to COVID-19 vaccines as a matter of priority; disseminate the information required to ensure immunization coverage beyond COVID-19; and strengthen health systems and empower communities and their health workers to enhance the reach and efficacy of their services. Such work should be done together, through WHO partnerships at the national, regional and global levels, by pooling collective resources and commitments to achieve a world where everyone, everywhere, at every age, fully benefited from vaccines for good health and well-being.

The Board noted the report.

3. INTEGRATED PEOPLE-CENTRED EYE CARE, INCLUDING PREVENTABLE VISION IMPAIRMENT AND BLINDNESS: Item 13 of the agenda (document EB148/15)

The representative of CHINA welcomed the focus in the report on equity in the feasible global targets for 2030 on integrated people-centred eye care, focusing on effective coverage of refractive error and effective coverage of cataract surgery. Feasibility and equity should be fully taken into account when developing a monitoring framework in that regard to promote achievement of the targets.

The representative of CHILE said that the Organization's global action plan 2014–2019 on universal eye health had been fundamental to progress at the country level. Outlining achievements in eye health care in his country, he noted, however, that the impact of the pandemic on eye care had been significant and had lengthened the waiting lists for eye treatment. In that context, the proposed targets were ambitious, given delays in treatment and the need to conduct national surveys on periodic eye tests. To achieve those targets, technical, financial and political support would be necessary, in addition to the ongoing support of PAHO.

The representative of BANGLADESH welcomed the well defined recommendations on feasible global targets relating to eye care, and the broad consultation on which they were based. The Secretariat should consider developing a monitoring framework and data collection system for action taken towards achieving the targets. He also requested the Secretariat to ensure technical support for attainment of the targets at the national level.

The representative of GUINEA-BISSAU, speaking on behalf of the Member States of the African Region, outlined the rates of vision impairment among the population in his Region, the common causes of which included cataracts and glaucoma. Progress had been made in addressing eye health needs, such as strengthening of health workers' capacities. Challenges remained, however, including insufficient national and multisectoral coordination and a shortage of qualified human resources. In addition, the COVID-19 pandemic had provoked disruption of eye care in almost all countries. He welcomed the recommendations on feasible global targets and called on WHO to, inter alia, provide support to countries to accelerate progress in eye care; reaffirm the importance of addressing eye issues by integrating eye care into universal health coverage; and strengthen capacities for planning and operationalizing eye care services.

The representative of AUSTRIA, highlighting the extremely high number of people living with vision impairment and other eye health conditions, said that low and uneven eye health-care coverage still needed to be addressed. She commended WHO for continuing to focus on eye care during the COVID-19 pandemic. She welcomed the consultative process around recommendations on feasible global targets for 2030 and noted the proposed targets and their differentiation of Member States by baseline. With a view to enabling implementation of the recommendations in WHO's *World report on vision* and resolution WHA73.4 (2020) on integrated people-centred eye care, including preventable vision impairment and blindness, she encouraged the Secretariat to develop more detailed strategic guidance on the range of instruments available and their implementation in Member States. She urged the Secretariat to continue taking steps to fulfil the requests set out in resolution WHA73.4.

The representative of BOTSWANA outlined the findings of studies into preventable vision impairment and blindness conducted in her country. Regional and global partnerships were pivotal to advancing the implementation of eye health plans at the national level, and WHO support was crucial to coordinating partnerships in the health sector. She requested WHO to support capacity-building, particularly in low- and middle-income countries where there were few specialists in eye care. Additional platforms were needed to increase knowledge, skills and information to achieve the targets of integrated eye care by 2030. She requested the Secretariat to include indicators for glaucoma and

diabetic retinopathy in the monitoring and evaluation framework. Further research should be conducted into the increasing rates of glaucoma and cataracts among young people.

The representative of AUSTRALIA said that the development of the global targets represented important progress in addressing the vast inequities in the prevalence of vision impairment and blindness. There was a genuine need for realistic but ambitious targets and the evidence-based strategy used to develop them was appreciated. She supported the proposal to use proxy indicators based on national health survey data and existing research literature, given that refractive error and cataract prevalence were not routinely measured. Further technical guidance from the Secretariat regarding practical and financially viable data collection would be required to redress information gaps.

The representative of INDONESIA expressed his support for the recommended feasible global targets for effective coverage of refractive error and cataract surgery. Vision impairment should be addressed as an integrated part of national health systems, and efforts should be made to ensure that everyone with vision impairment could access the required health services. Determining global targets and practical indicators was vital to measuring successful implementation of vision impairment management programmes at the country level.

The representative of the UNITED ARAB EMIRATES commended the efforts of the Secretariat to ensure that country perspectives were taken into account in the development of the targets. The consultative process regarding future technical guidance, developed in line with resolution WHA73.4, should be pursued. Member States should develop national targets and indicators based on the global targets to ensure structured contributions and monitor progress, and should strengthen national data and research into eye health care. The appropriate management of diabetes would reduce the risk of diabetic retinopathy and resulting vision impairment. The gap in eye health care was a matter of deep concern; the operationalization of resolution WHA73.4 should ensure the full and equitable fulfilment of the eye health needs of all people. She requested the Secretariat to continue providing the necessary technical support to Member States to strengthen integrated quality people-centred eye care as part of universal health coverage, and urged Member States to take action at the country level.

(For continuation of the discussion, see the summary record of the fourteenth meeting, section 3.)

The meeting rose at 17:05.

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