POLICY BRIEF

People's Health Movement
Health for All Now!

CONTENTS

Issued by the WHO watch Programme of People's Health Movement
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11.5 Universal Health Coverage

Access to healthcare is essential for health. Yet - if considered in isolation - it is simply not enough. The underlying factors driving and affecting healthcare must be addressed.

Key points

- PHC is much more than UHC: this should be recognized and taken into account in WHO documents
- In order to achieve Health for All, it is crucial to step back from the current fiscal and commercialized version of UHC and adopt a human-rights approach to health

Summary

WHA72 will discuss three reports concerning Universal Health Coverage (UHC):

- Primary health care (PHC) towards UHC (A72/12) and resolution EB144.R9
- Community health workers (CHW) delivering primary health care: opportunities and challenges (A72/13), and
- Preparation for the High-Level Meeting (HLM) of the United Nations General Assembly (UNGA) on UHC (A72/14).

In this section, only the reports on PHC (A72/12) and on the preparations for the HLM on UHC of the UNGA (A72/14) are discussed. The role of CHW in delivery of UHC is discussed in a separate section of the Policy Brief. The discussion will be held in light of the UN HLM on UHC that is to be held in 2019, as decided by the UNGA in Resolution 72/139. The intention of the reports is to renew the WHO's commitment to UHC and PHC, given their importance in achieving the Sustainable Development Goals (SDGs).

The majority of A72/12 and EB144.R9 focuses on the Astana Declaration of 2018, the consideration of its potential role in reorienting health systems around PHC in Member States, and a number of accompanying documents, such as the "Vision for PHC in the 21st century" and "Operational Framework Primary Health Care: Transforming Vision into Action." Whilst we see WHO's current work on PHC as a major step forward, **we call on Member States to adopt resolution EB144.R9 only if key changes are made.**

The 1978 Declaration of Alma-Ata put forward a vision of comprehensive, coordinated primary health care, rooted in "health...as a fundamental human right" and the "spirit of social justice." Alma-Ata proposed to achieve Health for All by the year 2000 through tackling the social determinants of health and critically through the creation of a New International Economic Order. **PHM calls on Member States to recall the original intention on the Declaration of Alma-Ata, and to insist on a human rights-based approach to health. We call for an approach to health that incorporates the redistribution of power and wealth, within countries and between countries, instead of focusing on a vision of UHC and PHC within the limited framework of preventing financial hardship for patients.**

Primary health care towards universal health coverage

Human rights based approach: PHC is more than UHC
The relationship between UHC and PHC in the executive summary of the Declaration of Astana is defined by saying: "UHC and health-related SDGs can be sustainably achieved with greater emphasis on PHC". Here, the role of PHC is limited by being a prerequisite necessary to achieve UHC. For example, paragraph 15 of A72/12 states that: "one of the major areas of focus of the global community is achieving UHC, and PHC is a necessary foundation for this effort."

As PHM has warned repeatedly for several years, in no case should PHC be subsumed under UHC, since it is a much more complex and broader concept than the latter. Alma-Ata advocates that "[Primary Health Care] forms an integral part both of the country's health system, of which it is the central function and main focus, and of the overall social and economic development of the community." The concept of social justice profoundly permeates the concept of PHC by promoting universal coverage and access to health services with particular attention to health promotion and disease prevention; the involvement of the community and the individual; inter-sectoral actions for health and the use of appropriate technologies. Comprehensive PHC recognises that if we want Health for All, we must look through the lens of the social determinants of health and advocate for 'health in all policies,' as recognised by the Helsinki Statement.

We commend WHO's call to reaffirm '[health] as a fundamental right of every human being' as outlined in paragraph 3 of A72/12. We are, however, seeing people's human right to health increasingly denied. In particular, vulnerable populations including migrants are discriminated against; their social determinants of health are eroded and they are being deterred from accessing the health system through the creation of a 'hostile environment' in all policies. UHC cannot be universal if access to care is limited in all aspects of society. **We urgently call for Member States to take a human rights-based approach to create systems free from discrimination and enable all people to exercise their human right to health.**

A return to the call for a New International Economic Order
The current neoliberal paradigm exacerbates economic and social inequities, representing a serious obstacle for the attainment of health for all and to the reduction of the gap in the health status within and between countries. The focus on UHC and a fiscal idea of health only reinforces such a situation by ignoring widening inequities, barriers to access, catastrophic out of pocket health care expenditures, inefficiencies and variable quality that commercialisation of health has brought us. This has been outlined previously: "UHC prescribes a clear split between health financing and health provision, allowing for the entry of private insurance companies, private health providers and private health management organisations (…) In short, the UHC model is built on, and lends itself to, standard neoliberal policies, steering policy-makers away from universal health options based on public systems" (Sengupta, 2013).

Even though it has been repeatedly proven that public health systems provide care of greater quality and safety for patients, while at the same time reflecting positively on other aspects of society, it comes as a disappointment that WHO continues to

back and promote policy options which are largely dependent on the private sector. **We urge Member States to insist on an Operational Framework that will make clear that the principal responsibility for health care delivery and governing lies with Member States' governments, and call on WHO to recall and move closer to an updated vision of a New International Economic Order.**

Preparation for the High-Level Meeting of the UN General Assembly on UHC

In 2017, the UNGA decided in Resolution 72/139 to hold a HLM on UHC in 2019. The present report [A72/14] is submitted for the consideration of the WHA in keeping with the request made in paragraph 24 of Resolution 72/139.

The current report [A72/14] reviews indicative data regarding service coverage and overviews recent data on catastrophic health expenditure and health care impoverishment. Based on this data, EB144.R10 regrets the stagnation of progress towards UHC, and urges Member States to progress towards UHC and PHC. It suggests a range of pathways, including: financing; planning; workforce development; access to medicines and various clinical technologies; R&D; health literacy; intersectoral action for health; and monitoring and evaluation.

Paragraph 3 of A72/14 highlights the vast inequity in attainment of health, including that "half of the world's population still lacks access to essential health services." WHO acknowledges that "these facts have provoked a shift in traditional development thinking, which has long focused on the challenge of fighting disease,". However WHO "continues to support this disease oriented focus." **We call on WHO and Member States to move away from vertical programmes and the current version of UHC that deters and prevents people from accessing care.**

A Political Declaration on UHC without commitment to PHC?
At its 73rd session, the UNGA adopted the Resolution 73/131, which defines the scope, modalities, format, and organization of the HLM on universal health coverage, which should result in a political declaration.

In paragraph 17, A72/14 reads: "more governmental fiscal space specifically dedicated to health, more investment in health delivery systems, primary health care and a committed health workforce." Nevertheless, the current report [A72/14] does not consider PHC as a key issue to be covered by the draft Political Declaration on UHC. Social determinants of health, as well as community and civil society engagement, have also been left out despite recognition in the Global Action Plan for Healthy Lives and Well-Being for All as being factors that could accelerate progress in global health.

More "High Level" and "Multi-stakeholder" meetings?
Besides the HLM on UHC, the UNGA has lately convened HLMs on HIV/AIDS, antimicrobial resistance, tuberculosis, and non-communicable diseases. It remains unclear why UN and WHO have approached health in such a fragmented way. Civil society has already warned about this issue, saying that "it is good that this process will end with the too long neglected focus on health systems - and on the related policies and political struggles."

During the HLM on UHC, UNGA A/RES/73/131 under point 4.c also foresees a place for multi-stakeholder panels and interactive multi-stakeholder hearings, “with a view to ensuring the most effective and efficient outcomes and potential deliverables and sharing experiences and lessons learned to address remaining implementation gaps.” The interactive multi-stakeholder hearing, which was held on April 29, 2019, was supposed to be “with the active participation of appropriate senior-level representatives of Member States, observers of the General Assembly, parliamentarians, representatives of local government, relevant United Nations entities” and the very broad group of non-state actors, invoking a participatory and transparent approach to planning. However, the “stakeholderization” of international organisations, including the WHO, has more often than not opened the door of participation to private and philanthropic entities, who bring to the table a very specific set of interests.

This prevailing ‘multi-stakeholder’ paradigm in the discourse on UHC tends to neglect or disguise the adverse impact of financialization, privatisation, commodification and commercialisation of health services on universal access to health care. **We insist on the responsibility and leadership of governments as main duty bearers that goes beyond regulation and stewardship. We call for strong public systems for both health care financing and delivery.**

11.5 Community health workers delivering primary health care: opportunities and challenges

Key points

- It is very problematic that the proposed resolution EB144.R4 mentions the use of digital technologies, while it disregards the importance of structural interventions to improve the position of CHW, i.e. regularization
- It is commendable to see that Guideline on Health Policy and System Support to Optimize Community Health Worker Programmes makes an explicit point about the importance of CHW remuneration

Summary

The Report by the Director-General under this agenda item (**A72/13**) highlights the significance of Community Health Workers (CHWs) as part of the contemporary approaches to strengthen health systems to achieve universal health coverage. The Report refers to the WHO Guideline on Health Policy and System Support to Optimize Community Health Worker Programmes, launched in October 2018, as a global policy framework for governments.[1] In addition to that, the WHO Global strategy on human resources for health: workforce 2030[2] (**A72/24**) acknowledges that CHW and other types of community-based health workforce are effective in the delivery of a continuum of healthcare, which includes preventive and promotive health care, especially in underserved areas. The incoming WHA is called to adopt resolution EB144.R4, while MS are invited to use the Guidelines to assess the design and implementation of their CHW programmes.

Considering the relevance of the Guidelines, **PHM and PSI considers that the original guideline document should be strongly endorsed by the WHA, by making its use mandatory**, and that **progress should be reported to the WHA every three years**, in line with Resolution WHA69.19 (2016) and other health workforce-linked resolutions.

The critical shortage of health workers is detrimentally affecting and undermining health around the world. WHO and MS need to take into consideration the devastating effects of a gap of about 18 million health care workers in the world, as well as the implications this has for the role we expect CHWs to play. The current approach to health workforce planning and training has created serious HRH gaps, especially in LMIC, and has therefore created an undeniable need for CHWs. The architects of the Guidelines recognize the paucity of robust written evidence with regard to the policy areas examined. People's Health Movement (PHM) and Public Services International (PSI) have member organizations working closely with, or consisting of, CHWs. We bring the lived experience of our members to this important discussion.

1 World Health Organization, Community-based Health Workers. https://www.who.int/hrh/community/en/[23 January 2019].

2 http://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_24-en.pdf

CHW programmes: Opportunities and policy options

In A72/13, para 14, on key principles to optimize the design and performance of CHW programmes, it is implicitly assumed that governments are the ones designing and implementing CHW programmes. For instance, the document is phrased so it seems that CHW programmes will be defined within holistic health systems that consider ideal service delivery modalities and policy recommendations. In para 15, it reads that CHW programmes will adopt "pre-service education, taking into account minimum education levels appropriate to the tasks to be performed, formal certification, supportive supervision strategies, financial package, written agreements, career ladder and adopting service delivery models in which community health workers are assigned general tasks as part of an integrated primary health care team and extension of the health system especially where there inadequate health workers". Even though the majority of CHW programmes are government run, there are countries where CHW programmes, even large-scale ones, are run by the private or NGO sector. Such models carry the risk to fragment and in the long run even weaken health systems, also slowing down the realization of better health outcomes.

While the Guidelines identify the role of communities in selection and monitoring of CHWs programmes, the Report fails to highlight the aspects of acceptability and accountability to the communities they serve, a central element of well-functioning CHW programmes. **The Report should clearly state that CHWs programmes should be government run, and with ensured community participation, at least, in the fields of selection and monitoring.**

CHWs as agents of social change

CHWs programmes were originally viewed as **both an extension of the healthcare system and agents of social change through community mobilization within a Comprehensive Primary Health Care** (CPHC) approach. Contemporary programmes emphasize their technical and community healthcare function, essentially treating CHWs as auxiliary extensions of the formal healthcare system[3], often within a selective primary health care model. This is an unfortunate shift in focus that is inadequate to realise the potential contribution of CHWs to CPHC and Universal Healthcare. We call upon WHO to revert to an approach to CHW programmes as part of a Comprehensive Primary Health Care system approach.

We encourage MS to discuss the fundamental role that CHWs can play in addressing the social determinants of health, incorporating multi and intersectoral connection and through community mobilization. The function of CHWs can be much more than an 'extension service providers' in health**.**

Adequate remuneration and gender equality

It is commendable that the Guideline discussed make an explicit recommendation for MS to introduce remuneration for CHWs. Adequate remuneration plays an important role in securing basic needs and dignity to all workers, including CHW.

3 World Health Organization. Community health workers: what do we know about them? Policy Brief I World Health Organization, Geneva (2007)

Exactly because of this, it has to be mentioned that across South Asia and sub-Saharan Africa, large-scale CHW programmes were designed on the assumption of deploying a volunteer, non-remunerated workforce, despite a substantial and increasing workload. Some NGO-led CHW programmes are run on the basis of dependent self-employment, while large-scale government-led programmes were most often designed to provide limited financial or non-financial incentives. It is only after CHWs' organizations raised their voices that, in some cases, a monthly honorarium or stipends, and in other cases regular wages, were introduced. Some CHWs are provided with task-based incentives for each health outcome or health service related task performed. This remuneration only amounts for a fraction of country's statutory minimum wage. In many low income countries, CHWs are paid far less of the national statutory minimum wage, which worsens and perpetuates exploitation under the terminology of "Community health volunteerism" or "activism" (ie in Kenya, South Africa Nepal and India).

In addition to facing issues related to labour rights, the topic of CHWs has strong connotations in the context of gender equality. The global health workforce is predominantly female, but women are concentrated in lower-skilled jobs, with less pay and at the bottom end of professional hierarchies[4]. CHWs, who often take the lowest place in the healthcare chain, are predominantly, if not exclusively, women. As they work within their communities and provide the care that women have traditionally performed without pay, such as maternal and child care, they are too often denied their status as workers of the public health system. Maintaining such a large part of the female workforce in informal employment conditions and below the statutory minimum wage represents a significant obstacle to achieving gender equality and reinforces the gender pay gap.

Regularization

In para 1, EB144.R4 reads: "to align the design, implementation, performance and evaluation of community health worker programmes, including through greater use of digital technology, with the consolidated evidence presented in the WHO guideline on health policy and system support to optimize community health worker programmes, with specific emphasis on implementing these programmes to enable community health workers to deliver safe and high-quality care". It is extremely problematic the resolution should make special mention of digital technology, but at the same time this does not give appropriate space to the topic of regularization. The introduction of digital technologies in community health work is marked as a priority, which will supposedly make all other problems faced by CHWs magically disappear. Digital technologies represent a good opportunity for easing the work of CHWs, challenges such as proper regularization and proliferation of pilot projects, especially in the context of weak health systems continue to arise. **PHM has repeatedly warned that the use of digital technology should not be regarded as a silver bullet solution for difficulties in health system functioning.** Instead of focusing on digital health, we believe the WHA should adopt a resolution that refers to key issues facing CHWS, like regularization.

4 International Labour Organisation. Improving Employment and working conditions in health services. Report for discussion at the Tripartite Meeting on Improving Employment and Working Conditions in Health Services, Geneva (2017).

The WHO Guidelines include recommendations with regard to both remuneration and formalization of employment through a "written agreement specifying role and responsibilities, working conditions, remuneration and workers' rights"[5]. **Para 15.5** mentions the need for "providing paid community health workers with a written agreement specifying role and responsibilities, working conditions, remuneration and workers' rights." PHM and PSI welcomes the recognition of the call for regularisation of CHWs employment conditions through formal contracts and invite MS to take this into consideration when implementing their national CHW programmes.

In countries where CHWs are considered as volunteers despite being deployed for a substantial amount of hours per day/week, there has been a recurring demand for them to be recognised as workers. This is for instance the case in Kenya, India, South Africa, Nepal, and in Pakistan prior to their recognition. Regularization is a complex process. Existing experiences need to be collected and best practices distilled to provide pointers and advice for other governments interested in taking up this administrative challenge.

MS should request the **WHO to undertake case studies of regularisation process of CHWs, health workers and other relevant experiences to be collected and systematized, to be used as a tool to develop experience-based tools for achieving regularization.** This can be taken up as part of the Working for Health programme, a joint initiative with the ILO (and OECD).

5 Recommendation 8, p.49. www.who.int/hrh/community/en/ [23 January 2019]

11.7 Access to Medicines and Vaccines

Exorbitant and arbitrary drug prices are a major problem affecting all countries. They keep essential lifesaving medicines from those who urgently need them and put undue strain on already overstretched health systems.

Key points

- PHM urges Member states to support the WHO Roadmap on access to medicine, vaccines and other health products 2019-2023.
- We reaffirm that a "fair price" can only be one that is affordable.
- Transparency of prices, research & development, clinical trials and patent landscapes is crucial for affordability and access of medicines, vaccines and health products to achieve health for all.
- Therefore, Member States should support a strong version of the Transparency Resolution.
- WHO's Guidelines on Evaluation of Similar Biotherapeutic Products should be updated to facilitate generic production in order to improve access.

WHO Roadmap on access to medicines, vaccines and other health products 2019-2023.

Summary

The draft roadmap 2019-2023 is a document that sets out to guide the work of the WHO in tandem with the 13th WHO General Program of Work (GPW-13). This document is a culmination of years of work on the issues of access to medicines, like UN HLP on Access to Medicines, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property[6], and Consultative Expert Working Group on Research and Development.

The draft roadmap is a well-structured document and coherently brings together a wide range of programs and commitments which have previously been addressed separately. For this, PHM would like to congratulate the Secretariat staff.

Context

The Draft Roadmap for Access to Medicines, Vaccines, and Other Health Products, 2019-2023 contains two main strategic areas of action for prioritization: ensuring the quality, safety and efficacy of health products; and improving equitable access to health products. Under each of the two strategic areas, the roadmap describes relevant activities and puts forward specific actions and deliverables, i.e.

(1) ensuring quality, safety and efficacy of health products through i) regulatory system strengthening, ii) assessment of the quality, safety and efficacy/performance of health products through prequalification, and iii) the use of market surveillance of quality, safety and performance; and

[6] https://www.who.int/phi/implementation/GlobalStrategyPlanofAction.pdf?ua=1

(2) improving equitable access to health products through i) research and development that meets public health needs and improves access to health products, ii) application and management of intellectual property to contribute to innovation and promote public health, iii) evidence-based selection and fair and affordable pricing, iv) procurement and supply chain management, and iv) appropriate prescribing, dispensing and rational use of health products.

Analysis

Although the draft road map brings together a wide range of programmes and commitments that have previously been addressed separately, it contains oversights that require further attention. We wish to highlight the following:

Fair Pricing

The following oversights in defining "fair prices" must be addressed in order to ensure that the public does not pay twice for R&D and receives a public return on public investments:

- The roadmap calls for "evidence-based selection and fair and affordable pricing" (par.42) The WHO defines fair price as "one that is affordable for health systems and patients and that at the same time provides sufficient market incentives for industry to invest in innovation and the production of medicines" (par. 18/1). As per the definition, a fair price is different from an affordable price and is dependent on market incentives. It effectively means that prices of the medicines need not be low or accessible.
- The roadmap does not require transparency of R&D costs and price setting decisions. This means that the public will still have to trust pharmaceutical companies' price-setting practices.
- It does not account for the substantial role of the public sector in funding and subsidising private corporations' R&D, and pre-supposes that R&D is always to be paid for through end prices of medicines. The definition thus excludes R&D models based on the principles of delinkage, in which R&D is incentivized through grants, subsidies and innovation inducement prizes, rather than monopoly-based high prices.

Absence of TRIPS Flexibilities

In the section which talks about fostering innovation through appropriate intellectual property rules, there is no reference to TRIPS+ provisions which impact negatively on access and affordability of medicines and vaccines, e.g. the introduction of data exclusivity acts as a barrier for generic production. The WHO should take a stronger position in supporting Member States that wish to use TRIPs flexibilities such as compulsory licensing as a tool to procure essential medicines at affordable prices.

Publicly-Owned Pharmaceutical Manufacturing

When talking about transparency, there is no mention of the role of publicly-owned pharmaceutical manufacturing to promote competition and ensure greater transparency in relation to costs of production. In fact the Roadmap appears to equate "the private sector" with "manufacturing" (see for example EB144/17 para 45). Furthermore, publicly-owned pharmaceutical manufacturing is a way to address the

current lack of innovation in areas where there is public health need but no commercial interest.

Negative Impact of High Harmonisation Standards
Although there are several references to quality standards and regulatory burden, the Roadmap fails to highlight that the drive for harmonisation of standards through trade agreements is one of the main barriers excluding new market entrants (particular from low- and middle- income countries), as it is associated with increasingly demanding standards that do not necessarily have any safety benefits. Focus on quality should never be a barrier to access and availability of health products at an affordable price. This is a particular risk where private sector 'partners' from advanced manufacturing settings are involved in standard setting.

GSPOA Implementation Plan
In paragraph 43 and 44, the Roadmap clearly acknowledges the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) as a "basic mandate for WHO's work in this area". The WHO has to, according to the updated milestones which reflect the 13th General Programme of Work (GPW), 2019–2023, report on the implementation of the GSPOA (in particular elements 4 and 5) by next year (2020). However since the 71st WHA nothing has been done on the implementation plan. Cuts in funding may be one of the important contributors to the lack of progress on GSPOA. It requires unrestricted funds.

Transparency Resolution

An important discussion in this year's assembly concerns the Transparency Resolution being proposed by 10 countries from Europe, Africa and Asia (Italy, Greece, Malaysia, Portugal, Serbia, Slovenia, South Africa, Spain, Turkey, and Uganda). The resolution is titled "Improving the transparency of markets for drugs, vaccines and other health-related technologies".

The draft resolution broadly outlines four areas of action:

- Transparency of prices:
    - Currently, there is no openly available information on prices of medicines in other countries. Prices are often negotiated non-publicly. However, greater transparency on prices could strengthen competition and the position of governments in price negotiations.
- Transparency of research & development
    - Pharmaceutical companies justify high medicine prices by framing them as a return on their investments for R&D. However, they generally do not disclose R&D costs in full. Increasing the transparency of R&D costs would put governments in a stronger position to negotiate prices, so that information asymmetry does not give undue power to companies in deciding prices.

- Transparency of clinical trials
    - Failure to report clinical trial results, in particular negative results, leads to duplications of research and evidence distortions. Negative public health implications of this can include loss of research funds, high drug prices and even patient harm. Therefore, the research design and results of all clinical trials should be reported on publicly accessible databases.
- Transparency of patent landscapes
    - Improved transparency of the patent landscape of medical technologies through information sharing can promote generic competition and thus access and affordability. The draft resolution also proposes to create a forum to develop alternative incentive frameworks to patent monopolies, which could lead to new models of R&D where we currently see market failures in the current patenting system.

PHM strongly supports the original resolution put forward. If passed it would be a major step towards improving affordable prices for all essential medical technologies worldwide. Currently, a lack of transparency around what different countries pay for medicines, and the actual cost of R&D and manufacturing of medicines, allows pharmaceutical corporations to charge exorbitant and arbitrary prices. This leads to profit-maximisation by the companies at the cost of people's lives.

The resolution, if passed, will be effective in empowering governments and the public to have greater transparency and more equal access to information, in order to have greater power in dealing with the crisis in the pricing of medical technologies. It gives the World Health Organization and national governments strong mandates to collect, share, and analyze data on drug prices, R&D costs, clinical trial results and costs, patent landscapes, and more. This will help them take informed decisions and ensure access to affordable medical products.

It is to be noted that many developed countries are trying to significantly dilute the language in the resolution that seeks to address the issue of lack of transparency. We would like the Member States to support a strong version of the resolution in favour of affordable prices.

Biosimilars: making access to biologicals a reality

Biotherapeutic drugs (commonly referred to as 'biologics' or 'biopharmaceuticals') are drugs produced through biological processes. In contrast to chemically synthesized small molecule drugs, biologics are produced in living cells, are relatively large in size, and are much more complex and difficult to characterize. In 2018, biotherapeutics accounted for 6 of the 10 top selling branded drugs in terms of revenues. The 2017 WHO model list of essential medicines also includes three of the top-selling biotherapeutics – trastuzumab, rituximab, and bevacizumab.

The generic equivalent of the biologics are known as Similar Biotherapeutic Products (SBP). Unlike small molecules (pharmaceutical products), access to biologicals through usage of generic versions is not very easy. The current regulatory framework for SBP approvals in many countries is in accordance with WHO's Guidelines on Evaluation of Similar Biotherapeutic Products (SBP Guidelines) which was adopted

in 2009. The regulatory barriers as suggested in the 2009 guidelines are one of the major impediments affecting their accessibility and affordability.

To correct this, In 2014, the 67th World Health Assembly had adopted Resolution WHA 67.21 to consider the access challenges emanating from the existing regulatory pathway for SBPs. Taking cognizance of regulatory implications for SBPs on affordability and better access to treatments of biotherapeutic drugs Operational Paragraph 1 (3) requested the Member States "*to work to ensure that the introduction of new national regulations, where appropriate, does not constitute a barrier to access to quality, safe, efficacious and affordable biotherapeutic products, including similar biotherapeutic products.*"

In addition, Operational Paragraph 2 (4) requested the WHO Director-General "*to convene the WHO Expert Committee on Biological Standardization to update the 2009 guidelines, taking into account the technological advances for the characterization of biotherapeutic products and considering national regulatory needs and capacities and to report on the update to the Executive Board."* From this mandate it can be inferred that the scientific reasons on which the 2009 Guidelines were based are out of sync with the current advancements in science and technology.

In this context, PHM would request WHO to update its guidelines and ease the regulatory barriers to make access to Biotherapeutics a reality as mandated during WHA-67.

11.8 Follow-up to the high-level meetings of the United Nations General Assembly on health-related issues – Antimicrobial resistance

Key points

- MSs must recognize that there are many functions which will simply not be put in place unless there are binding requirements arising from conventions, treaties or regulations. And this can only be effective by a process of discussion that is independent from private interests
- MSs should make sure that WHO together with FAO, OIE and UNEP take forward the IACG recommendations;
- MSs should set a deadline for WHO to finish the Stewardship and Development Framework, so it can help to mobilize finance for the implementation of MSs national action plans.

Summary

WHA72 will discuss two reports and one resolution concerning antimicrobial resistance:

- Reports A72/18 and EB144/2019/REC/1
- Resolution EB144.R11

Although resistance is a natural process, the misuse and overuse of antimicrobials in humans, animals and plants – a consequence of rising incomes, easy access to over-the-counter antibiotics and poor access to primary health care – is causing the rate of resistance to accelerate. WHO estimates that antibiotic consumption has increased 65% globally between 2000-2015. With 558,000 people now resistant to rifampicin (the most effective first line drug for TB), and resistance of sexually transmitted diseases such as gonorrhoea to cephalosporins also on the increase, the challenge of antimicrobial resistance remains a global health priority[7] [1] .

Resistance to microbial pathogens (microbials) occurs in all parts of the world and affects patients of all age groups. Increasing prevalence narrows the options to treat diseases and threatens the success of medical procedures, from the most common to the most complex. A report from the Interagency Coordination Group on Antimicrobial Resistance (IACG) in April 2019 warns that if no action is taken, by 2050 AMR could lead to 10 million deaths globally, every year[8] [2] .

WHO's Report by the Director General (A72/18) provides an update on its global action plan on antimicrobial resistance and on the United Nations General

[7] WHO (2018) Antimicrobial resistance and primary health care. Technical Series on Primary Health Care.
https://www.who.int/docs/default-source/primary-health-care-conference/amr.pdf?sfvrsn=8817d5ba_2

[8] IACG (2019) No Time to Wait: securing the future from drug-resistant infections.
https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1

Assembly's high level meeting (HLM). While describing some progress in combating antimicrobial resistance, a close examination of the report reveals serious omissions in WHO's response that will weaken significantly its ability to address this global health threat.

Regulation
There is only one reference in the report to regulation, with the WHO offering guidance to Member States (MS) on "regulatory options" (para. 38). There is no mention of the importance of regulation as a tool for ensuring that agribusiness terminates its use of antimicrobials in animal husbandry, nor that regulation could functions as a mechanism for impeding Big Pharma's marketing strategy to stimulate health professionals to prescribe antimicrobials indiscriminately. Neither is there mention of findings from the IACG report highlighting how uncontrolled antimicrobial resistance could have the same disruptive effect in the global economy as the shocks experienced during the 2008-2009 global financial crisis – a crisis that directly resulted from a lack of regulation of the stock market.

Market failure and the importance of de-linkage
When we talk about antimicrobial resistance it is also important to recognise that it is the result of market failure. The last time a class of antibiotics was developed was in 1987. In 1990, 18 pharmaceutical corporations had programs to address antimicrobial resistance; by 2010, only four remained active.

One of the core principles of two previous resolutions on antimicrobial resistance (at the World Health Assembly in 2015, and by the UN General Assembly in 2016) is de-linkage. De-linkage refers to the need to delink the return on investment in R&D from both the price and quantity of the drug in an effort to promote equitable and affordable access to new antimicrobial products[9].

Governing AMR
The report invites stakeholders to increase efforts to develop and apply tools to address antimicrobial resistance following a One Health approach, including through coordinated, responsible, sustainable and innovative approaches to research and development, including but not limited to quality, safe, efficacious and affordable antimicrobials, and alternative medicines and therapies, vaccines and diagnostic tools. The Report thus opens the door to a more flexible but less progressive interpretation of de-linkage.

The report also describes how various actors – the Tripartite WHO/FAO/OIE, UNEP, MS and "all relevant stakeholders" – have developed a global framework for development and stewardship to combat antimicrobial resistance. The emphasis in the report is very much on enhancing both civil society and private sector engagement. But it remains unclear exactly which stakeholders will be consulted to adjust the process and scope of the global framework. There is clearly a potential for

[9] Saetz, C. (2017) Antimicrobial Resistance Needs New R&D Models, NGOs Say. Intellectual Property Watch. https://www.ip-watch.org/2017/05/24/antimicrobial-resistance-needs-new-rd-models-ngos-say/

conflict of interest, with those actors implicated in the rise of antimicrobial resistance also participating in its governance.

Engaging actors from the private sector will impede efforts to provide a framework that reflects the need for robust regulatory mechanisms and full accountability. It also brings into doubt the potential for de-linkage to become a cornerstone of efforts to combat microbial resistance.

Finally, there is no mention in the documents of the challenges faced by low and middle income countries. These challenges will worsen if there is insufficient funding for MSs to finance their national action plans.

12.10 The public health implications of implementation of the Nagoya Protocol

In document A72/32, WHO seeks a mandate to address the subject of pathogen access and benefit sharing. Paragraph 13 states “WHO is ready 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”. However, this conclusion may be rather premature.

This agenda item will have significant implications for national access and benefit-sharing policies, laws and regulations, and for the sovereign right to regulate access to pathogen and fair and equitable benefit sharing. Therefore, Member States should seek more information regarding the current landscape of sharing of biomaterials and the role of WHO. Decision on this agenda item should be limited only to seeking information to facilitate an informed decision making in the next WHA. Any discussion on the matter of access and benefit sharing should be through an open-ended intergovernmental process and should not be a WHO Secretariat led process.

Member States should be cognizant of this matter during the World Health Assembly. There is no mention in the International Health Regulations (IHR) of a requirement for sharing biological samples or sequence data. Article 57 of the IHR makes clear that it “shall not affect the rights and obligations of any State Party deriving from other international agreements.” We are extremely concerned that this may be used as an opportunity to undermine the rights countries have under the Convention on Biodiversity (CBD, 19992) and the Nagoya Protocol (2010) with respect to access and benefit sharing. Historically, pathogens have been acquired without information or consent of provider communities and countries. Medical products that result from research on them, be it vaccines or medicines, are sold at very high prices without giving share of profits to the provider country. Attempts are being made to balance this out through the concept of access and benefit sharing.

12.1 Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

The PIP Framework came about to address inequities prevalent in the then Global Influenza Surveillance Network (GISN), which only emphasized virus sharing and was operating in conflict with the Convention on Biological Diversity (CBD). The Convention establishes sovereign rights of a country over its biological resources and that access is subject to prior informed consent of the country providing the resources, with “commercial and other utilization” of such resources triggering fair and equitable benefit sharing on mutually agreed terms with the providing country. Based on the same premise, the Nagoya Protocol elaborates on the access and benefit sharing aspect of the CBD.

The H5N1 outbreak in the South-east Asia region in 2006 revealed the GISN to be a system of winners and losers. Countries would share virus samples with the WHO

designated laboratories (mostly based in developed countries) that made up the GISN system. These laboratories would develop a candidate vaccine virus which would be shared with the pharmaceutical industry, often without the consent of the country providing the virus sample. The industry received virus samples for making vaccines, received government grants, and made profits from vaccine sales.

Developed countries entered into advance purchase agreements with the pharmaceutical industry to reserve supplies of vaccines and anti-virals in the event of a pandemic. Industry and several WHO designated laboratories also claimed patents over parts of the shared biological materials and sequences. Meanwhile countries that freely shared the virus samples (often developing countries) did not have timely access to affordable vaccines and anti-virals or to relevant information about the virus samples shared.

The WHO virus sharing mechanism, GISN, was renamed WHO Global Influenza Surveillance and Response System ("WHO GISRS"), with the adoption of the PIP Framework (PIPFw) in 2011 following four years of contentious negotiations that began in 2007.

A key decision point for WHO Members at the upcoming WHA is the handling of genetic sequence data (GSD), which remains unresolved in the context of the Framework. GSD is part of the Framework: it states that GSD "should be shared in a rapid, timely and systematic manner with the originating laboratory and among WHO GISRS laboratories". It also recognizes that access to GSD "is important to public health" and that "in some instances the publication of GSD has been considered sensitive by the country providing the virus". However, the "handling of genetic sequence data" was an issue left to further decision among WHO Members as the Framework was adopted. Success of PIPFw is dependent on how WHO Members address the subject of GSD.

WHO's 2018 factsheet titled "New technologies using genetic sequence data" points to technological advances where manufacturers use GSD to synthesize biological material for vaccine development. GSD can now be used to develop synthetic virus material including candidate vaccine virus without using original influenza virus material. These synthetic candidate vaccine viruses can then be used to develop vaccines through traditional vaccine production methods (e.g. egg-based or cell-based).

As with the PIP biological material, the PIPFw requires the sharing of GSD, and yet GSD and the physical biological materials are dealt with differently under the PIPFw. Presently the use of GSD does not trigger provisions of access and benefit sharing. For example, a major gap is the non-application of SMTA1 to GSD, meaning there are no terms and conditions governing the sharing of GSD. So, for example, can patent claims be made by GISRS laboratories in connection with the GSD? Similar concerns also arise in relation to SMTA2.

The WHO Secretariat found two fundamental loopholes with regard to manufacturers using GSD wherein SMTA2 is presently not applied.

The first loophole is where certain influenza manufacturers developing vaccines with GSD rely on or engage with laboratories having PIP biological material to do testing of the products for marketing, without receiving the physical material per se. The second loophole is where the development and marketing of influenza pandemic products is done solely by using GSD, a reality in the near future as technologies mature. WHO's general observation on its findings is that "as new influenza manufacturers enter the market, this 'loophole' may reduce WHO's access to certain benefits and potentially jeopardize PIPFw implementation".

As physical materials become increasingly irrelevant, and reliance on GSD increases, even existing signed agreements and the pro-poor benefit sharing arrangements they institutionalise may be in jeopardy.

We urge that maintaining the equal footing principle requires accepting that the PIP Framework components should apply to GSD as they apply to PIP biological material. This can be achieved by a simple resolution adopted by the WHO.