

PROVISIONAL SUMMARY RECORD OF THE FIFTH MEETING

**Palais des Nations, Geneva
Wednesday, 23 May 2018, scheduled at 14:30**

Chairman: DR MARTÍNEZ MENDUIÑO (Ecuador)

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COMMITTEE A

FIFTH MEETING

Wednesday, 23 May 2018, at 14:40

Chairman: DR MARTÍNEZ MENDUIÑO (Ecuador)

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

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

The representative of CARITAS INTERNATIONALIS, speaking at the invitation of the CHAIRMAN, urged WHO to prioritize actions to increase transparency throughout the value chain; strengthen mechanisms to delink research and development costs from final medicine prices; strengthen guidance and provide further support to Member States to promote transparency throughout the value chain; and promote regulatory frameworks to ensure access to quality and affordable biotherapeutic products in line with current scientific advancements. Furthermore, WHO should include a clear monitoring mechanism in its road map. His organization's recent collaboration with the Holy See, WHO and other key stakeholders to co-organize a dialogue among leaders of major pharmaceutical and medical technology companies had resulted in agreement on an action plan for collaboration on the development, registration, introduction and roll-out of the most optimal paediatric formulations and diagnostics for children living with HIV. It was an example of collaboration that could inspire action to improve access to medicines and vaccines for all.

The representative of the EUROPEAN SOCIETY FOR MEDICAL ONCOLOGY, speaking at the invitation of the CHAIRMAN, said that the main barriers to access to cancer medicines were shortages of inexpensive essential cancer medicines and high out-of-pocket costs for innovative, expensive cancer medicines. She therefore welcomed the development of a global reporting system to monitor the supply of essential medicines and generics on the WHO Model List of Essential Medicines. Her organization, together with the Economist Intelligence Unit, had issued policy recommendations on managing and preventing shortages in Europe, and she called on WHO to consider including those recommendations in its technical report on access to cancer medicines. She agreed that investments in access to cancer medicines should be made when they offered the greatest value for money. To that end, her association had developed a tool to grade cancer medicines according to their potential to improve patient outcomes, which could be valuable to WHO.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, encouraged WHO to support a comprehensive approach to tackling barriers to access to essential health products and to implement strong regulatory systems and harmonized processes to support access. The challenge of inadequate supply was particularly acute for children, who had unique physiological and pharmacokinetic needs and required equitable access to health care, including paediatric formulations of essential medicines. WHO could leverage the expertise of innovative structures, including product development partnerships and other novel mechanisms, to secure sustainable access commitments and accelerate the development of essential health technologies for all conditions.

The representative of the INTERNATIONAL ASSOCIATION FOR HOSPICE AND PALLIATIVE CARE INC., speaking at the invitation of the CHAIRMAN, welcomed WHO's preliminary work on the morphine palliative care indicator. Safe, effective and quality medicines and vaccines for all included opioids such as oral morphine. He welcomed collaboration to ensure that the morphine indicator was achieved by a trained workforce through a balanced regulatory framework. Moreover, supply chains for internationally controlled essential medicines should be strengthened through training and capacity-building for all health professionals. One barrier to access was that morphine, a long-established generic medicine, yielded no profit for pharmaceutical companies in registering and marketing it to patients with life-limiting conditions. Highlighting that several governments had succeeded in making morphine available free of charge, he recommended that governments should use mechanisms such as the PAHO Revolving Fund for Strategic Public Health Supplies and other cooperative buying strategies for essential generic medicines such as morphine. He urged all Member States to consider adopting the low-cost palliative care package recommended by the Lancet Commission Report.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that WHO played a pivotal role in ensuring access to safe, effective, quality and affordable medicines and vaccines for all, a goal closely linked to that of achieving universal health coverage. Thus, all actions must focus on leaving no one behind. Such an approach required a needs-based focus in research and development and coverage interventions. Member States were also encouraged to implement equitable pricing schemes, including pricing control mechanisms, to ensure fair access to essential medicines. Subsidizing essential medicines and offering further discounts to people living in poverty were essential to ensure that everyone had access to the health products and services they needed.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, welcomed WHO's progress in delivering a framework to avert shortages caused by a wide range of factors, and encouraged partners to address the main challenges of national stock outs. It was important to: establish dialogue and collaboration between manufacturers and public health authorities to prevent shortages; anticipate the evolution of national health programmes; ensure more accurate demand forecasting; and reduce and harmonize regulatory approval times for post-approval changes and in-country testing for lot release. The road map should take into account all aspects of access to medicines, a highly complex issue. The importance of strong intellectual property protection to the development and diffusion of medicines must also be recognized. He expressed regret at the attention given to the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, which had failed to address the genuine barriers to access that were critical to meet the targets of the Sustainable Development Goals. Therefore, neither the report nor its recommendations could be a sound basis for the road map.

The representative of the INTERNATIONAL PEDIATRIC ASSOCIATION, speaking at the invitation of the CHAIRMAN, said that health systems should plan for the needs of children and young people, including ensuring equitable access to affordable and quality essential medicines and life-saving technologies. Children had unique physiological and pharmacokinetic needs, thus all applications for inclusion in, change to, or deletion from the WHO Model List of Essential Medicines should also be evaluated for the WHO Model List of Essential Medicines for Children. Children and adolescents suffered from noncommunicable diseases not limited to cancer, heart disease, asthma and diabetes; they deserved better access to existing products, including vaccines for human papillomavirus and hepatitis B.

He recommended that WHO should: restructure the WHO Model List of Essential Medicines for Children with a human focus to address children's and young people's special health-care needs;

include equipment enhancing children's and young people's health and well-being and ensuring affordable options; and facilitate collaborative purchasing partnerships with neighbouring regions. He urged Member States to incentivize universal health care to include free access to essential medicines for children, and to support the establishment of guidelines and systems on access, prescribing and prevention and treatment standards.

The representative of the INTERNATIONAL PHARMACEUTICAL FEDERATION, speaking at the invitation of the CHAIRMAN, said that access to safe, effective and quality medicines and vaccines could not be achieved without supply chain integrity and efficiency, which required a competent workforce of pharmacists at every stage of the chain. The Federation was working with WHO to ensure that pharmacists were competent, sufficient in number and equitably distributed, and it supported a systematic approach to ensure that the pharmaceutical workforce corresponded to local needs. With a growing number of initiatives to address the global shortages of and inadequate access to medicines and vaccines, WHO's leadership was essential.

The representative of the INTERNATIONAL PHARMACEUTICAL STUDENTS' FEDERATION, speaking at the invitation of the CHAIRMAN, said that equitable and sustainable access to medicines could not be achieved without well-trained and competent pharmacists. She therefore re-emphasized the importance of providing high standards of training and technical support to improve professional skills. Another area of concern was access to vaccines during epidemics and outbreaks, and the priority given by WHO to research and development was welcome in that regard. Pharmacists were able to mitigate the potential harm to patients caused by gaps in the supply chain through medication substitution, cost-effective procurement and equitable medicine allocation. The Secretariat and Member States should recognize the role of pharmacists in ensuring access to medicines and medical products as, being at the forefront of patient care, their first-hand experience provided valuable insight into emerging challenges to access to medicines and vaccines in the health-care system.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, to evaluate the impact of the current system and any proposed reforms to the set of incentives and funding mechanisms for research and development to simulate the development of new medical products, better quality, disaggregated data were needed on research and development costs of specific products and services. Better and more transparent information was also needed on resource flows by research target, data on access disaggregated by country, annual and cumulative sales revenues, pricing, patents and registration, exceptions and limitations to intellectual property rights, the texts of proposed trade agreements relevant to innovation, and access to medical technologies. The current failure to ensure healthy competition for biological medicines must also be addressed. Moreover, effectively regulating monopolies remained a problem; efforts to delink research and development funding from the price of medical products and services should therefore be stepped up.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, urged the Secretariat and Member States to prioritize the promotion of alternative research and development approaches and an agenda driven by health needs that fostered sustainable innovation and access, ended reliance on high prices and monopolies and addressed innovation and access concerns relating to all diseases, health technologies and countries.

WHO was also urged to: overcome intellectual property barriers to access to medicines and vaccines by strengthening its leadership role and the technical support provided to Member States working to address the barriers, and adopt and implement public health safeguards in intellectual property laws and policies; strengthen its mandate to improve data and cost and price transparency in research and development, manufacturing and marketing; provide the additional resources required to

support and strengthen quality assurance for safe, effective medicines, vaccines and diagnostics to meet public health needs, specifically through additional investment in the WHO Prequalification of Medicines Programme; ensure policy coherence between the road map and WHO and United Nations health programmes and interventions, while also promoting leadership and accountability among organizations of the United Nations system to safeguard public health; and fund the development of a road map based on the global strategy and plan of action on public health, innovation and intellectual property and the recommendations of the United Nations Secretary-General's High-Level Panel on Access to Medicines.

The representative of the MEDICINES PATENT POOL, speaking at the invitation of the CHAIRMAN, said that one of the actions considered by the Secretariat as having the greatest potential impact on access to safe, effective and quality medicines was the expansion of the remit of the Medicines Patent Pool to include all antimicrobial medicines and patented medicines from the WHO Model List of Essential Medicines. In the past, its mandate had been limited to medicines to treat HIV, hepatitis C and tuberculosis. The potential for expansion of its remit had recently been the subject of a feasibility study; the results would be made public on 24 May 2018.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, urged Member States to endorse the priority actions contained in document A71/12 and provide WHO with a strong mandate to: establish a needs-based innovative system for medicines and health technologies, endorsing the principle of delinkage; prioritize actions based on impact; and commit themselves to fully funding WHO's work on access to medicines, especially in implementing the resolutions in Appendix 1 of document A71/12. She also urged Member States to promote publicly funded research that was mindful of public-health needs, based on epidemiological factors and social determinants of health. The Secretariat should help Member States to promote transparency in clinical trials, research and development and production costs, procurement prices and supply chain mark-ups. The Secretariat should provide technical advice to Member States on making the most effective use of the flexibilities of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).

The representative of OXFAM, speaking at the invitation of the CHAIRMAN, said that the road map would provide the cornerstone for global and national policies and strategies on access to medicines and vaccines. The recent Ebola virus outbreak in the Democratic Republic of the Congo was a reminder of the importance of innovation to produce vaccines and medicines dictated by public health needs, not market incentives. The report on the preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases was also reminder that, even when available, medicines were often priced beyond the reach of those in need. Inequality of access was a global problem; there were glaring differences between developing and developed countries, for example with regard to access to breast cancer treatment. She urged WHO to include strategies in the road map to curb high medicine prices and create innovative models that led to affordable products. WHO should also lead efforts to delink research and development costs from product prices. Lastly, the road map must be fully funded if Member States were serious about ensuring access to medicines.

The representative of PASTEUR INTERNATIONAL NETWORK ASSOCIATION, speaking at the invitation of the CHAIRMAN, emphasized the need to improve quality in the local production of medicines, vaccines and diagnostics, human skills and infrastructure, so as to meet future needs. She called for significant and sustainable support to organizations at the country level, in order to maintain and optimize their capacity to produce safe, effective, quality and affordable medicines, vaccines and diagnostics. She encouraged Member States and organizations to support qualitative

research and development to facilitate the testing of innovations at the country level, especially in countries where new products were needed. She highlighted progress made through the research and development blueprint mechanism to help to prepare for and combat emerging epidemics, especially by developing effective health products that would be accessible to all those in need.

The representative of the PATH, speaking at the invitation of the CHAIRMAN, agreed on the need for stronger regulatory systems and harmonized processes. Member States should build on the progress made by platforms such as the African Vaccine Regulatory Forum in strengthening local capacity and streamlining regulatory reviews, and support other regulatory strengthening efforts such as the WHO Prequalification of Medicines Programme. Establishing a globally coordinated approach to research and development was critical; she therefore supported the Global Observatory on Health Research and Development, but emphasized the need for funding and support from Member States. WHO should better leverage the expertise and experience of product development partnerships in negotiating and securing sustainable access commitments from partners.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that WHO should engage with a wide range of stakeholders in its efforts to improve access to medicines. In doing so, it was important to respect rules governing conflicts of interest. The road map required greater transparency in key areas such as research and development, pricing and patents, and should include recommendations from other entities, including the Consultative Expert Working Group on Research and Development and the United Nations Secretary-General's High-Level Panel on Access to Medicines. Intellectual property management tools and the TRIPS Agreement flexibilities should also be a core part of the road map. His organization opposed all attempts to erode the legitimacy of TRIPS flexibilities as a public health tool. Access to medicines should not be addressed through short-sighted unilateral actions aimed at defending private interests.

The representative of the SAVE THE CHILDREN FUND, speaking at the invitation of the CHAIRMAN, said that affordability was key to increasing vaccine coverage, particularly in the poorest countries and among the poorest children. WHO should claim its critical convening role in coordinating fund replenishments and transitions, and Member States should work together to demand more affordable vaccines, push for greater price transparency and oppose patents that obstructed market entry by new suppliers. They should also invest in innovative financing mechanisms to increase competition to ensure healthy markets, drive down vaccine prices and accelerate access. All national immunization programmes should include the pneumococcal conjugate vaccine.

The representative of the WORLD FEDERATION OF SOCIETIES OF ANAESTHESIOLOGISTS, speaking at the invitation of the CHAIRMAN, called on the Health Assembly to highlight the anaesthetic medicines that were essential to safe anaesthesia and therefore to safe surgery. Any plan to ensure the manufacture and supply of essential medicines must include essential anaesthetic medicines; of particular note were ketamine and potent opioids, whose availability was threatened by legislation ignoring their medical value. She commended the recent work of the WHO Expert Committee on Drug Dependence in helping to inform high-level debates on the issue. The Health Assembly should ensure that decision-makers understood the global health arguments for essential medicines and the negative effects of legislation on their manufacture, supply and availability.

The representative of the WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, said that access to safe, effective and quality medicines and vaccines helped to mitigate health inequities and promoted universal health coverage. WHO should help to address gaps in research and development and facilitate the introduction of new systems to tackle

global challenges such as antimicrobial resistance. She urged Member States to seize the TRIPS Agreement opportunities and flexibilities and take action against high medicine prices. They should also collaborate with the private sector to find innovative, effective solutions to the pricing, quality and safety of essential medicines and vaccines and supply-chain management. National medicine policies should be developed, implemented and monitored, including strengthening regulatory systems and tackling inappropriate pricing and use of medicines.

The representative of the UNION FOR INTERNATIONAL CANCER CONTROL, speaking at the invitation of the CHAIRMAN, urged Member States to prioritize access to essential cancer medicines and technologies in national plans on noncommunicable diseases and universal health coverage. They should include data-collection systems to track costs and the effective use of essential medicines and vaccines nationally. It was also important to leverage support available through WHO to make the most of cost-effective investments, using national essential medicine lists as a critical tool to analyse and prioritize the purchasing of medicines and vaccines for cancer and other noncommunicable diseases. Partnerships across sectors were essential to delivering sustainable access to medicines and vaccines. Essential technologies played an important role in reducing premature mortality from cancer and noncommunicable diseases. He welcomed the announcement of an initiative on cervical cancer elimination, and expressed his organization's interest in working closely with WHO on the project.

The representative of the INTERNATIONAL UNION AGAINST TUBERCULOSIS AND LUNG DISEASE, speaking at the invitation of the CHAIRMAN, said that it was essential to find adequate financing for research and development into tuberculosis. She urged Member States convening at the United Nations High-level Meeting of the General Assembly on ending tuberculosis in September 2018 to accelerate development of effective essential tuberculosis medicines, diagnostics and vaccines. They should create an enabling environment for research and uptake of new tools, including open-data sharing, strategies on intellectual property and treating final products as common goods to ensure their affordability, availability, accessibility and quality. She expressed the hope that the road map would take into consideration the norms and principles underpinning initiatives such as the Life Prize for research and development on tuberculosis medicines, which supported broader research and development and access to medicines.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) said that there was a broad consensus on some issues. For example, many delegations had drawn attention to the need for regulatory mechanisms at global and regional level to prevent shortages of medicines and vaccines. WHO would work bilaterally with the delegation of Madagascar to address vaccine shortages. She also noted strong support for increased efficiency in the supply chain, including through joint procurement and price negotiation. WHO would organize a second fair pricing forum in 2019.

There were also several issues on which there was no consensus. Those issues included funding for research and development, and the linkages between costs for development and final prices. Speakers had also expressed conflicting views regarding the protection of innovation versus the management of intellectual property. It was important that innovation was both accessible and affordable. WHO would discuss those issues at future assemblies.

The road map must be a collective effort by all stakeholders. It would address universal health coverage as well as the three missions of the draft thirteenth general programme of work 2019–2023. The Secretariat expected to have an estimate of the costs by the next session of the Executive Board. Some development partners had already shown an interest in providing funding. Given that the Health Assembly had approved about 50 access-related resolutions in the previous 10 years, WHO had both the mandate and scope to go ahead with the road map. The only new issue was the expansion of the

Medicines Patent Pool. WHO would soon hold consultations with partners and discussions in the regional committees with a view to preparing an advanced draft of the road map by November 2018.

The DIRECTOR-GENERAL said that universal health coverage, and therefore access to medicines, was key to the Sustainable Development Goals and the general programme of work. WHO would do everything possible to enhance access to medicines, for instance, by addressing affordability and quality. However, political commitment from Member States was vital to achieving the goal. It must start with the development and implementation of national policies. Interorganizational collaboration at national and global level was also very important. All actions would be categorized into immediate, medium- and long-term efforts.

The draft decision was approved.¹

Global strategy and plan of action on public health, innovation and intellectual property:
Item 11.6 of the agenda (documents A71/13 and EB142/2018/REC/1, decision EB142(4))

The CHAIRMAN invited the Committee to note the report in document A71/13.

The representative of BULGARIA, speaking on behalf of the European Union and its Member States, Montenegro, the candidate countries Montenegro and Serbia, the country of the Stabilization and Association Process and potential candidate Bosnia and Herzegovina, as well as Ukraine and Georgia, aligned themselves with his statement. Innovation was important in finding medical and public-health solutions for Type I, II and III diseases, including noncommunicable diseases, which disproportionately affected developing countries. The Secretariat and Member States must prioritize actions to implement the global strategy and plan of action on public health, innovation and intellectual property, since limited progress had been made thus far. He supported the draft decision contained in document EB142(4).

The representative of SAUDI ARABIA said that his Government supported the draft decision. Member States and other stakeholders must hold consultations and take action on the global strategy and plan of action. He highlighted the need for research and development on medicines, especially for emerging diseases. It was also important to have the necessary technologies.

The representative of ARGENTINA expressed concern that the estimated budget for implementing the review panel's recommended actions would not be fully covered by existing resources. At the 142nd session of the Executive Board, the Secretariat had been asked to provide details on the estimated budget and shortfall for each priority action, while in decision EB140(8) there had been a request to indicate possible sources of funding to meet the implementation costs of the recommendations of the programme review and to present those to the Seventy-first World Health Assembly. However, the present report only referred to mobilizing additional resources from assessed or voluntary contributions. It would be useful to have an analysis of alternative, innovative financing methods versus traditional resources. Too great a reliance on voluntary contributions could restrict the capacity of least developed countries to participate in the research prioritization process. She therefore asked the Secretariat to prepare a report on alternative financing sources that would provide full funding of the 33 priority actions.

¹ Transmitted to the Health Assembly in the Committee's first report and adopted as decision WHA71(8).

The representative of JAPAN supported the draft decision, which would move the global strategy and plan of action forward. Improving access to medicines and vaccines required a comprehensive approach, encompassing intellectual property rights, medicine prices, national health administration, human resources, access to medical facilities and the medicine and vaccine supply chain; the decision's focus on country ownership was therefore welcome. In order to implement the global strategy and plan of action, securing financial resources and considering budget priorities and value for money were paramount. WHO should remain within its mandate and focus on areas in which it had a comparative advantage.

The representative of MALAYSIA expressed appreciation for the recommendations calling for the Secretariat to provide support to strengthen the capacity of national regulatory functions and systems; to develop and share good practices on evidence-based selection and health technology assessment; and to promote best practices in countries and regional institutions to improve procurement and supply chain efficiency. In addition, Member States with transitioning health systems would benefit from the recommendation regarding guidance on promoting and monitoring transparency in medicine prices. She urged the Secretariat to coordinate initiatives to improve human capital and skills at the regional level and mobilize resources to upgrade physical infrastructure in least developed countries.

The representative of INDIA said that the recommendations of the review panel would provide greater, more specific focus for implementing the global strategy and plan of action through measurable indicators. He expressed appreciation for the recommendations on promoting sustainable financial mechanisms, particularly on delinking product prices from research and development costs, which resonated well with the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines. A lack of funding was the primary hurdle in implementation, which could be addressed with an increase in assessed contributions and unearmarked voluntary contributions.

The representative of the RUSSIAN FEDERATION welcomed the Organization's work on innovation and the recommendations made in the global strategy and plan of action, which sought to strike a balance between the interests of the pharmaceutical sector and public health. He also expressed support for its efforts to ensure that full use was made of the provisions of the 2001 Doha Declaration on the TRIPS Agreement and Public Health, including compulsory licensing. Having ratified the Protocol adding Article 31*bis* to the TRIPS Agreement, the Russian Federation supported the expansion of the Medicines Patent Pool to include basic medicines, and suggested that consideration be given to creating a permanent information platform, under the auspices of WHO, for countries to exchange experience in using TRIPS mechanisms.

Data collected from the Organization's monitoring of basic medicine prices around the world were extremely useful to regulators in agreeing fair prices with manufacturers. Cooperation among organizations of the United Nations system, regional and national regulators and expert bodies in developing new medicines and setting prices and standards would help to rationalize the use of resources and make treatment more effective for patients.

The representative of the UNITED STATES OF AMERICA, supporting the draft decision, said that there were many of the review panel's recommendations that all Member States should feel able to support, and on which the Secretariat and regional offices could make a meaningful impact, notably regarding the strengthening of regulations and research capacity. However, other recommendations had not been drawn from the global strategy and plan of action, and did not reflect Member State consensus. Policies requiring companies to disclose research and development costs were impractical, unlikely to be effective and might encourage companies to abandon high-risk research that could ultimately be of most benefit to patients.

Her Government opposed calls for senior WHO officials and the Secretariat to engage in advocacy in areas outside the Organization's remit, and strongly urged it to refrain from political advocacy targeting the lawful protection of intellectual property rights. WHO had no mandate to intervene in attempts to interpret Member State's legally binding obligations under the TRIPS Agreement; such highly sensitive issues fell within the domain of WIPO and WTO.

She urged Member States and the Secretariat to focus on areas of consensus and prioritize policies that would promote access to medicines while strengthening the global innovation system.

The representative of CANADA supported the draft decision, but requested further clarification regarding the associated resources and operational implications. Implementation of the 33 recommendations would require the Secretariat to take on many new responsibilities without any new resources; Member States should have received an operational plan and information on the full cost implications before being asked to endorse additional costs outside the core budget and organizational priorities that could fall outside the general programme of work.

The representative of COLOMBIA expressed appreciation for the priority actions identified to respond to current needs in terms of research and development and access to medicines, and for the recommendation on delinking product prices from research and development costs. However, specific measures were needed to ensure the effective implementation and follow-up of the global strategy and plan of action, hence the importance of a review to inform future actions and policies. She asked the Secretariat to strengthen efforts to mobilize the resources needed for implementation and follow-up; to that end, a specific budget line for the global strategy and plan of action should be included in the proposed programme budget for 2020–2021. She supported the draft decision.

The representative of COSTA RICA welcomed the global strategy and plan of action, which would stimulate innovation and the exchange of good practices between countries. It was important to promote the transfer of technology between countries while respecting intellectual property rights under the TRIPS Agreement, particularly in an increasingly globalized world.

The representative of the BOLIVARIAN REPUBLIC OF VENEZUELA said that health ministries should be urged to promote the health of humans and animals through the use of patent exclusions and/or flexibilities under the TRIPS Agreement, notably Article 27, with a view to ensuring the unimpeded development of new and effective health products, particularly for Type I, II and III diseases. They should also ensure consistent implementation of the global strategy and plan of action, and identify new mechanisms for stakeholders involved in the commercial, customs and health aspects of patents in the pharmaceutical field. Other important provisions included the "Bolar" provision, the harmonization of licence authorizations under Article 31 of the TRIPS Agreement and measures such as databases on patents and non-confidential licence agreements and the Medicine Patent Pool. He supported the draft decision.

The representative of PANAMA requested further information on the process to evaluate implementation of the global strategy and plan of action and identify areas for improvement. Extending the implementation timeline to 2018–2022 was a positive step, and would help low- and middle-income countries to prioritize research and development needs, improve innovation capacity, promote technology transfer and effectively manage intellectual property rights, with a view to greater innovation in public health and a reduction in medicine prices. She called on Member States, the Secretariat and other relevant international organizations to continue supporting countries in the implementation of the global strategy and plan of action, and on Member States to appoint liaison officials to ensure work was harmonized. Regarding intellectual property, there was no need to further develop the existing provisions in the TRIPS Agreement; there should be a balance between the

interests of intellectual property rights and public health. Efforts should be made to ensure that those rights did not hinder people's access to medicines, adequate nutrition or technology transfer.

The representative of the REPUBLIC OF KOREA supported the recommended actions, noting the need for improved management of critical areas such as research and development capacity, sustainable financing and the flexibility of intellectual property rights. The Secretariat and Member States therefore needed to cooperate to ensure that the global strategy and plan of action on public health, innovation and intellectual property had an impact on the ground.

The representative of ALGERIA expressed concern at the numerous obstacles identified in the report, which would have to be overcome to achieve a sustainable framework and create an environment conducive to innovative research and development. It was crucial for the Secretariat, Member States and relevant stakeholders to set up sustainable financial mechanisms to accelerate implementation of the recommended actions. Particular emphasis should be given to the recommendations on joint work by the WHO and WTO secretariats to identify how the TRIPS Agreement could be implemented more effectively in relation to health technology transfer, and on the development of databases of patents and non-confidential licence agreements for health products, which would improve access to those products. He supported the draft decision.

The representative of the UNITED REPUBLIC OF TANZANIA welcomed the report and detailed work undertaken by his country to implement the global strategy and plan of action, notably through the promotion of local pharmaceutical production with a view to exploiting flexibilities under the TRIPS Agreement. He therefore welcomed the recommendation calling on the Secretariat to work with other international organizations to advocate for the development of national legislation to fully reflect those flexibilities; awareness needed to be raised in that area. Given the weak links between research organizations, the market and pharmaceutical manufacturers, steps to promote collaboration among research organizations and strengthen public-private partnerships were also welcome.

The representative of the DOMINICAN REPUBLIC requested the Secretariat to link the indicators for the recommendations made by the review panel to the indicators provided under each element of the global strategy and plan of action. She suggested that the first recommendation, which asked Member States to establish sustainable financing for the Global Observatory on Health Research and Development and the Expert Committee on Health Research and Development, be moved from the heading "Prioritize research and development needs" to "Promote sustainable financing mechanisms", as that financing would be part of the 0.01% of gross domestic product that Member States should allocate to the evaluation of the implementation of the eight elements in the global strategy and plan of action. With those reservations, she supported the draft decision.

The representative of PARAGUAY said that the Secretariat should support the strengthening of national and regional regulatory function and system capacities, and promote the exchange of information between both countries and internationally recognized centres for research and development. Those steps would improve decision-making capacities, including in relation to clinical trials and resource preservation in traditional medicine. Other welcome recommendations included those calling for the Secretariat to promote technology transfer between Member States; to advocate for the development of national legislation to fully reflect the flexibilities under the TRIPS Agreement; and to promote the development of databases of patents and non-confidential licence agreements. She agreed that Member States and funders should support the WHO Prequalification of Medicines Programme. The strengthening of good practices on evidence-based selection and health technology assessment would improve transparency on medicine prices, which would have a direct impact on patients' capacity to defray the cost of medical products. Lastly, she agreed on the importance of the appropriate use of medicines, and procurement and supply chain efficiency.

The representative of CÔTE D'IVOIRE acknowledged WHO's prioritization of research and development needs and capacity-building among national bodies, research institutes and universities. Although her Government had taken measures to further contribute to research and development, resource mobilization was still a challenge. WHO should develop strategies for additional financial resource mobilization to ensure the implementation of the global strategy and plan of action.

The representative of the ISLAMIC REPUBLIC OF IRAN said that access to essential medicines at affordable prices was a key element of the fundamental human right of access to health care. Since there was no other international forum in which countries shared experiences on health-related patent flexibilities, WHO's work in that regard was vital. The recommendations on the use of TRIPS flexibilities, promotion of research and development, and bolstering of health-related innovations were imperative for addressing the public-health needs of developing countries. Research and development should be needs-driven rather than market-driven. WHO should provide an opportunity to analyse potential obstacles in accessing medicines, including legal, structural and capacity-related constraints, and how to overcome them. The report of United Nations Secretary-General's High-level Panel on Access to Medicines was useful in that connection.

The representative of GERMANY stressed the importance of intellectual property rights and patents as incentives for the private sector to invest in research and development, and supported the possible expansion of the Medicines Patent Pool. There was also a need to ensure the availability of medicines in pharmacies and hospitals. A balance should be maintained between WHO's shared goals and reporting burden. She also called for a review of existing structures, initiatives and synergies prior to developing new information platforms, database systems or open-access regulations. She supported the draft decision.

The representative of INDONESIA supported the review panel's recommended actions, but considered that they should be directed to all relevant stakeholders, including the Secretariat, Member States, the private sector and think tanks, and specify stakeholders' roles. The Director-General should also ensure that Member States could discuss the review panel's suggested indicators from a technical perspective prior to their finalization.

The representative of SWITZERLAND welcomed the draft decision, specifically because Member States were urged to implement the recommendations of the review panel that were consistent with those of the global strategy and plan of action. In implementing the review panel's recommendations, the Secretariat must adhere to the consensus reached on the adoption of the global strategy and plan of action. He supported the recommendations to prioritize research and development needs for Type II and Type III diseases and the specific research and development needs of low- and middle-income countries for Type I diseases. Member States must maintain a sense of a shared responsibility and acknowledge their important role in the implementation of priority actions.

The representative of the PHILIPPINES reiterated his country's position on the exclusion of TRIPS-plus provisions in free trade agreements, given that they conflicted with national patent laws. He supported capacity-building in countries for the implementation of intellectual property regimes in line with the TRIPS Agreement, enabling those countries to use TRIPS flexibilities. Furthermore, the Medicines Patent Pool should be expanded to cover all medicines in the WHO Model List of Essential Medicines so as to address emerging challenges such as HIV/AIDS, noncommunicable diseases, hepatitis C and tuberculosis. He supported the promotion of transparency in medicine prices, reimbursement policies and the cost of research and development, as well as the global sharing of medicine price databases and best practices in reducing out-of-pocket expenses. He also supported the establishment of sustainable financing mechanisms for the Global Observatory on Health Research and Development.

The representative of BRAZIL supported the draft decision and called for further efforts on the review panel's recommendations, specifically on price transparency, shortages and minimum investment in research and development. For the global strategy and plan of action to be implemented, Member States and the Secretariat should provide adequate funding and mobilize resources. He recalled that Brazil would make a voluntary contribution to finance the work on access to medicines.

The representative of PAKISTAN said that, pursuant to target 3.b of the Sustainable Development Goals, research and development must be aimed at health products and access to medicines for diseases primarily affecting developing countries. It was important to establish sustainable financing mechanisms, ensure greater transparency in costs, patenting and licensing and to expand patent pooling to promote the safe access to and delivery of health care and health products. He agreed that Member States could commit themselves to dedicating at least 0.01% of their gross domestic product to government-funded research and development. Coordination in research and development could also be improved through an information-sharing mechanism. Research and development experts from the public and private sectors should be involved in certified training courses, technology transfer should be promoted, and new opportunities for collaboration should be identified.

The representative of ZAMBIA fully supported the global strategy and action plan, but expressed concern about the ongoing and new challenges related to public health, innovation and intellectual property, primarily because of lack of implementation by Member States. She agreed with the recommendation that priority actions should be country-specific and feasible. She also agreed with the recommendations to prioritize research and development needs; to develop strategies and strengthen capacity for policy formulation, regulation, research methodology and ethics, and resource preservation in traditional medicine; and to improve research capacity, especially in low- and middle-income countries, to ensure that policy formulation and regulation were evidence-based.

The representative of THAILAND, noting the slow progress and uneven outcomes of the global strategy and plan of action, said that more focused and realistic priority actions with measurable indicators were required. Improved access to health products was essential in attaining universal health coverage and target 3.b of the Sustainable Development Goals. She welcomed the review panel's recommendations and indicators, and urged the Secretariat, Member States and stakeholders to implement the priority actions. Regular monitoring by the Secretariat and resource mobilization from assessed or voluntary contributions were also needed. She supported the draft decision.

The representative of MEXICO said that the review panel should specify how WHO would collaborate with other sectors to reach its objectives over the coming years. Regarding traditional medicine, the recommendations should take into account the institutions, objectives and research projects being implemented in all countries in order to achieve harmonization between legal frameworks, policies and implementation programmes and strategies. As for research conducted in indigenous regions and communities, safeguards must be established to protect traditional knowledge and respect the social and cultural rights of their populations, and consultations held with the communities involved. The research should adhere to intercultural principles and methodologies and involve the participation of community authorities and representatives, following their procedures. Finally, patent issues in the area of health should always be treated from an ethical point of view that respected human rights.

The representative of CHINA welcomed the creation of a methodology to prioritize research and development needs. WHO should consider how best to display leadership and help Member States to consider global needs when establishing their own research and development priorities. That would prevent Member States with advanced research and development capacities from focusing solely on

their needs, while diseases affecting developing countries were being neglected due to the lack of research and development capacities in those countries. He expressed concern that the proposed budget was not within existing resources and expenses; the Director-General should assess the potential human and financial resource challenges that might arise during implementation and draw up a plan based on allocated resources to implement substantive action as quickly as possible. He supported the draft decision.

The representative of SOUTH AFRICA, speaking on behalf of the Member States of the African Region, said implementing the global strategy and plan of action would be a key enabler towards achievement of the Sustainable Development Goals. He urged the Secretariat and stakeholders to take the necessary steps to meet the estimated budget requirement for implementation of the recommendations, and specifically the high-priority actions. Barriers to access to medicines included high prices, weak health-delivery systems, inadequate sustainable and equitable financing, and insufficient innovation and use of TRIPS flexibilities. Medicine shortages affected health-care delivery for communicable and noncommunicable diseases and impeded access to medicines and vaccines during health emergencies and epidemics. To address antimicrobial resistance and communicable and noncommunicable diseases, research and the strengthening of health systems and regulatory authorities were critical. He supported the draft decision.

The representative of QATAR said that the One Health approach should be a priority since human health, animal health and the environment were interconnected, as evidenced by emerging and re-emerging diseases such as Middle East respiratory syndrome, coronavirus, Ebola and Zika. Animal health and vaccination efforts and initiatives to combat vector-borne diseases should serve as protective measures for human health, given that they could save considerable effort and money owing to their relatively easy implementation. He looked forward to receiving the WHO guide on zoonotic diseases and thanked it for its efforts.

The representative of ZIMBABWE said that access to medicines could only be sustainable if countries led efforts with the support of WHO. She therefore welcomed the recommendation to develop and share good practices on evidence-based selection and health technology assessment for health products for national use. Bilateral and regional collaboration would allow countries to leverage each other's strengths to improve the availability of quality, affordable medicines that met their individual needs. It was essential to support innovation and strengthen procurement and supply chain management, which were critical in ensuring that quality, affordable medicines were available at the facilities closest to those in need. She supported the draft decision.

The representative of CARITAS INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that implementation of the review panel's recommendations would be part of a global paradigm shift aimed at upholding the dignity of all people. He called on the Health Assembly to adopt the decision and to implement all of the recommendations. He urged Member States to expedite implementation of the recommendations to promote transparency in, and understanding of, research and development costs, and to dedicate at least 0.01% of gross domestic product to basic and applied research relevant to the health needs of developing countries.

The representative of the INTERNATIONAL FEDERATION OF MEDICAL STUDENTS' ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that more efforts were needed to address the inequalities in universal health coverage. A global plan would promote new thinking on innovation and access to medicines, and encourage needs-driven research to target diseases affecting poor or vulnerable people. To achieve equitable access, it was essential to ensure that new products and technologies were not subject to unfair patent pricing and that the TRIPS Agreement was fully upheld. WHO should continue to play a strategic and central role in the relationship between public

health, innovation and intellectual property. He highlighted the potential of technology and innovation in revolutionizing health-care delivery.

The representative of KNOWLEDGE ECOLOGY INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that, while the global strategy and plan of action included notable objectives, there were some omissions. The modest goals on transparency were welcome. However, it was appalling that one country had opposed the transparency of research and development costs. Reliable data on research and development costs were essential to prevent the endless manipulation of large pharmaceuticals. Given the income disparities between and within countries, universal access was only feasible if prices were allowed to fall to generic levels and new incentives to reward successful research and development efforts were not linked to prices. Feasibility studies were necessary. Governments should end provisions in trade agreements that made it more difficult to obtain access to affordable products. He expressed concern that one country had recently announced a policy on raising medicine prices around the world, and he urged that country to revise its thinking.

The representative of the MEDICINES PATENT POOL, speaking at the invitation of the CHAIRMAN, said that the global strategy and plan of action had provided an important road map over the past 10 years on strategies to promote innovation, access and technology transfer. Indeed, the Medicines Patent Pool was a good example of strategy implementation, growing to become a vital component of the international response to HIV, hepatitis and tuberculosis. She welcomed the recommendation to expand the Medicines Patent Pool to other diseases and technologies, and the focus on essential medicines. She also welcomed the recommendation to promote further development of databases and patents and licence agreements for health products; transparency of the patent and licence status of medicines was critical to expanding access.

The representative of STICHTING HEALTH ACTION INTERNATIONAL, speaking at the invitation of the CHAIRMAN, expressed regret at the failure to turn the momentum created when the global strategy and plan of action had been agreed into a tool for change. Member States should fund implementation of the remaining activities in the global strategy and plan of action, and renew their commitment to fixing a broken research and development system that still did not respond to the public health needs of large population groups. He supported collaboration with other organizations to move towards more effective implementation of Article 66.2 on technology transfer of the TRIPS Agreement. WHO should support the drafting of national legislation to make full use of the TRIPS flexibilities, and continue its work with the Medicines Patent Pool. Member States and other international bodies must consider the public health implications of provisions that went beyond the requirements of the TRIPS Agreement when negotiating trade agreements. It was critical not to forget, or leave unfulfilled, previous commitments on access to medical innovation.

The representative of the WORLD MEDICAL ASSOCIATION, INC., speaking at the invitation of the CHAIRMAN, said that the inclusion of newer essential health products required harmonized and accurate intellectual property regulations, as well as sustainable and transparent sources of funding that responded to public health needs. It was regrettable that adequate prioritization of action on research and development and the development of innovative funding mechanisms had still not been included. In a globalized economy, national and international intellectual property regulations should always serve the people and not put some at a disadvantage compared with others.

The representative of MÉDECINS SANS FRONTIÈRES INTERNATIONAL, speaking at the invitation of the CHAIRMAN, said that the Secretariat and Member States had not done enough to deliver on the global strategy and plan of action since its adoption 10 years previously. Urgent efforts were needed to promote new thinking on innovation and access to medicines. He urged Member States to take action and endorse the review panel's recommendations. They should ensure that the

Secretariat had a clear mandate to draft an implementation plan for roll-out in 2018, including a monitoring mechanism and an annual accountability report. Member States should also ensure that there were clear funding commitments in the draft thirteenth general programme of work, 2019–2023.

The representative of the INTERNATIONAL FEDERATION OF PHARMACEUTICAL MANUFACTURERS AND ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that the review panel had not fully recognized all progress made in research and development, and that it was moving into areas not previously agreed on by Member States. Over half of the panel's recommendations were, to some degree, inconsistent with the original global strategy and plan of action. Therefore, to encourage innovation and create a spirit of partnership and consensus, Member States should only consider recommendations that were in line with the original mandate. The Secretariat should not implement the remaining recommendations until it had held close and regular consultations with Member States. A combination of several incentive models could unlock further research and development potential, including proposals relating to product development partnerships, orphan medicines legislation and advance market commitments.

The representative of the GLOBAL HEALTH COUNCIL, INC., speaking at the invitation of the CHAIRMAN, supported the review panel's recommendations to prioritize research and development needs for Type III diseases and to support collaboration between internationally recognized centres for research and development and relevant institutions in developing countries. Multisectoral global partnerships were essential not only for developing and scaling up the use of health innovations, but also for strengthening health capacities in developing countries. She strongly supported the recommendation to implement delinkage mechanisms for the sales of certain products from developer returns on investment, as well as the call for Member States to provide dedicated research and development funding relevant to the health needs of developing countries.

The representative of MEDICUS MUNDI INTERNATIONAL – INTERNATIONAL ORGANISATION FOR COOPERATION IN HEALTH CARE, speaking at the invitation of the CHAIRMAN, expressed disappointment at the poor record of implementation of the global strategy and plan of action, for which funding remained obstructed. She urged Member States to take decisive steps towards implementation and to commit themselves to the financial contribution of at least 0.01% of their gross domestic product for basic and applied research relevant to the health needs of developing countries. She also urged Member States to establish a clear time frame so that concrete time-bound targets could be set and progress monitored. The classification of diseases by type was irrational, as it ignored the actual health needs of developing countries; she called on Member States and the Secretariat to move beyond such a narrative. WHO should immediately begin negotiating a binding research and development agreement.

The representative of the WORLD FEDERATION OF PUBLIC HEALTH ASSOCIATIONS, speaking at the invitation of the CHAIRMAN, said that research and development capacities should include clinical trials and disease-oriented activities, particularly those with a focus on health and well-being. It was necessary to be aware of how public health practitioners and institutions applied technology across different models of society. Public trust must be built and maintained by ensuring the preservation of individual rights and privileges. Ethical considerations concerning the responsible use of “big data” in research must be addressed in the interests of public health. All public health professionals should be fully aware of the impact of the use of digital technology, and examine the sources of pressure that could indirectly influence their basic values.

The ASSISTANT DIRECTOR-GENERAL (Access to Medicines, Vaccines and Pharmaceuticals) noted the concerns raised by Member States with regard to funding. Public health, innovation and intellectual property were, more than ever, part of a global agenda on access to health.

Quoting the Director-General of the WHO who had spoken at the seventh technical symposium organized by WHO, WIPO and WTO held earlier in 2018, she said that innovation without access did not help address the problems being discussed by the Committee.

The CHAIRMAN took it that the Committee agreed to approve the draft decision contained in A71/13.

The draft decision was approved.¹

Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018: Item 11.7 of the agenda (documents A71/14 and A71/14 Add.1)

The CHAIRMAN drew attention to the following draft resolution on preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018, proposed by Argentina, Australia, Brazil, Canada, Chile, China, Colombia, the Dominican Republic, Ecuador, Finland, Norway, Pakistan, Panama, Peru, the Russian Federation, South Africa, Switzerland and Uruguay.

The Seventy-first World Health Assembly,

(PP1) Having considered the reports on the Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018;²

(PP2) Having recognized that the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases³ has catalysed action and retains great potential for engendering progress towards Sustainable Development Goal target 3.4 (by 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being);⁴

(PP3) Noting with concern that, according to WHO, each year, 15 million people between the ages of 30 and 69 years die from a noncommunicable disease and that the current levels of decline in the risk of dying prematurely from noncommunicable diseases are insufficient to attain Sustainable Development Goal target 3.4 by 2030;

(PP4) Welcoming the convening of the WHO Global Conference on Non-communicable Diseases,⁵ which was organized by Uruguay and WHO, co-chaired by Finland, the Russian Federation and Uruguay, from 18 to 20 October 2017 in Montevideo;

(PP5) Welcoming also the convening of the WHO Global Dialogue on Partnerships for Sustainable Financing of Noncommunicable Disease (NCD) Prevention and Control hosted by the Government of Denmark and WHO, from 9 to 11 April 2018 in Copenhagen, recognizing the need to prioritize tackling noncommunicable diseases as an essential pillar of sustainable development and an integral part of countries' efforts towards universal health coverage;

¹ Transmitted to the Health Assembly in the Committee's first report and adopted as decision WHA71(9).

² Documents A71/14 and A71/14 Add.1.

³ United Nations General Assembly resolution 66/2.

⁴ United Nations General Assembly resolution 70/1.

⁵ WHO Global Conference on Noncommunicable diseases: Enhancing policy coherence between different spheres of policy making that have a bearing on attaining SDG target 3.4 on NCDs by 2030 [website]. Geneva; World Health Organization: 2018 (<http://www.who.int/nmh/events/2017/montevideo/about/en/>, accessed 18 May 2018).

(PP6) Recalling the Shanghai Declaration on promoting health in the 2030 Agenda for Sustainable Development, adopted at the 9th Global Conference on Health Promotion, held in China, from 21 to 24 November 2016;

(PP7) Taking note that the Director-General has established a WHO Independent High-level Commission on Noncommunicable Diseases¹ and a WHO Civil Society Working Group on the third High-level Meeting of the General Assembly on NCDs;²

(PP8) Recalling United Nations General Assembly resolution 72/274 (2018) on the scope, modalities, format and organization of the third high-level meeting of the General Assembly on the prevention and control of non-communicable diseases,

OP1. WELCOMES the outcome document of the WHO Global Conference on the Prevention and Control of Non-communicable Diseases entitled “Montevideo roadmap (2018-2030) on the prevention and control of Noncommunicable Diseases as a sustainable development priority”,^{3,4} as a contribution to the preparatory process leading to the third High-level Meeting;

OP2. URGES Member States:⁵

(1) to continue to step up efforts on the prevention and control of noncommunicable diseases in order to attain Sustainable Development Goal target 3.4 by 2030;

(2) to actively engage in the preparations at national, regional and global levels for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018;

(3) to be represented at the level of Heads of State and Government at the High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and to call for action through a concise, action-oriented outcome document;

OP3. REQUESTS the Director-General:

(1) to continue to support Member States, in coordination with United Nations specialized agencies, funds and programmes as well as other stakeholders, in their efforts to reduce by one third premature mortality from noncommunicable diseases through prevention and control and promote mental health and well-being, including by applying evidence-based multisectoral and multistakeholder approaches;

(2) to report to the Seventy-second World Health Assembly, through the Executive Board, on the outcomes of the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases and its follow-up.

¹WHO Independent High-level Commission on NCDs [website] Geneva: World Health Organization: 2018 (<http://www.who.int/ncds/governance/high-level-commission/en/>, accessed 18 May 2018).

²WHO Civil Society Working Group on the third High-level Meeting of the UN General Assembly on NCDs [website] Geneva: World Health Organization: 2018 (<http://www.who.int/ncds/governance/high-level-meetings/working-group-third-high-level-meeting/en/>, accessed 18 May 2018).

³ See Annex 1.

⁴ Clarification Statement: http://www.who.int/conferences/global-ncd-conference/USA_statement_EOP_montevideo_roadmap.pdf?ua=1, accessed 18 May 2018.

⁵ And, where applicable, regional economic integration organizations.

WHO Global Conference on NCDs
Pursuing policy coherence to achieve SDG target 3.4 on NCDs
(Montevideo, Uruguay, 18-20 October 2017)

MONTEVIDEO ROADMAP 2018-2030 ON NCDs AS A SUSTAINABLE DEVELOPMENT PRIORITY

1. We, Heads of State and Government, Ministers and representatives of State and Government participating in this Conference, have come together to restate our commitment to take bold action and accelerate progress to, by 2030, reduce by one third the premature mortality from non-communicable diseases (NCDs) in line with the 2030 Agenda for Sustainable Development. We continue to be inspired by the action catalysed by the 2011 Political Declaration of the UN General Assembly on NCDs, and the WHO Global Action Plan for the Prevention and Control of NCDs 2013-2020. We reaffirm our commitment to their implementation, according to national context.
2. We acknowledge that premature mortality from NCDs¹ continues to constitute one of the major challenges for development in the 21st century, driven by economic, environmental and social determinants of health. Despite the remarkable progress achieved in some countries or regions, this has been highly uneven and insufficient to reach the global target on NCDs. Each year, 15 million people between the ages of 30 and 69 years die from an NCD; over 80% of these premature deaths occur in developing countries, disproportionately affecting the poorest and those furthest behind. Implementing coherent policies and ensuring that cost-effective, affordable and evidenced-based NCD interventions are available to all countries, according to national context and priorities, can reduce inequities and premature deaths from NCDs.
3. We recognize the importance of SDG 3 and ensuring that people not just survive, but live long and healthy lives, as well as the importance of preventing NCDs as specified in SDG target 3.4 on NCDs in achieving this overall goal. We also recognize that there are obstacles that countries must overcome to achieving SDG target 3.4². Addressing the complexity of the main risk factors, namely: tobacco use, physical inactivity, harmful use of alcohol and unhealthy diets, as well as air pollution, and the determinants of NCDs, including health literacy, requires multisectoral responses which are challenging to develop and implement, particularly when robust monitoring of NCD risk factors is absent at country level. Consequently, successful action requires enhanced political leadership to advance strategic, outcome-oriented action across sectors and policy coherence for the prevention and control of NCDs, in line with whole-of-government and health-in-all-policies approaches.
4. One obstacle at country level is the lack of capacity to effectively address public health goals when they are in conflict with private sector interests, in order to effectively leverage the roles and contributions of the diverse range of stakeholders in combatting NCDs. Policies to prevent and control NCDs, including effective regulatory and fiscal measures, may be negatively influenced by private sector and other non-State actors' interests, and may be subject to legal disputes or other means to delay, curtail or prevent their effective use to reach public health goals. Health systems

¹ Mainly four types of noncommunicable diseases (NCDs): cardiovascular diseases, cancers, chronic respiratory diseases and diabetes.

² By 2030, reduce by one third premature mortality from noncommunicable diseases through prevention and treatment and promote mental health and well-being.

need to improve NCD prevention, diagnosis and management and to strengthen effective health promotion over the life course, as part of efforts to achieve universal health coverage and reduce health inequities, including in the context of population ageing. Reducing NCDs should be a higher priority across the relevant UN Agencies, NGOs, philanthropic foundations and academic institutions. The increasing disease burden from NCDs should be taken fully into account in international cooperation and development policies with a view to address the unmet demand for technical cooperation to strengthen national capacities.

5. Unless coherent political action to address these obstacles is accelerated, engaging across sectors and across stakeholders, the current rate of decline in premature mortality from NCDs is insufficient to meet SDG 3.4 by 2030. In order to address the premature mortality and excess morbidity caused by NCDs, we commit to pursue these actions:

Reinvigorate political action

6. We will continue to address the complexity and challenging nature of developing and implementing coherent multisectoral policies across government through a health-in-all-policies approach in order to achieve improved outcomes from the perspectives of health, health equity and health system functioning.

7. We will prioritize the most cost-effective, affordable, equitable and evidence-based interventions that will bring the highest public health return on investment, in accordance with national context and priorities. We will emphasize health as a political priority, with measures that address the impact of the major NCD risk factors, including regulation, standard setting and fiscal policies and other measures that are consistent with countries' domestic legal frameworks and international obligations.

8. We will act across relevant government sectors to create health-conducive environments and identify opportunities to establish concrete cross-sectoral commitments in order to promote co-benefits and to reduce negative impacts on health, including through health impact assessments. We will encourage NCDs implementation research to enhance the operationalization of national strategies and integrate them, where possible, within wider health sector strategic planning. We will work collaboratively to share and improve the implementation of best practices towards implementing innovative approaches to ensure improved surveillance and monitoring systems to support these actions.

Enable health systems to respond more effectively to NCDs

9. We will strengthen, as necessary, essential population level, people-centred public health functions and institutions for effective prevention and control of NCDs, including palliative care, and to promote mental health and wellbeing.

10. We will continue investing in health workers as an essential part of strengthening health systems and social protection. We will work to ensure a highly skilled, well-trained and well-resourced health workforce to lead and implement actions to promote health and prevent and control NCDs.

11. We commit to improve implementation of cost-effective measures of health promotion, including health literacy, and disease prevention throughout the lifecycle, early detection, health surveillance, and reduction of risk factors, including exposure to environmental risk factors, and sustained efforts to address people at risk, as well as the treatment and care for people with NCDs.
12. Recognizing that mental disorders and other mental health conditions contribute to the global NCD burden and that people with mental disorders and other mental health conditions have an increased risk of other NCDs and higher rates of morbidity and mortality, we commit to implementing measures to improve mental health and well-being, address their social determinants and other health needs and human rights of people with mental disorders and other mental health conditions and prevent suicides as part of a comprehensive response to NCDs.
13. We will work towards enhancing synergies in preventing and controlling communicable diseases and NCDs at the national, regional, and global levels, where appropriate, recognizing the opportunity to achieve gains through integrated approaches.
14. We will work to ensure the availability of resources and strengthen the capacity to respond more effectively and equitably to NCDs as part of Universal Health Coverage, including through strengthened community-level prevention and health services delivery and access to essential NCD medicines and technologies for all. In our health systems, we will strive to secure access to quality basic and specialised health services, including with financial risk protection in order to avoid social and economic hardship.
15. Recalling previous commitments, we will better measure and respond to the critical differences in specific risk factors and determinants affecting morbidity and mortality from NCDs for children, adolescents, women and men across the life course, and pursue and promote gender-based approaches for the prevention and control of NCDs to address these critical differences. We invite WHO to provide guidance on how to accelerate the implementation of national efforts to address the critical differences in the risks of morbidity and mortality from NCDs for men and women, boys and girls.

Increase significantly the financing of national NCD responses and international cooperation

16. We acknowledge that national NCDs responses – supported through domestic, bilateral and multilateral channels – require adequate, predictable and sustained financing, commensurate with the global health and socioeconomic burden they impose. We will start by prioritizing domestic budgetary allocations for addressing NCDs, where possible.
17. Where needed, we will work on national investments cases for the prevention and control of NCDs, their risk factors and determinants, to create the fiscal space for action. We will consider applying policy options that, in addition to having a positive effect on reducing the occurrence of NCDs throughout the life course, also have the capacity to generate complementary revenues to finance national NCD responses, as appropriate. These options may include, consistent with national policies and international obligations, taxation, including of tobacco as well as other products. We will continue to explore other complementary financing options, including voluntary innovative financing mechanisms, as appropriate.

18. We call upon UN agencies and other global health actors to scale up support to governments in developing and implementing the national responses for the prevention and control of NCDs, including palliative care aligned with national priorities. We look to WHO to continue to exercise its global leadership and coordination role and to explore how existing mechanisms could best be leveraged to identify and share information on existing and potential sources of finance and development cooperation mechanisms for the prevention and control of NCDs at the local, national, regional and global levels to support action to reach SDG 3.4 on NCDs and better integrate NCDs into development funding mechanisms.

19. NCDs can perpetuate poverty. For the poor and near poor, chronic illness and disability can be an economic catastrophe. Hard fought economic gains can be quickly wiped out, especially when diagnosis, treatment, and palliative care services are not available or accessible. Women face a double NCD burden, often assuming gender-based roles as unpaid caregivers for the sick. We will take action on the impacts of NCDs on poverty and development using gender-based approaches. We strongly encourage including the prevention and control of NCDs in Official Development Assistance to complement domestic resources and catalyse additional resources for action, including research.

Increase efforts to engage sectors beyond health

20. We acknowledge that working constructively with public sectors beyond health is essential in reducing NCD risk factors and achieving health gains to reduce premature deaths from NCDs. In addition, we recognize the interconnectedness between the prevention and control of NCDs and the achievement of the SDGs beyond target 3.4, including targets related to poverty, substance abuse, nutrition, hazardous environmental exposure, sustainable cities and others. Coordinated upstream action across sectors, including agriculture, environment, industry, trade and finance, education and urban planning, as well as research, will help to create a healthy and enabling environment that promotes effective, coherent policies and supports healthy behaviours and lifestyles. The health sector has a role to play in advocating for these actions, presenting evidence-based information, supporting health impact assessments and providing policy reviews and analyses on how decisions impact health, including implementation research with a view to increase and scale up implementation of best practices. We therefore commit to strong leadership and to fostering collaboration among sectors to implement policies to achieve shared goals.

21. We will enhance policy and legal expertise to develop NCDs responses in order to achieve the SDGs. We call upon the UN Inter-Agency Task Force on the Prevention and Control of NCDs and its Members, within their mandates, to scale up and broaden intersectoral work integrating expertise relevant to public health-related legal issues into NCD country support, including by providing evidence, technical advice, and case studies relevant to legal challenges. We encourage the UN Inter-Agency Task Force on the Prevention and Control of NCDs to explore the relationship between NCDs and the law to improve support to Member States in this area and to raise the priority it gives to this work.

22. We recognize that access to education that promotes health literacy at all levels of society and contexts is a key determinant of health. In particular, the school environment will be enabled to provide evidence-based education, including information and skills. We will improve awareness-raising on health and well-being throughout society, including the prevention and control of NCDs supported through public awareness campaigns and health-conducive environments that make the

healthy choice the easier choice and facilitate behavioral changes. Besides the general responsibility of relevant sectors to promote health, it is in particular the task of the health sector to develop and provide appropriate information to increase health literacy.

23. We will scale up efforts to use information and communication technologies, including e-health and m-health, and other non-traditional and innovative solutions, to accelerate action towards achieving SDG target 3.4 by 2030.

24. We are concerned that the increased production and consumption of energy-dense, nutrient poor foods has contributed to diets that are high in saturated fats, sugars and salts. We will work towards advancing the implementation of global strategies and recommendations that aim at strengthening national food and nutrition policies, and their monitoring. This would include, inter alia, developing guidelines and recommendations that support and encourage healthy diets throughout the life course of our citizens, increasing the availability and affordability of healthy, safe nutritious food, including fruits and vegetables, while enabling healthier food choices as part of a balanced diet, and ensuring access to clean and safe drinking water. We call on WHO and FAO and other relevant international organizations to fully leverage the UN Decade of Action on Nutrition to promote health-conducive food production and supply systems reduce diet-related NCDs and contribute to ensure healthy diets for all.

25. We call on WHO to fast-track its review of national and regional experience of intersectoral policies to achieve SDG 3, and particularly target 3.4 on NCDs, to update its guidance on multisectoral and multi-stakeholder action for the prevention and control of NCDs and disseminate knowledge and best practices through WHO GCM/NCD's¹ communities of practice in a manner supportive of action at country level.

Reinforce the role of non-State actors

26. We acknowledge the need to engage with non-State actors in view of their significant role for the advancement and promotion of the highest attainable standard of health and to encourage non-State actors to use their own activities to protect and promote public health, in line with national context and priorities.

27. We will increase opportunities for meaningful participation of, where and as appropriate, nongovernmental organizations, private sector entities, philanthropic foundations and academic institutions, in building coalitions and alliances across the spheres of sustainable development in the prevention and control of NCDs, recognizing that they can complement the efforts of governments at varying levels and support the achievement of SDG target 3.4, in particular in developing countries.

28. We call on the private sector, ranging from micro-enterprises to cooperatives to multinationals, to contribute to addressing NCDs as a development priority, in the context of the achievement of the SDGs, in particular SDG 17².

¹ WHO Global Coordination Mechanism on the Prevention and Control of NCDs (WHO GCM/NCD).

² Strengthen the means of implementation and revitalize the global partnership for sustainable development.

Seek measures to address the negative impact of products and environmental factors harmful for health and strengthen the contribution and accountability of the private sector and other non-State actors

29. One notable challenge for the prevention and control of NCDs is that public health objectives and private sector interests can conflict. We commit to enhancing the national capacity to engage constructively with the private sector for NCDs prevention and control in a way that maximizes public health benefits.

30. We acknowledge that we need to continue to develop coordinated and coherent policies, strengthen evidence-based policy and regulatory frameworks, and align private sector incentives with public health goals, to make health conducive choices available and affordable in healthy environments, and in particular, to empower and provide people with the necessary resources and knowledge, including health literacy, in order to enable healthy choices and active lifestyles.

31. We further encourage the private sector to produce and promote more food and beverage products consistent with a healthy diet including by reformulating products, especially those products with the largest impacts on health, to provide healthier options that are affordable and accessible for all and that follow appropriate nutrition facts and labelling standards, including information on sugars, salt and fats and, where relevant, trans-fat content. We also encourage the private sector to reduce the exposure of and impact on children of marketing of foods and non-alcoholic beverages, consistent with WHO recommendations and guidance, and in accordance with national legislation, policies, and relevant international obligations.

32. We acknowledge the importance of improving environmental determinants and reducing risk factors in the prevention and control of NCDs and the inter linkage of SDG targets 3.4 and 3.9¹. These interlinkages illustrate that the prevention and control NCDs can also contribute positively to the SDG goal 13 on climate change. We will promote actions that are mutually reinforcing and support achievement of these goals and targets.

33. We will continue to work with all stakeholders, including industry, food business operators, health and consumer NGOs, and academia, towards the achievement of the nine voluntary NCD targets for 2025. This may include, as appropriate, promoting the recording and making publicly available of the verifiable commitments of non-State actors, as well as their reporting on the implementation of those commitments. We call on WHO to continue the development of expertise, tools, guidance and approaches that can be used to register and publish contributions of non-State actors in the achievement of these targets, and to assist Member States in effectively engaging non-State actors and leveraging their strengths in the implementation of national NCD responses.

34. We call upon States parties, to accelerate the full implementation of the WHO Framework Convention on Tobacco Control, as one of the cornerstones of the global response to NCDs and encourage countries that have not yet done so to consider becoming a Party to the Convention. Recognizing the fundamental and irreconcilable conflict of interest between the tobacco industry and

¹ By 2030, substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination.

public health, we will continue to implement tobacco control measures without any tobacco industry interference.

35. We encourage the WHO GCM/NCD to explore the impact of economic, market and commercial factors on the prevention and control of NCDs to better improve the understanding of their implications for health outcomes and opportunities to advance action in the global NCD agenda.

Continue relying on WHO's leadership and key role in the global response to NCDs

36. We reaffirm WHO as the directing and coordinating authority on international health work and all its functions in this regard, including its normative work and convening role. WHO's support is essential in the development of national NCD and mental health responses as an integral part of the implementation of the 2030 Agenda for Sustainable Development. WHO's advice to Member States on how to address the determinants and risk factors remains indispensable for the global action on NCDs and mental health.

37. We also reaffirm WHO's leadership and coordination role in promoting and monitoring global action against NCDs in relation to the work of other UN agencies, development banks, and other regional and international organizations in addressing NCDs in a coordinated manner.

38. We call on WHO to strengthen its capacity to provide technical and policy advice and enhance multistakeholder engagement and dialogue, through platforms such as the WHO GCM/NCD and the UN Inter-Agency Task Force on NCDs.

39. We further call on WHO to consider prioritizing the implementation of strategic actions, including cost-effective and evidence-based policies and interventions, in preparation of the third United Nations High-level Meeting on NCDs in 2018.

Act in unity

40. We acknowledge that the inclusion of NCDs in the 2030 Agenda for Sustainable Development provides the best opportunity to place health and in particular NCDs at the core of the pursuit of shared progress and sustainable development. Ultimately, the aspiration of the 2030 Agenda is to create a just and prosperous world where all people can exercise their rights and live long and healthy lives.

41. Acting in unity to address NCDs demands a renewed and strengthened commitment to show that we can be effective in shaping a world free of the avoidable burden of NCDs. In so doing, we will continue to listen to and involve the peoples of the world – those exposed to NCD risk factors, and those with health care needs for NCDs and mental health. We will continue to build a future that ensures present and future generations enjoy the highest attainable standard of health and wellbeing.

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

Resolution:	Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018
A. Link to the programme budget	
1. Programme area, outcome and output(s) in the Programme budget 2018–2019 to which this draft resolution would contribute if adopted	<p>Programme area: 2. Noncommunicable diseases</p> <p>Outcome: 2.1. Increased access to interventions to prevent and manage noncommunicable diseases and their risk factors</p> <p>Outputs:</p> <p>2.1.1. Development and implementation of national multisectoral policies and plans to prevent and control noncommunicable diseases accelerated</p> <p>2.1.2. Countries enabled to implement strategies to reduce modifiable risk factors for noncommunicable diseases (tobacco use, diet, physical inactivity and harmful use of alcohol), including the underlying social determinants</p> <p>2.1.3. Countries enabled to improve health care coverage for the management of cardiovascular diseases, cancer, diabetes and chronic respiratory diseases and their risk factors, including in crises and emergencies</p>
2. Short justification for considering the draft resolution, if there is no link to the results as indicated in the Programme budget 2018–2019:	Not applicable.
3. Brief description of any additional Secretariat deliverables during the biennium 2018–2019, which are not already included in the Programme budget 2018–2019:	Not applicable.
4. Estimated implementation time frame (in years or months) to achieve the resolution:	Eight years: all activities referred to in the resolution will be carried out during the bienniums 2020–2021, 2022–2023 and 2024–2025.
B. Resource implications for the Secretariat for implementation of the resolution	
1. Total resource requirements to implement the resolution, in US\$ millions:	US\$ 179 million (2018–2019).
2.a. Estimated resource requirements already planned for in the Programme budget 2018–2019, in US\$ millions:	US\$ 179 million was planned for in the Programme budget 2018–2019: thus there are no additional requirements.
2.b. Estimated resource requirements in addition to those already planned for in the Programme budget 2018–2019, in US\$ millions:	Not applicable.

<p>3. Estimated resource requirements in the Programme budget 2020–2021, in US\$ millions:</p> <p>Same as those in the Programme budget 2018–2019.</p>
<p>4. Estimated resource requirements in future programme budgets, in US\$ millions:</p> <p>Programme budget 2022–2023: same as those in the Programme budget 2018–2019. Programme budget 2024–2025: same as those in the Programme budget 2018–2019.</p>
<p>5. Resources available to fund the implementation of the resolution in the current biennium, in US\$ millions</p> <ul style="list-style-type: none"> – Resources available to fund the resolution in the current biennium: US\$ 82 million (46% of US\$ 179 million). – Remaining financing gap in the current biennium: US\$ 97 million (US\$ 179 million minus US\$ 82 million). – Estimated resources, foreseen but not yet available, which would help to close the financing gap in the current biennium: US\$ 97 million.

The representative of GABON, speaking on behalf of the Member States of the African Region, said that insufficient progress had been made in fulfilling the commitments and meeting the time frames since the first two high-level meetings held in 2011 and 2014, particularly in his Region. Member States in the African Region were still facing enormous challenges, which made it difficult for them to fulfil national commitments. WHO and its partners should continue to provide technical support to increase implementation of measures to address noncommunicable diseases. Member States should step up implementation of resolutions WHA66.10 and WHA69.6 on the prevention and control of noncommunicable diseases, by ratifying the Protocol to Eliminate Illicit Trade in Tobacco Products to the WHO Framework Convention on Tobacco Control and strengthening regulations on, and control of, the marketing of products such as tobacco, alcohol and sugar-sweetened beverages, with WHO support. He encouraged Member States to participate actively at the highest level in the third high-level meeting.

The representative of ZAMBIA said that, in many countries, the rate of decline of premature deaths due to noncommunicable diseases was too low. The political commitments made at the United Nations General Assembly in 2011 and 2014 must be fully implemented in order to achieve the targets of the 2030 Agenda for Sustainable Development. Member States had made slow progress in applying sectoral strategies. Most Member States had no capacity to establish cross-sectoral partnerships for the prevention and control of noncommunicable diseases, or to manage their complexity during implementation. If significant investments were not made immediately, target 3.4 of Sustainable Development Goal 3 might not be achieved. She therefore supported the recommendation to invest in prevention and better management of the four main noncommunicable diseases to prevent premature deaths.

The meeting rose at 17:30.

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