

Major Outcomes of the 2019 World Health Assembly

By Mirza Alas and Nirmalya Syam*

I. Universal Health Coverage: preparation for the high-level meeting of the United Nations General Assembly on universal health coverage

The World Health Assembly (WHA) in May 2019 approved the resolution WHA72.4¹ "Preparation for the high-level meeting of the United Nations General Assembly on universal health coverage." This resolution follows from a 2017 United Nations General Assembly (UNGA) resolution 72/139 that agreed to hold a high-level meeting on Universal Health Coverage (UHC) in 2019 and requested the World Health Organization (WHO) to collaborate closely with the President of the General Assembly, in consultation with the Member States, to ensure the most effective and efficient outcomes.

The WHO resolution calls for countries to accelerate progress towards achieving Sustainable Development Goal (SDG) target 3.8 on universal health coverage by 2030, support the preparation for the high-level meeting, to participate at the highest level, continue to mobilize resources, support better prioritization and invest in strengthening primary health care. The text also calls for promoting access to affordable, safe, effective, and quality medicines, vaccines, diagnostics, and other technologies, among other vital issues that the Member States are

called to address. The resolution also requests the Director-General (DG) of WHO to support countries with assistance including capacity building, technical assistance and policy advice, including on how to strengthen health systems. The Director-General is also requested to raise awareness among parliamentarians on UHC.

During the discussions at the WHA, developing countries commented on the low health coverage levels in many regions of the world and how this continues to be a cause of impoverishment. Developing countries called for the UNGA declaration to be action-oriented, to promote access to medicines and the use of TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) flexibilities, and similarly, to ensure that equity issues are also addressed as well as other broader determinants of health such as the environment, education and housing. Countries also called for the centrality of Primary Health Care (PHC), the need to look into financing strategies and to have assistance in developing a road map to UHC that will include health system strengthening.

The High-Level meeting on UHC took place on September 23rd during the first day of the United Nations General Assembly (UNGA). The UNGA adopted a political declaration which gives a high-level political mandate for the achievement of UHC. Importantly, the declaration

Abstract

This policy brief provides an overview of the outcomes of selected agenda items that were discussed at the 72nd session of the World Health Assembly (WHA) of the World Health Organization (WHO), held from 21 to 26 May 2019 in Geneva. These items reflect some of the health priorities of developing countries.

Cette note de synthèse donne un aperçu des décisions adoptées concernant certains points de l'ordre du jour qui ont été examinés lors de la 72e session de l'Assemblée mondiale de la santé de l'Organisation mondiale de la santé (OMS), qui s'est tenue du 21 au 26 mai 2019 à Genève. Ces points reflètent certaines des priorités des pays en développement en matière de santé.

El presente informe de políticas ofrece una sinopsis de los resultados de determinados puntos del orden del día de la 72.ª Asamblea Mundial de la Salud de la Organización Mundial de la Salud (OMS), celebrada del 21 al 26 de mayo de 2019 en Ginebra. Estos puntos abordan algunas de las prioridades en materia de salud de los países en desarrollo.

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contains essential elements for the realization of UHC including the centrality of primary health care, affordable access to medicines and vaccines as well as the linkages with efforts to tackle antimicrobial resistance.

II. Access to medicines, vaccines and other health products

The issues considered under this agenda item are part of the implementation of the WHO [Global Strategy on public health, innovation and intellectual property \(GSPOA\)](#). While the GSPOA was not an agenda item for the 72nd session of the WHA, the GSPOA provides guidance on these issues. The GSPOA implementation and follow up remain a priority for the WHO. The GSPOA will be discussed in the 73rd session of the WHA.

a) Roadmap on Access to Medicines, Vaccines and Other Health Products

The WHA took note of a roadmap on access to medicines, vaccines and other technologies prepared by the WHO secretariat. The roadmap describes the actions, activities and deliverables envisaged by the secretariat for the period 2019-2023 for improving access to medicines and vaccines.

The 2018 Health Assembly had adopted decision WHA71(8) that requested the WHO Director-General to elaborate the roadmap and submit the report to the Assembly in 2019 through the 144th session of the Executive Board (EB). Consultations were held on a zero draft of the roadmap with member States and intergovernmental organizations and non-State actors from July to September 2018. Based on the feedback received from these consultations, the draft roadmap was updated and presented for the consideration of the Executive Board in January 2019. A revised version of this report was presented for the consideration of the WHA 2019. The revision described the linkage between the Thirteenth General Programme of Work, 2019-2023, and the activities, actions, deliverables and milestones set out in the roadmap. It also reflected issues raised by the Executive Board relating to providing health products for primary health care, monitoring access, optimizing the use of biosimilars, addressing the challenges faced by Small Island States, and supporting countries transitioning from donor funding.

The revised roadmap is aligned to the following outputs of the WHO General Programme of Work for 2019-2023: a) providing guidance on quality, safety and efficacy of health products, including through prequalification services, essential medicines and diagnostics lists; b) improved and more equitable access to health products through global market shaping and supporting countries to monitor and ensure efficient and transparent procurement and supply systems; c) strengthening country and regional regulatory capacity and improving supply of quality-assured and safe health products; d) defining the research and development (R&D) agenda and coordinating research in line

with public health priorities; and e) enabling countries to address antimicrobial resistance through strengthened surveillance systems, laboratory capacity, infection prevention and control, awareness-raising and evidence-based policies and practices.

The roadmap sought to address two broad strategic objectives: a) ensuring quality, safety and efficacy of health products; and b) ensuring equitable access to health products. The roadmap describes activities, specific actions and deliverables for each of these strategic areas. With regard to quality, safety and efficacy, the roadmap focuses on regulatory system strengthening, prequalification and market surveillance. In respect of equitable access, the roadmap focuses on aligning R&D to public health needs, application and management of intellectual property, evidence-based selection and fair and affordable pricing, procurement and supply chain management, appropriate prescribing, dispensing and rational use.

The roadmap states at the outset that it is based on key WHA resolutions over the last 10 years relating to access to medicines. This implies that the roadmap considers resolutions that go back up to 2008 only. Hence, it ignores a number of major WHA resolutions prior to 2008 that give the WHO specific mandate for activities on access to medicines, and the use of TRIPS flexibilities to that end. These include resolutions WHA49.14, WHA52.19, WHA53.14, WHA54.10, WHA57.14, WHA58.34 and WHA59.26.

In respect of regulatory systems strengthening, the roadmap refers to the role of WHO in developing regulatory norms and standards and expanding reliance on national regulatory authorities that meet international performance benchmarks under the WHO Global Benchmarking Tool for assessment of national regulatory systems. The roadmap focuses on the promotion of work-sharing and convergence among national regulatory systems. This appears to be an implied reference to the promotion of regulatory harmonization. It should be recalled that in the negotiations during the 2014 WHO Assembly on resolution WHA67.20, developing countries had strongly objected to any reference to promotion of regulatory harmonisation or the inclusion of standards developed by the International Conference on Harmonisation (ICH) – a partnership of regulatory agencies of developed countries and multinational pharmaceutical companies to which the WHO is a permanent observer. In this context, it will be critical to ensure that WHO activities in the area of regulatory system strengthening are not unduly influenced by commercial interests of multinational pharmaceutical companies and do not lead to harmonization of untenable regulatory standards for developing countries.

With regard to health research and development, the roadmap does not go beyond the business as usual approach and limits itself to gathering and processing information under the Global Observatory on Health Research and Development. There is no mention of the recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination

(CEWG) for negotiating a global biomedical R&D treaty, the need for which has also been endorsed by the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines (UNHLP).

On intellectual property (IP), the roadmap focuses on the application of appropriate IP rules and management of IP for fostering innovation and access to health products and providing technical support and capacity building. With regard to application and management of IP rules, the roadmap focuses on promotion of public health oriented licensing agreements, transparency on patent status of health technologies, sharing country experiences on public health approaches to the use of TRIPS flexibilities, review of mechanisms and initiatives for access to affordable health technologies enabled by publicly funded R&D, and support for the expansion of the Medicines Patent Pool to patented essential medicines in the WHO treatment guidelines through identification of potential products for licensing. WHO can also provide on-demand technical assistance to countries on making use of the TRIPS flexibilities, assessing the public health implications when negotiating bilateral and multilateral trade agreements, and assessment of the patent status of essential medicines. The roadmap also focuses on the continuation of the trilateral cooperation with the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO), and also with the United Nations Conference on Trade and Development (UNCTAD) and the United Nations Development Programme (UNDP).

While it is important that WHO provides support to countries in adopting a public health approach to the use of TRIPS flexibilities, it will be important to ensure that WHO raises awareness about the importance and the full scope of the TRIPS flexibilities for access to medicines. However, the roadmap does not make any mention of the importance and scope of TRIPS flexibilities in the introduction of the action areas in the report. Hence, while technical support for the use of TRIPS flexibilities is available from WHO, it is somewhat undersold in this report. Another aspect of the roadmap is that it focuses on management and licensing of IP rights which is not within the competence of WHO. The report also gives undue prominence to the trilateral collaboration between WHO, WTO and WIPO.

The roadmap also refers to ensuring fair pricing as an action area. In this regard, it is important to stress that there is no common understanding of fair pricing among WHO member States. WHO's activities on fair pricing based on the roadmap should not undermine the need to ensure affordable pricing of health products.

Finally, it will be critical to ensure that the roadmap ensures complementarity and synergy with other WHO policy documents in the area of cancer medicines, non-communicable diseases, biomedical R&D, and antimicrobial resistance.

b) Resolution on Improving the Transparency of Markets for Medicines, Vaccines and Other Health Products

The WHA adopted a resolution on "Improving the transparency of markets for medicines, vaccines and other health products" after intense negotiations in several drafting group sessions. The resolution was strongly opposed by major developed countries. After unsuccessful attempts to delay the discussions till the next WHA in 2020, the resolution was adopted. Germany, UK and Hungary dissociated themselves from the resolution.

The resolution urges the WHO member States to do the following with regard to medicines, vaccines and other health products:

- Take appropriate measures to publicly share information about the net price.
- Support dissemination, enhanced availability and access to aggregated results data and, if already publicly-available or voluntarily-provided, costs from human subject clinical trials, while ensuring patient confidentiality.
- Work collaboratively to improve the reporting of information by suppliers on registered health products, such as reports on sales revenues, prices, units sold, marketing costs, and subsidies and incentives.
- Facilitate improved public reporting of patent status information and marketing approval status of health products.
- Improve national capacities, including through international cooperation, open and collaborative research for development and production of health products, especially in developing countries and low- and middle-income countries (LMICs), including for diseases that primarily affect them.

The resolution only urges WHO member States to "take appropriate measures to publicly share information on the net prices of health products" defined as the amount received by manufacturers after subtraction of all rebates, discounts, and other incentives. Thus, the resolution only exhorts governments to take measures to share information about the final price and not the procurement price, wholesale price and distributors' mark-up price, all of which constitute elements of the final price. Besides this, the resolution does not create any obligation for WHO member States to ensure transparency on the cost of R&D and clinical trials, which were the core objectives of the initial draft resolution. While member States are urged to take measures to support the dissemination and make available the results of clinical trials data, the information about costs of clinical trials is to be disclosed only where the cost information is publicly available or voluntarily provided. It also does not obligate member States to gather information from suppliers on pricing, etc. but work collaboratively to improve the reporting of such information by suppliers.

The resolution was co-sponsored by 19 countries led by

Italy along with Andorra, Brazil, Egypt, Eswatini, Greece, India, Kenya, Luxembourg, Malaysia, Malta, Portugal, Russia, Serbia, Slovenia, South Africa, Spain, Sri Lanka and Uganda. The resolution aimed to improve the transparency around prices of medicines, vaccines and other health technologies. It was submitted in the context of the report by the WHO Secretariat on the roadmap for access to medicines, a report by the secretariat on cancer medicines presented at the Executive Board meeting in January 2019, and the consensus reached at the Fair Pricing Forum in South Africa in 2019 on promoting transparency in the prices of medicines, vaccines and health technologies.

The adopted resolution on transparency does not ensure the availability of pricing and cost information that is required in order to take informed decisions concerning the affordability of specific medicines, vaccines and other health technologies. Nevertheless, the resolution was welcomed as a step towards enhanced transparency. The resolution provides a mandate to the WHO secretariat to support member States to analyse information on economic data across the value chain for health products and data for relevant policy development and implementation towards achieving Universal Health Coverage, and national policies relevant to the transparency of markets for health products, including national capacities for local production, rapid and timely adoption of generic and biosimilar products, cost-effective procurement, product selection, quality assurance and supply-chain management of health products.

The WHO member States should ensure that the WHO secretariat aligns its roadmap on access to medicines and the implementation of the transparency resolution to the Global Strategy on public health, innovation and intellectual property (GSPOA). The GSPOA should guide related work in these areas. It is integral to the WHO General Programme of Work for 2019-2023. The WHO secretariat should also develop new activities to support member States in this regard.

III. Follow up of the high-level meetings of the United Nations General Assembly on health-related issues:

a) Antimicrobial resistance

Antimicrobial resistance (AMR) continues to be a vital issue both at the WHO and at the United Nations (UN) level. The WHA adopted resolution WHA72.5² to renew commitments for action on AMR and also a resolution on water, sanitation and hygiene in health care facilities drawing critical linkages between the strengthening of prevention measures and combating the spread of AMR.

The resolution on antimicrobial resistance calls on countries to remain committed at the highest political level, increase efforts for implementation, develop and strengthen monitoring systems and enhance cooperation for action, among others. It also invites internation-

al, regional and national partners to continue their support for the Member States in their development and implementation of national action plans, to coordinate their efforts to avoid duplication, to increase collaboration for research and development and to consider AMR in funding.

The resolution requests the Director-General to accelerate the implementation of actions in line with the global action plan on AMR, to increase support and technical assistance including for surveillance, to inform Member States of the work of the Tripartite³ and the United Nations Environmental Program (UNEP). The Director-General was also requested to consult with Member States and other relevant stakeholders to adjust the process and scope of the global development and stewardship framework, to support countries in mobilizing funding and developing a process to allow the Member States to consider the United Nations General Assembly report on AMR. Moreover, WHO is also requested to update the WHO list of Critically Important Antimicrobials for human medicine and to submit biennial reports until 2025.

At the UN level the Secretary-General submitted a report on the progress of implementation of the UN High-level political declaration on AMR, adopted in 2016. The report, under the agenda item on Global Health and Foreign Policy, includes information on the progress including on national action plans, global action and work of the tripartite agencies. The Secretary-General's report also consists of a summary of the recommendations of the Inter-Agency Coordination Group (IACG) on AMR and has identified five critical shifts that emerged from the recommendations of the IACG. These shifts include the urgency of AMR, the need for a One Health approach, need for stakeholder engagement, implementation of national action plans and resource mobilization. Member States at the UN this year have an opportunity to use this report to continue the high political commitment and to provide guidance on the best way to implement the recommendations.

Deliberations at the WHA by developing countries for the adoption of the resolution on AMR focused on the urgency of tackling AMR, the need for resources for the national action plans and how essential investment in developing new treatments are. Moreover, developing countries also mentioned their current challenges, including issues of access, supply chain, surveillance capacity, human resources, guidance needed and funding. States called for the implementation of the IACG recommendations and the further coordination of the tripartite agencies and UNEP to assist countries nationally.

b) Prevention of noncommunicable diseases

The WHA adopted decision WHA72 (11)⁴ following up the report on the progress of the implementation of the high-level political declarations on the prevention and control of non-communicable diseases (NCDs). There have been three high-level meetings on NCDs. The last high-level meeting on NCDs took place in September 2018 at the United Nations General Assembly.

The decision text that was approved requests the Director-General for several deliverables relating to the implementation on current commitments to address NCDs including updates to the appendices of WHO's global action plan for the prevention and control of noncommunicable diseases 2013–2020 and WHO's comprehensive mental health action plan 2013–2020. The WHO is also requested to prepare and update a menu of policy options to support the Member States to promote mental health and well-being and a menu of policy options to reduce the number of premature deaths from noncommunicable diseases attributed to air pollution.

The text also requests the Director-General to prepare a report to the Seventy-third WHA in 2020 on the implementation of WHO global strategy to reduce the harmful use of alcohol and an annual report of progress to be submitted to the Health Assembly from 2021 to 2031. The request also includes the need to facilitate further guidance to strengthen health literacy through education programs and mass- and social media campaigns. Also, to collect and share best practices for the prevention of overweight and obesity and to provide the necessary technical support in integrating the prevention and control of NCDs and the promotion of mental health into primary health care services. The decision text also requests making available adequate financial and human resources to support the Member States with technical assistance to strengthen their national efforts for the prevention and control of noncommunicable diseases.

During the discussions at the WHA developing countries expressed the importance of the issue and the impact it is having in the different regions. Countries emphasized the need to work on taxation and develop guidance on how to use it as a tool to fight NCDs. They also pointed out the importance of primary health care for the management of NCDs and the fact that this is a chronic issue that requires long term support including human and financial resources to support the implementation of the political declaration. They also requested WHO to provide leadership in standard-setting and technical assistance, including for identifying strategies for alcohol prevention. Developing countries also pointed out that there needs to be a stronger prominence in identifying the causes of NCDs, including the commercial determinants of health and affordable access to medicines and vaccines.

c) Ending tuberculosis

The WHA considered a report on the progress of the implementation of the political declaration on tuberculosis (TB) that was adopted in 2016 after the high-level meeting. This critical event provided a high-level platform to highlight what continues to be one of the deadliest infectious diseases. The implementation of the STOP TB strategy, as well as the political declaration on TB, will be essential on the path to elimination.

Part of the requests to WHO in the political declara-

tion is the development of a global strategy for tuberculosis research and innovation. A draft of this was made available for public comments and a revised draft will be reviewed by WHO regional committees where countries will be able to submit further comments. This strategy could potentially ensure that innovative mechanism for the funding of R&D and newer and more effective treatments address ways in which new therapies will be accessible and affordable. The final draft strategy will be presented to the WHO Executive Board at its 146th session and the Seventy-third World Health Assembly.

Developing countries during the WHA noted the criticality of TB, including concerns on the increase of multi-drug resistance TB (MDR-TB) and their support for the targets and commitments made at the high-level meeting. They also mentioned the need to increase capacity building, strengthen primary health services and training for health care professionals. Countries also commented on how essential it is to understand the socioeconomic reasons for the disease, the social determinants and ensure the accessibility and affordability of treatments, especially for MDR-TB. They also agreed on the need for more significant mobilization of funding and investment in research and development.

IV. Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits

In 2011 the WHO member States had adopted the Pandemic Influenza Preparedness (PIP) Framework to improve and strengthen the sharing of influenza viruses with human pandemic potential, and to increase the access for developing countries to vaccines and other pandemic related supplies. The PIP Framework was reviewed 5 years after its establishment, as mandated by the Framework.

The 70th session of the WHA in 2017 had adopted a decision WHA 70(10) that requested the Director-General to undertake a thorough and deliberative analysis of the issues raised in the recommendations of the 2016 PIP Framework Review Group concerning seasonal influenza and Genetic Sequence Data (GSD). The PIP Framework Review Group had recommended that the WHO secretariat should undertake a study to determine the implications and desirability of including seasonal influenza viruses within the PIP Framework. It had also pointed to the need for clarity on the issue of handling genetic sequence data under the PIP Framework as GSD is becoming increasingly critical in influenza research and can in some cases substitute for physical samples for pandemic risk assessment and development of commercial products, and made a number of recommendations in this regard, including that the WHO DG should recommend member States to amend the definition of PIP Biological Material under the PIP Framework to include GSD.

At the 71st WHA in 2018 the secretariat reported that it intended to complete this analysis and submit a draft report to the WHA 72 in 2019. The WHA adopted decision

WHA 71(11) which requested the WHO secretariat to submit the report accordingly.

The report by the secretariat to the 72nd Assembly in 2019 suggested that it may be difficult to identify or develop the best approach to sharing of seasonal influenza viruses until the outcome of discussions under the Nagoya Protocol on the criteria and process for recognising specialised international ABS instruments are resolved.

The WHA adopted decision WHA 72 (12) which *inter alia* requested the WHO DG to prepare a report on the treatment of influenza virus sharing and the public health considerations in that respect by existing relevant laws and regulatory measures, including laws and regulatory measures that implement the Nagoya Protocol. It also requested the DG to continue providing information on challenges and opportunities posed by new technologies in the context of the PIP Framework.

V. The public health implications of implementation of the Nagoya Protocol

The WHA discussed a report by the WHO secretariat on the public health implications of implementation of the Nagoya Protocol on Access and Benefit-Sharing related to genetic resources of the Convention on Biological Diversity (CBD).

In this report, the WHO secretariat indicated its readiness for a broad mandate "... to explore, in close dialogue and collaboration with all relevant partners, possible options, including codes of conduct, guidelines and best practices, and global multilateral mechanisms, for pathogen access and benefit sharing. Such work would be done in harmony with the Nagoya Protocol and its principles, under the overarching framework of reaching the objectives of the health-related Sustainable Development Goals, and in furtherance of the objectives of the International Health Regulations (2005) and WHO's Thirteenth General Programme of Work, 2019–2023."

During the discussions on this report, developed countries laid stress on the impact of the Nagoya Protocol on pathogen sharing and expressed concerns on delays in sharing of pathogen samples. On the other hand, developing countries emphasized that the objectives and principles of the Nagoya Protocol provided an opportunity for equity through fair and equitable benefit sharing which can reinforce public health preparedness and response during an emergency. Many developing countries expressed a preference for the work of the WHO secretariat to be limited to collecting more information on the nature and modalities of pathogen sharing rather than setting norms.

The WHA adopted decision WHA 72 (13) which requests the WHO Director-General to broaden engagement with member States, the secretariat of the CBD, and other relevant international organizations and stakeholders to provide information on current patho-

gen sharing practices and arrangements, the implementation of access and benefit-sharing measures, and their public health outcomes and other implications. The WHO secretariat was also requested to present a report to the WHA in 2020 through the 148th session of the Executive Board in January 2021 and also present an interim report to the EB in its 146th session in January 2020.

VI. Conclusion

The 72nd session of the WHA in May 2019 discussed and decided on a number of issues. Several are highlighted in this paper. These include the preparation for the UNGA High Level Meeting on Universal Health Coverage in September 2019 that resulted in a political declaration on UHC from the UNGA. Another central theme of the 2019 WHA was advancing access to medicines, vaccines and other health technologies. The WHO was requested to advance work on a mid-term roadmap of activities including the implementation of the global strategy and plan of action on public health, innovation and intellectual property. The WHA also discussed the importance of increasing transparency of prices and costs of R&D for medicines, in the context of exorbitant prices for new therapies, and agreed to the text of a soft resolution on transparency. The WHA also discussed follow up to various UNGA high level meetings, for tackling antimicrobial resistance, ending tuberculosis and preventing non-communicable diseases. The WHA also continued consideration of the PIP Framework for the sharing of influenza viruses with human pandemic potential and access to vaccines and other benefits and whether it should be expanded to include seasonal influenza viruses, as well as how to handle genetic sequence data. Relatedly, the WHO secretariat was tasked to produce a report on current pathogen sharing practices and arrangements, the implementation of access and benefit-sharing measures in accordance to the Nagoya Protocol of the CBD, and their public health outcomes and other implications.

The Executive Board of the WHO will meet on 3 – 8 February 2020. The 73rd Session of the WHA will meet on 17– 21 May 2020.

Endnotes:

¹ http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R4-en.pdf

² http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_R5-en.pdf

³ This refers to the WHO, the Food and Agriculture Organization (FAO) and the World Organisation for Animal Health (OIE) work in this area.

⁴ [http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72\(11\)-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72(11)-en.pdf)

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