Policy Briefs on Important Issues at EB146

Issued through the aegis of the People’s Health Movement’s WHO Watch Programme

Equity, ecologically-sustainable development and peace are at the heart of our vision of a better world – a world in which a healthy life for all is a reality; a world that respects, appreciates and celebrates all life and diversity; a world that enables the flowering of people’s talents and abilities to enrich each other; a world in which people’s voices guide the decisions that shape our lives.

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Refer to our detailed Commentary on the entire agenda of EB 146 at:

https://who-track.phmovement.org/eb146

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The principles of CPHC were first outlined in the Declaration of Alma-Ata in 1978 in pursuit of health for all. The signatory States declared their commitment to the broad principles of CPHC: health is a human right, health inequalities within and between countries are unjust and unacceptable, and the underlying determinants of health are not purely connected with the biological or medical field but include a wide range of political, social, economic and cultural factors which protect and promote this human right.

Forty years later, the Global Conference on Primary Health Care took place in Astana in which Member States renewed their commitment to primary health care through a whole-of-society approach around primary health care as a cornerstone of a sustainable health system for universal health coverage and the health-related Sustainable Development Goals, in particular target 3.8 on achieving universal health coverage. The concept of CPHC had, and must continue to have, strong sociopolitical implications. Alma Ata explicitly outlined a strategy which responded more equitably, appropriately and effectively to basic health care needs while also addressing the underlying social, economic and political causes of poor health. It is important to maintain this strategy in order to tackle inequalities in health.

Achieving universal health coverage means that all individuals should access promotive, preventive, curative, rehabilitative and palliative health care on an equity basis, of sufficient quality to be effective and without being exposed to financial hardship. It follows that where the cost burden of health care is too heavy for families, the financing systems may become unsustainable, thus being inconsistent with the global commitment made by world leaders to achieve universal health coverage by 2030.

**OVERVIEW**

**RECOMMENDATIONS**

- In order to achieve SDG indicator 3.8.2. (reduction in catastrophic expenditure and preventing out of pocket expenditure on health) we urge MS and WHO to strengthen public health systems through the introduction of single payer systems, and public provisioning of health services based on CPHC principles.
- We ask WHO to include Community empowerment as an operational lever of PHC in which communities must be included in determining the acceptability and responsiveness of services, grievance redressal systems, systems for planning, and review and monitoring processes.
- We ask the WHO to develop recommendations in order to strengthen public health systems based on PHC and UHC.
- We urge the Secretariat to continue its analysis of the implementation of PHC worldwide through case study methodology, as it can contribute to amplifying knowledge to address inequalities in health in a more context specific way, and in reinforcing the importance of an intersectoral approach with social participation and accountability within the health system.
- We urge WHO to approach health care from a human rights perspective and to monitor the effective compliance of MS’ national legislation with international human rights standards.
- We call upon WHO to produce a full analysis of the costs and benefits of mixed service delivery and health insurance financing, including the regulatory requirements and management capacity needed to defend equity, efficiency and quality in each case.
- We ask the WHO to consider PHC for addressing the commercial drivers of NCDs and climate change which represent fundamental global health challenges.

**AT A GLANCE**

- Comprehensive Primary Health Care (CPHC) is a necessary prerequisite for the achievement of Universal Health Coverage (UHC) and should not be subordinated to it.
- Health care should be approached from a human rights perspective. This means that States should provide accessible, available, acceptable and good quality health services for all.
- Tax based financing should be prioritized over health insurance to reduce the cost burden of health care on families.
- An effective PHC system necessitates strong regulation of the private sector providers (price control, accountability, grievance redressal and protection of patient’s rights).
- Comprehensive Primary Health Care approach informs the organizing principles of healthcare and attends to the social determinants of health, and it should not be substituted by selective primary care.

**ISSUES AT EB146**

Both reports (EB146/5 & EB 146/6) contain an interpretation of CPHC as a means for achieving UHC, i.e. totally subordinated to this goal. However, defining CPHC as a precondition for achieving both UHC and the SDGs would properly reflect the crucial role of CPHC in advancing health systems. CPHC is so much more than a means to UHC.

Responding to the request in resolution WHA 72.2 (2019) on primary health care, EB 146/5 conveys a draft operational framework for primary health care. EB 146/5 outlines the levers of the draft operational framework that are essential to strengthening primary health care implementation towards universal health coverage at country level. It contains 4 core levers: political commitment and leadership; governance and policy frameworks; funding and allocation resources; engagement of communities and other stakeholders. 10 operational levers are also included in the report: models of care, PHC workforce, medicines and other health products to improve health; engagement
with private-sector providers; purchasing and payment systems; digital technologies for health; PHC-oriented research; and monitoring and evaluation.

This operational framework is a useful tool for countries to implement CPHC systems. Nevertheless, we would like to add some proposals:

- The second core lever, “Governance and policy frameworks”, should explicitly include regulation of the private health sector, industries and their markets, action on commercial determinants of health and promotion of fair trade, as well as more strategies to ensure accountability and transparency amongst these actors. In relation to the “Funding and allocation core lever”, the responsibility of governments in ensuring public and high-quality health services should be emphasized.

- Regarding “models of care”, in which equity should be explicitly named, the Integrated and comprehensive health networks represent a good example as they are considered by the PAHO to be essential to providing equitable, comprehensive, integrated and continuous health services to the population.

- The operational lever focus on “PHC workforce” points out the importance of community-based health workers who should be included in broader policies on health workforce and health system development. The interdisciplinary PHC team plays a key role in giving comprehensive care and addressing the social determinants of health of the population. Additionally, there should be conflict of interest policies in place to mitigate commercial influence in health. Moreover, aggressive international recruitment of health workforce poses challenges to the strength and sustainability of health systems in countries of origin.

- In relation to “Private-sector providers”, we urge the use of evidence-based studies in order to compare the health and equity impacts of privatized vs publicly funded health systems. Moreover, the engagement with the private sector providers should be informed by an underlying commitment to ensuring price regulation, accountability, grievance redressal processes, and protection of patient’s rights, in recognition of the fact that health is a basic human right.

- Regarding the “Monitoring and evaluation” of PHC programs we consider that the community (including local governance systems and elected representatives) and patients need to be acknowledged as active participants in them.

Apart from the core and operational levers for PHC presented in the draft, we would like to highlight the important role of CPHC in two senses. First CPHC is integral to addressing the main health problems in the community, by providing appropriate promotive, preventative, curative, and rehabilitative services in a comprehensive way. Second, CPHC is key to addressing the commercial drivers of NCDs and climate change which are fundamental global health challenges.

EB146/6 follows up on the Political Declaration of the High-Level Meeting of the UN General Assembly on UHC held in September 2019. The document recalls the global commitment made by world leaders to achieve universal health coverage within SDG 3 of the 2030 Agenda. EB146/6 clearly lays out the shortfalls with respect to the SDG goals and targets relating to UHC. The report analyses WHO’s 2019 monitoring report, “Primary health care on the road to universal health coverage”, which provides data on the wide variations in service coverage, increasing health care impoverishment and catastrophic expenditure. However, EB146/6 does not offer any explanation for the increase in catastrophic health expenditure between 2000 and 2015.

WHO REFORM & ENGAGEMENT WITH NON-STATE ACTORS

OVERVIEW

Despite ongoing reform efforts, the WHO faces a crisis of identity, legitimacy and financing. Is the WHO’s core mission to set norms and provide leadership, or to operationalize programs on the ground? Has the proliferation of new actors in global health usurped the WHO’s mandate to lead? Can the WHO secure sustainable financing (i.e. untied funds) that will provide the necessary autonomy to act as an independent leader in global health?

Central to and exacerbating these issues is the WHO’s relationships with non-state actors, which include private sector entities (PSE), philanthropies, academic institutions and civil society organisations. The current reports consider their more direct relationships with the WHO (e.g. participation in meetings, registrar of NSA’s in official relations, and contracts and secondments). Equally important (but not discussed here) is their influence on WHO priorities via tied financial contributions. WHO has a constitutional duty to consult with civil society as rights holders whereas corporations do not have these rights.

AT A GLANCE

- There are concerns regarding the effectiveness of existing approaches to WHO-NSA engagement, however the proposed reforms risk silencing the diverse voices of civil society and must be carefully considered prior to implementation.

- The current reporting on the WHO’s due diligence assessments lacks transparency and adequate detail to facilitate an informed assessment about the FENSA implementation.

- The proposed “nil-remuneration contracts” should not bypass the FENSA provisions on secondment facilitate secondment form the private sector through backdoors.
It has been felt that at times civil society engagement is not as efficient as it could be. The WHO is considering several proposals to change its engagement with civil society (and other NSA). Some of these run the risk of homogenizing and/or restricting the diversity of voices that currently engage with the WHO. There is the need for open and cooperative dialogue on this issue.

### RECOMMENDATIONS

- It has been proposed that the WHO implement some of the suggested changes to NSA engagement at WHA73. We urge the WHO and MS to postpone any piloting of changes to provide time to consider the practicalities and feasibility of the proposed changes to NSA engagement with the WHO.
- We ask for the development of a clear plan of action and implementation for the proposed changes as well as technical support from the WHO. This could include a platform whereby NSA’s express interest in contributing to statements on specific items. Additionally, for this approach to be feasible, it is important that EB reports are made available in a timely fashion to give adequate time for consideration and discussion between NSA.
- We urge the secretariat and MS to not limit the size of the delegations as this is an arbitrary measure and discriminates against federated organizations. Additionally, we have concerns regarding separate informal meetings with the WHO as this would bring with it the risks of multistakeholderism, additionally this informal fora already exists in the form of WHO side events.
- We urge the MS to put an end to possibilities to bypass the FENSA provisions on secondment through nil-remuneration contracts.
- We ask that as the WHO continues to develop and refine its proposed approach to NSA participation that it also revisit its definition of conflicts of interest set out in para 13 of the Framework of Engagement with Non-State Actors (A69/6):
  - *WHO will determine through its due diligence if a non-State actor is subject to the influence of private sector entities to the extent that the non-State actor has to be considered itself a private sector entity. Such influence can be exerted through financing, participation in decision making or otherwise.*
- Lastly, we call for renewed efforts to implement transparency around all WHO engagements with NSA.

### ISSUES AT EB146

Agenda Item 22.1 (WHO Reform) and Item 22.2 (Engagement with Non-State Actors) look at two different aspects of NSA engagement with the WHO. 22.1 looks more at direct involvement in governing body meetings, and 22.2 looks more at financial and procedural involvement, e.g. consultants, secondments, etc. There are several issues with these two items.

The document EB146/33 (Agenda 22.1) contains the following proposals as part of WHO reform. First, it proposes constituency-based consensus statements instated of individual statements from NSAs in governing body meetings. Second, proposes limits the on the number of statements from NSAs to 7, which would be allowed based on first come first serve basis. Third, the number of statements for each NSA would be limited to three. Fourth, the number of delegates of NSA to attend the governing body meetings would be limited to 25.

These proposals effectively restrict the participation of civil societies and movements and fail to consider the diversity of voices and interests of NSA. The participation of civil society organizations and movements should not be compromised in the name of managing agenda pressures at governing body meetings. Therefore, the current proposals contained in document EB146/33 require further discussion and should not be accepted.

A key impetus for FENSA is the provision of greater transparency around the WHO’s relationships with NSAs, however the FENSA implementation report contained in EB 146/34 has the effect of undermining or circumventing the safeguards provided in FENSA. There is no transparency regarding:

- The outcome of the 1500 due diligence discussions (para 17) held by the “specialized unit” responsible;
- The content of the “simplified assessment procedure for new engagements” discussed in para 18;
- The outcomes of WHO discussions with NSA (para 7) to “reinforce WHO’s normative mandate”
- There are no details about secondments. Details were provided in the 2018 and 2019 annual reports.

These discussions and assessments must be made public.

Of special concern is the proposal in para 10 of EB146/34 for “proposed nil-remuneration contracts” that open the door for deploying persons from the private sector. As mentioned above, FENSA prohibits secondments from the private sector. These contracts effectively bypass the conditions placed on secondments to manage conflicts of interest and raise potential conflicts of interest. Contracts must be subject to due diligence and should not bypass the FENSA provisions on secondments.

Further, the register of NSAs in official relations with the WHO should include details of the type and nature of interactions with the WHO, e.g. participation in working groups, meetings, funding reports, offering technical advice, etc. Further, the register should provide the financial resources involved in the implementation of collaborative work programs between NSA and WHO.
The Convention on Biological Diversity (CBD) is premised on the notion that States have sovereign rights over their own natural resources and the authority to determine access to genetic resources rests with the national governments and is subject to national legislation (Article 15.1 of the CBD).

Following this premise, the Nagoya Protocol elaborates on the access and benefit sharing aspect of the CBD. In accordance with the principles established by the CBD, under the Protocol, genetic resources may be accessed subject to “prior informed consent”, “fair and equitable sharing of benefits” on “mutually agreed terms” with the country of origin. Details for implementing them are left to domestic legislation. Pathogens are included within the scope of the Nagoya Protocol.

It is important to note that the premise of the development of CBD and Nagoya Protocol is to prevent misappropriation of biological resources through intellectual property or other mechanisms and to ensure equity in the sharing of biological materials through fair and equitable benefit sharing.

The PIP Framework which governs the sharing of influenza viruses of pandemic potential (IVPP) and fair and equitable benefit sharing is a clear example of the opportunity for public health arising from principles of the CBD and the Nagoya Protocol. In 2016 WHO’s Expert Review Group on the PIP Framework concluded that it is a: “bold and innovative tool for pandemic influenza preparedness, is being well implemented, and that the principle of the PIP Framework of placing virus sharing and benefit sharing on an equal footing remains relevant today.” With the PIP Framework, benefits such as anti-virals, vaccines as well as cash contributions amounting to US$191 million (as of September 2019) have been secured. Cash contributions have enabled further capacity building, improving surveillance capacity as well as sharing of IVPP.

The issues of ABS arise under two agenda items: Agenda Item 15.3 Influenza Preparedness and Agenda item 15.4 The Public Health Implications of the Nagoya Protocol.

Agenda Item 15.3: Influenza Preparedness

EB146/18 reports on implementation of actions points in WHA 72(12) and highlights a Global Influenza Strategy 2019-2030 prepared by the Secretariat. The EB is invited to note this report with a proposed focus on “suggestions for further sensitizing Member States to the importance of timely influenza virus sharing” and “ways to promote influenza prevention and control strategies, including through the use of seasonal vaccination.”

The Global Influenza Strategy is lacking in equity as it fails to adequately address the question of fair and equitable benefit sharing including timely access to...
affordable treatment. The development of this strategy has also bypassed the governing bodies of WHO.

The Secretariat takes a biased narrow approach against the Nagoya Protocol (para 12-20). It fails to recognize that the scope of WHA72(12) is broader than the topic of the Protocol, there is no international obligation to share seasonal viruses, as well as the absence of a regulated access and equitable benefit sharing framework in WHO for seasonal flu viruses.

Agenda item 15.4: The Public Health Implications of the Nagoya Protocol

According to decision WHA72(13), this year WHO was supposed to focus on fact-finding and this issue was to be on the agenda of WHA in 2021. WHO is likely to emerge with results of its fact finding sometime in April. Member states need time to digest the information and undertake consultations after the results of fact finding are released rather than rushing into a decision at the current EB or at the 2020 WHA. Hence, it is best that any further decision only be taken at the 2021 WHA, when the agenda item is due to come up again.

The current survey has several methodological limitations, for example missing questions around the legal instruments for sharing pathogens and the terms and conditions for sharing the pathogens. There is also the risk that, depending on who completes the survey, the information collected may be inadequate, incorrect and/or maybe even just a personal view or opinion of the official completing the survey.

ACCES TO MEDICINE & THE GSPOA

OVERVIEW

Access to medicines is a historic item at WHO Governing Body Meetings and is a topic which resurfaces time and again under different prefaces. Despite this recognition an estimated 2 billion people are still without access to medicines, resulting in millions of unnecessary deaths either due to issues of unaffordability or that no treatment exists. The root of this issue is the current R&D system that is driven by financial incentives and facilitated by treaties such as TRIPs in which precedence is put upon Intellectual Property. This has created an environment whereby the motivation of innovation is not to meet public health needs, but to discover the most profitable drugs. Member states have so far been weak in tackling this issue which highlights the insidious undue influence of the private pharmaceutical sector, a symptom of the era of neoliberalism.

The GSPOA was developed in attempts to rectify the damaging impact of TRIPs on public health and to create actions leading from the Doha Declaration insofar that its mandate was to promote innovative methods of promoting R&D relevant to the needs of LMIC countries. However, since it was passed in 2008 this mandate has only weakened. There has been strong pushback on transparency of R&D costs and funding, and prioritisation of reporting shortages, resource mobilisation, R&D capacity building in LMICs and the exploration of delinkage. This in turn also weakens the success of other agenda items such as the Global Vaccine Action Plan, Ending TB and Neglected Tropical Diseases due to a lack of R&D funding, market monopolies resulting in affordable prices and poor regulatory, manufacturing and procurement capacity particularly in LMICs.

RECOMMENDATIONS

- We urge the Secretariat to immediately initiate a process to establish an Expert Committee on Health Research and Development
- We urge the Secretariat to consider the Global Observatory as a core function and use its core budget for the operation of global observatory
- We urge the MS to highlight the need for commitments to sustainable, adequate and untied funding mechanisms (especially from HICs), and to ensure that decisions over funding allocations are not captured by donors.
- We urge the Secretariat and MS to remember the original mandate of the GSPOA to promote innovative new methods of approaching R&D to ensure public health needs are met and to provide support for TRIPS flexibilities to be effectively utilised without barriers.

ISSUES AT EB146

The compromised decision reached at the EB142 restricted the original scope of the implementation plan. This is seen in the current EB report in which the WHO reports on only 22 of the 33 actions. It is important that MS give the WHO a clear mandate to implement all 33 recommendations. This includes providing technical advice to member states who want to exercise TRIPS flexibilities in the name of public health and to develop, and implement new schemes which partially or wholly delink product prices from research and development (i.e delinkage).

Due to this compromised decision, the GSPOA implementation plan only refers to activities related
to the secretariat and is consequently without any accountability framework for MS implementation of the GSPOA recommendations. There is virtually no information provided in EB146/15 regarding any progress on the recommendations which were largely addressed to MSs. The report provides no information regarding discussions among MSs regarding the recommendations of the Review Panel identified as “not emanating from the GSPOA.” An effective implementation plan must include measures for monitoring and accountability regarding recommendations addressed to the MSs.

Report EB146/15 describes a range of structures and activities in which the Secretariat has been involved which have in various ways responded to the recommendations of the Review Panel. In several cases the proposed actions do not respond fully to the recommendations of the Review Panel or have been significantly weakened.

In previous debates, some countries have argued that the WHO’s actions around TRIPS flexibilities go beyond its mandate. Multiple resolutions have affirmed the WHO’s mandate to work on IP and trade (see for instance the WHO’s background documents [1] on GSPOA). Resource mobilisation remains a key obstacle in the implementation of any relevant access to medicines initiatives and resolutions, not excluding the GSPOA. The WHO needs much greater budgetary discretion to facilitate democratic decision making in the governing bodies.


DATA AND INNOVATION: GLOBAL STRATEGY ON DIGITAL HEALTH

OVERVIEW

Digital health is “the field of knowledge and practice associated with the development and use of digital technologies to improve health.” The capabilities of digital technologies and data have grown exponentially in recent times. Given the growing space and importance of digital health there are concerns over the impact this will have on health systems.

Health digitalization is a double-edged sword, whilst it can bring societal benefits in the way of more efficient care and health management, it brings with it the potential misuse and exploitation of human data. There is the risk that a society's health data is appropriated by a few corporations to control digital health systems. Alternatively, health data can be under collective community ownership towards developing digital health systems that are fair and equitable. This will also allow wide sharing of such data to maximize innovation and productivity to benefit everyone’s health.

However, herein poses a key question: who owns data on human health—the data source (i.e the individual whose data it is) or the data collector (i.e the company who created the technology which gathers the data)? Whilst this is perhaps an ideological debate, we can take guidance from existing mandates surrounding the ownership of natural resources in the form of the Nagoya Protocol. The assumption underlying this protocol is that natural resources and biodiversity belong to communities and therefore should be protected. We can then apply this same argument to the concept of digital health—communities should be able to retain ownership over the data gathered on human health. Whilst this data can be shared and appropriated by the private sector, it should be done in a manner that prioritises public health and not only corporate interests.

AT A GLANCE

- The application of digital technologies on health care is reshaping and redefining public health.
- The potential consequences of health data privatization and monetization need to be appropriately addressed. A society and community must own and control its health data, with the required technical and legal means of such control.
- Data collected on health should be viewed as a public good, not a commercial good. Therefore, there needs to be appropriate controls in place to ensure this data is not misappropriated.
- The draft strategy requires revision in order to include the above suggestions before forwarding it to the WHA.

ISSUES AT EB146

EB146/26 provides a draft global strategy on digital health with the purpose of advancing and applying digital technologies towards the vision of health for all. However, the strategic objectives are not based on clear analysis of trends, opportunities, risks, and critical levers which could potentially shape the drivers of development in this field.

It is necessary to explore the origin of the funding that ignited and shaped the development of the strategy and the reasons of it being disclosed to remove doubt concerning potential conflicts of interest. Health data policies and strategies are missing in the elaboration of the second objective. Governance of digital health systems does not mention the development of public health data exchanges and other kinds of public health data infrastructures. Furthermore, people-centric digital health systems principally require individual and collective ownership and control over their health data, with the required institutional means of exercising such power.

Uses of digital technologies and their implications on health systems, such as artificial intelligence and machine learning, require additional consideration. The potential consequences of health data privatization and monetization are enormous, albeit not thoroughly explored. On
the one hand, the public sector needs to have a central role on data ownership whereas on the other hand, community rights should be safeguarded for which specific legal and enforcement regimes are required.

The significance of reduced and easily replaced staffing levels, as a consequence of digital health implementation, is not taken into consideration in the draft strategy. This may have severe implications on the quality of care and the unemployment rate in the health sector.

Finally, it seems likely that the draft strategy was finalized or close to finalized before the new Digital Health Technical Advisory Group was appointed. The inaugural meeting of the DH TAG was on the 24-25 October 2019 and EB146/26 was published 23 December.

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**RECOMMENDATIONS**

- We urge Member States to be extremely careful when interpreting the strategy. Both the technical and legal aspects of data ownership need to be safeguarded so as to promote the strengthening of public health systems within a “right to health” framework.
- With regards to the first strategic objective, global instruments for people’s individual and collective rights over their health data should be included. WHO should provide guidance and capacity building to countries to develop public health data ownership, infrastructures as well as laws and institutions in order to protect them.
- A society's health data consists of both biological and social data resources. It should be a commons resource, governed as a common property by the community itself. The Convention on Biological Diversity seeks national and community ownership and control over its biological resources and benefits from such data should primarily accrue to it, in a manner decided by the concerned community.