Health for All Now!
People's Health Movement

Policy Briefs
on Important Issues before WHA 70

Issued through the aegis of the People's Health Movement's (www.phmovement.org) WHO Watch Programme

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CONTENTS

Human resources for health

13.1 "Human resources for health and implementation of the outcomes of the United Nations' High-Level Commission on Health Employment and Economic Growth"

Background

At WHA70 the WHO Secretariat will be submitting a report on the work of the UN High-Level Commission on Health Employment and Economic Growth for noting,[1] as well as a five-year action plan (2017-2021) for consideration by the Assembly (described in WHA70/18).

The work of the Commission was authorised by UNGASS Resolution (70/183), which was passed in December 2015. It focused largely on strengthening the management of international health crises. This was clearly influenced by the outbreak of Ebola in West Africa and the failure of weak health systems to address it promptly and adequately. The Commission submitted its report in December 2016 and encourages LMICs to invest in their health systems but frames this primarily as an investment in their economic growth. It emphasises the instrumental value of investing in HRH.

We welcome the Commission's emphasis on expanding HRH in LMICs, as articulated in the report and the action plan. **However, it is problematic that the Commission emphasises the economic "payoffs" of investing in HRH. Investing in HRH is inherently valuable when it strengthens health systems, encourages public provision of health services, and creates decent jobs for health workers.**

Analysis

The World Health Organization (WHO) Global Code of Practice on the International Recruitment of Health Personnel was implemented by the World Health Assembly in May 2010 and which raised some awareness of problems associated with migration and staff shortages in source countries. However, the knowledge and implementation of the Code is still variable across levels of governance in both the source and destination countries. The new draft plan for 2017-2021 does not address this issue, and has a number of shortcomings of its own.

The discussion about investing in HRH takes place in the context of fiscal austerity. **Declining investments in health systems, particularly public health systems, and social services has long been a reality in the developing countries.** In the wake of the 2008 financial crisis, austerity policies have also been imposed on developed countries and seem to be intensifying in the low and middle income countries. This reality makes it unlikely that the first recommendation of the Commission, that is "Stimulate investments in creating decent health sector jobs, particularly for women and youths, with the right skills, in the right numbers and in the right places", will be implemented. Austerity policies have translated into a decline in public sector jobs, particularly in social sectors like health.

[1] Available here: http://www.who.int/hrh/com-heeg/

Recommendation 7 emphasizes the importance of "adequate funding and broad-based health financing reform" as mechanisms "to invest in the right skills, decent working conditions and an appropriate number of health workers". **It is unlikely that the universal health coverage (UHC) agenda, which also emphasizes investment in health systems, will mitigate this trend in declining funding of public health systems.** UHC emphasises the importance of financing access to health services, but does not express a preference for public sector provision of health services. Instead, it argues that patients should be allowed to purchase health care from both public and private sector providers, as long as the overall system is fair and efficient. Successful implementation of health financing plans may well expand HRH in LMICs. However, unless this is informed by a commitment to strengthening public health institutions, UHC may mainly lead to growth of the private sector health workforce. This is problematic as health workers in the private sector are often subjected to precarious working conditions. Moreover, the private sector is not necessarily more efficient in providing health care, it does not necessarily provide a higher standard of care, and access to care by the poor who are often the sickest is often compromised. Typically, it remains difficult to purchase comprehensive and long-term care in the private sector even when patients have health insurance.

The **issue of health worker emigration** is addressed under Recommendation 9, which calls for "Advanc[ing] international recognition of health workers' qualifications to optimize skills use, increase the benefits from and reduce the negative effects of health worker migration, and safeguard migrants' rights". This recommendation fails to recognise the importance of labour rights in improving the working conditions of health workers, and in contributing to the retention of the health workforce in LMICs. For example, 500 doctors who work at Kenya's public hospitals began a strike in December 2016 to demand higher pay and better conditions. Unfortunately, the government of Kenya responded by jailing seven officials from the doctors' union. In March 2017 the Tanzanian Government announced a plan to dispatch Tanzanian doctors after a recent meeting in Dar es Salaam with a visiting Kenyan delegation that included Kenya's health cabinet secretary. The deal was framed as a deal that would benefit both countries. However, in Tanzania the doctor-to-patient ratio stands at 1 doctor for every 20,000 patients. In Kenya, it is 1 doctor for every 16,000. The internationally recommended doctor-patient ratio is one to 300. **Without the rights to unionise and engage in collective bargaining, health workers remain vulnerable to exploitation by their employers and in some cases, their governments**. Ultimately this also means that public health is undermined, as health workers may emigrate or lose their jobs if they engage in efforts to improve their terms of employment.

Recommendation 9 acknowledges the need to "reduce the negative effects of health worker migration, and safeguard migrants' rights". This is a complex issue, as health workers are not a homogeneous group. Some of these workers are highly skilled doctors and nurses, while others emigrate to take up jobs as caregivers for the elderly or to work as cleaners in health settings. In addition, some workers emigrate from countries that rely on their earnings in the receiving country to subsidise improvements in wellbeing in the sending country. A significant number of countries in the Global South depend on remittances from health workers who work abroad. **It should not be necessary for health workers to leave their families in order to earn a decent salary, or for governments to create new revenue streams. Northern states should build their own health workforce**. The WHO's voluntary code on the international recruitment of health workers has not been effective. The key weakness is its voluntary nature. Legally binding interventions are required to ensure that health-workers enjoy decent working conditions wherever they are located, and that

developing countries get reimbursed, through an agreed mechanism for compensation, for the costs of educating and training low- and highly skilled health workers that emigrate.

Recommendations 1 and 7 both mention the importance of creating decent jobs and decent working conditions. Work, is not a gender neutral phenomenon. The majority of health workers are women. Women also bear the primary responsibility for care work in their households and communities. Much of this work, whether in the formal or informal sector, is undervalued and underpaid. This is unacceptable. Recommendations 1 and 2 acknowledge aspects of this reality. Recommendation 1 calls for creating more jobs for women and youth in the health sector. Recommendation 2 advocates for "addressing gender biases and inequities in education and the health labour market, and tackling gender concerns in health reform processes", and for "maximiz[ing] women's economic participation" in this sector. Unfortunately, the document includes very little detail on what this means in practice. **It is silent on the fact that many community health workers (CHWs) are called "volunteers" and thus receive no salaries or benefits.** They are nevertheless expected to act like workers with jobs: they have to work set hours, report to health facilities, meet minimum targets for the week or a month, provide a minimum quality of care to patients, and so forth.

The work that CHWs do to sustain health systems in LMICs is recognised, even though it is not, or inadequately, remunerated and their labour rights are not protected. This is in contrast to other forms of healthcare work, particularly care work done within the household by women without formal training, which is not even recognised as work. Women and girls subsidise the health system by protecting and managing the health of children, sick and elderly. They do this within their own households, and in the case of migrants, in the homes of strangers. Migrant care workers work under precarious conditions. They are invisible, as their place of work is in "private sphere". Some of them are undocumented, which means they have no recourse when they are abused or exploited. Even documented workers are often subjected to very restrictive labour regimes which place them at the mercy of their employers. **The draft plan completely fails to acknowledge this type of work and its contribution to advancing health.**

Recommendations

The recommendation from the High Level Commission on Health Employment and economic growth are positive. However, we would suggest the following changes to the initial recommendations by the HLC HEEG.

- Recommendation seven suggests the following: "Raise adequate funding from domestic and international sources, public and private where appropriate, and consider broad-based health financing reform where needed, to invest in the right skills, decent working conditions and an appropriate number of health workers." We would like to add to this recommendation that **fiscal space for human resources for health in the public sector should be created**, which is a precondition for a well-functioning health system and to reach UHC. It is concerning that international aid is being withdrawn without an existing credible alternative. For now reliance on domestic funding to assure adequate recruitment and retention in public services remains an idle hope in most countries. This is not merely an LIC country issue, also European countries lack fiscal space in the context of strict austerity measures.

- Recommendation eight suggests the following: “Promote intersectoral collaboration at national, regional and international levels; engage civil society, unions and other health workers’ organizations and the private sector; and align international cooperation to support investments in the health workforce, as part of national health and education strategies and plans.” However, currently justified strikes by the health workforce are being undermined by governments and neighbouring countries .**We would like to add to recommendation eight that labour rights should be retained and respected as well as unionisation and the right to organise.**

- Recommendation one talks about ‘creating decent health sector jobs’. **We believe that community health workers should be recognised as human resources for health and should be on a pay-roll. They should not be used as cheap labour.**

- Health worker migration, or brain drain remains a pertinent issue globally. Recommendation number nine mentions to ‘reduce negative effects of health worker migration’. Currently there is a well-developed global code of practice on the international recruitment of health personnel. **However we believe that this agreement should contain a binding element.** WHO should stress that HICs should develop the capacity to train their own human resources for health. Moreover, the feasibility of financial compensation to LICs should be urgently explored, without commodification of the health workforce.

Issues in the Agenda of WHA70 related to Access to Medicines

"*Unless the world, the UN […] act now [on the UNHLP recommendations], there is no way that we will attain SDG3 by 2030. Millions will be left behind and millions will die..."*

Honourable Michael Kirby
Former Member of the UN High Level Panel on Access to Medicines

Overall Background

The Crisis of compromised access to medicines is a global crisis

Currently people in almost all parts of the word, both in the global North and South, face barriers while accessing needed medicines. Since the harmonisation of patent law after adoption of the TRIPS Agreement, persistent challenges remain as regards the full use of TRIPS flexibilities for public health protection in many countries. Moreover, Free Trade Agreements (FTAs) routinely include TRIPs+ provisions, which undermine the ability of States to adopt and make full use of TRIPS flexibilities to promote public health. Millions of people have died because they were not able to afford essential and lifesaving medicines. While Low and Middle Income Countries (LMICs) continue to bear the major burden related to lack of access to medicines, patients in High Income Countries (HICs) are also starting to encounter major barriers to access. Recognizing the skewed balance between IP protection and public health promotion, health ministers of the EU have committed themselves to a review of options to address this imbalance.[2]

The current Research and Development (R&D) system relies on countries granting patent monopolies to pharmaceutical companies as the main way to incentivise innovation. This market-driven approach to R&D means that innovation mostly focuses on diseases affecting wealthy patients. However, diagnostics, vaccines and medicines are missing for many diseases affecting patients in both LMICs and HICs. The patent driven R&D system is clearly not delivering needed medicines. In the past 10 years only 25% of new medicines that received marketing approval provide an increased therapeutic benefit for patients over existing products (Revue Prescrire, 2015). The current crisis of antimicrobial resistance also highlights the inadequacy of the current R&D.

Report of the UN High Level Panel on Access to Medicines (UNHLP)

In November 2015, the former UN Secretary General Ban Ki-Moon convened a panel of experts with the mandate to "*review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies*". In September 2016, the UNHLP released its report, including recommendations to address the global challenges caused by high prices of medicines and lack of health needs-driven innovation. The report recognizes that access to medicines is, now, a global issue.

[2] http://www.consilium.europa.eu/en/press/press-releases/2016/06/17-epsco-conclusions-balance-pharmaceutical-system/

The report does not represent a novel proposition but it does provide a holistic picture of previously-proposed actions (by WHO bodies and other institutions) that should be coordinated together to finally address the current imbalance in innovation and access to medicines.

A series of actions proposed in the report are directed at Member States, International Organizations, and a range of other actors. **The report refers to the WHO as a natural forum to lead discussions, and as an anchor for coordination between UN agencies.** While many countries and organizations embraced the report and echoed some of its recommendations[3], the report was met with hostility by a few powerful HICs before it was even published. In November 2016, the former UN Secretary General Ban Ki-Moon issued a statement praising the report and calling on all governments and agencies to review the report and its recommendations and to chart a way forward to address the access and innovation problems.

The UNHLP report is of paramount importance to guide the work of the WHO and its Member States in the area of medicines. Unfortunately a full discussion on the report was not scheduled at EB 140 in January 2017 in spite of a request by a number Member States to have a separate agenda item in EB 140 on this issue. In contrast the UNHLP report has been addressed at the WTO TRIPs Council, the WIPO Standing Committee on Patents, the UNAIDS Programme Coordinating Board meeting, as well as within the UN Human Rights Council. WHO's credibility as the premier global agency on health is at stake if comprehensive discussions on the UNHLP report are not held at WHA 70. As the eminent jurist Michael Kirby stated *"Unless the UNHLP's recommendations impinge on our hearts and minds, a vital opportunity may be lost, perhaps forever. [...] [WHO] cannot shirk that responsibility or surrender it to others – Trilateral or otherwise. It thus has the primary responsibility to lead for attainment of Sustainable Development Goal 3. WHO must find its own voice and powerfully support action on the UNHLP."*

13.3: Addressing the global shortage of, and access to, medicines and vaccines

Background

During EB140, in spite of opposition from a few high-income countries, Member States had the opportunity to make remarks and share insights on the UNHLP report within a sub-item under the follow-up of the CEWG report. In the course of these discussions, Eritrea (on behalf of the African Group) asked the Secretariat to include a separate agenda item dedicated exclusively to the UNHLP report, to be addressed and discussed at the WHA70. The published report (WHA70/20), which addresses the global shortage of, and access to, medicines and vaccines under the agenda item 13.3, is therefore a compromise on this matter proposed by the Director-General to Member States.

Need to promote a comprehensive discussion on the UNHLP report

The "Access to Medicines" part of Document **WHA70/20** provides an overview of the latest initiatives undertaken by WHO and other relevant actors, aimed at improving access to quality, efficacious and affordable medicines. Para 4 in this sections very briefly refers to the UNHLP report. The section on

[3] Ploumen L, Schippers E., *Better life through medicine — let's leave no one behind*. Lancet 2016 November 4 (Epub ahead of print). *Belgian and Dutch health ministers.

"Shortages" in the latter part of WHA70/20 discusses issues related to shortages of essential medicines in different settings.

Thus several issues, such as those relating to shortages, access and the UNHLP report, are mixed together in a single document. This might prevent a comprehensive discussion on each of these important issues. Particularly, the parking of a discussion on the UNHLP report in a document that discusses several other issues could dilute the debate on the UNHLP report and on obstacles posed by intellectual property rights (IPRs) to access to medicines. The UNHLP report is a unique opportunity to revive discussions on IPRs and access to medicines within the WHO. It is unfortunate that **WHA70/20** only cursorily refers to the UNHLP report.

Prices and barriers caused by IPRs not adequately addressed

The report indicates that shortages and stock-outs of medicines and vaccines contribute to the prevalence of substandard and falsified medicines. However lack of access is not related only to shortages and stock-outs but also relate to high prices of medicines, often because of the application of IPRs. It is not appropriate to separate the discussions on medicine prices from those on IPRs and access.

13.5: Follow-up of the Consultative Expert Working Group on Research and Development: Financing and coordination (CEWG)

Background

The CEWG was established under Element 7 of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA). The recommendations in the CEWG report are the results obtained through deliberations in four working groups, working under the mandate of *"exploring innovative approaches of ensuring access to medicines for people most in need"* to achieve the *"development and delivery of affordable, effective and safe health products for which existing market mechanisms fail to provide incentives for health research and development"* (GSPOA) (with four reports respectively). The focus of these groups was mainly developing countries, but the 'CEWG principles' are generally relevant to all R&D initiatives.

Document WHA70/22 is a revised version of document **EB140/21** (2017), which contains the DG's report on the progress made in the implementation of resolution **WHA69.23** (2016) and the implementation of the strategic work plan endorsed in **WHA66.22** (2013). The main items reported on are:

- The development of WHO's Global Observatory on Health R&D, with terms of references included in Annex 1.
- The progress by the health R&D Demonstration projects.
- The establishment of an Expert Committee on Health R&D to provide technical advice on the prioritization of health R&D. The secretariat reports on its terms of reference of this committee in document EB140/22.
- The exploration of the feasibility of a voluntary pooled fund to support R&D for Type III and Type II diseases and R&D needs of developing countries in relation to Type I diseases.

Beyond status quo -- a new approach is needed

While progress made on the items listed above is to be appreciated, the strategic workplan in **WHA66.22** does not address the core aspiration of the CEWG process – a sustainable and novel model of incentivising, coordinating, financing and regulating R&D, independent of market incentives, and protecting public health by a legally-binding R&D Convention. Further, WHA70/21 outlines that the gap in funding for the current initiatives (demonstration projects) is over 85%. This clearly reveals that progress has been slow and that not all demonstration projects have received funding. The funding gap is proof that mandatory contributions are needed for sustainable financing. The demonstration projects do not encourage a paradigm shift, and they alone will not address the aims behind establishing the GSPOA and the CEWG. The negotiation of an R&D Convention was also a key recommendation of the UN High Level Panel on Access to Medicines (UNHLP) report (2016).

R&D Convention

There has been no advance in initiating discussions on a R&D in spite of strong support from several Member States and civil society organizations. Discussions on the R&D Convention were side-tracked in the 2012 meeting in follow-up to the CEWG report. A new Open Ended Meeting was convened in May 2016 with the aim to address the so called "remaining issues" in the follow-up to the CEWG report. Despite the R&D Convention being the main issue remaining, this was again not discussed in the meeting. Also unfortunate is that reference to a R&D convention is missing in resolution **WHA69.23** (2016).

CEWG principles are relevant for all R&D initiatives

In resolution **WHA69.23**, Member States agreed on some important propositions that **WHA70/22** fails to address:

- Promoting Policy coherence in R&D initiatives, in terms of application of the core principles of affordability, effectiveness, efficiency and equity and the objective of de-linkage.
- An Open Ended Meeting in 2017 to continue discussions on following up the CEWG report.

The CEWG Principles have a norm-setting character which is relevant to and necessary in all health R&D. We welcome that the Principles are being applied in some WHO R&D initiatives. As AMR initiatives progress fast within and outside the WHO, we stress that these should abide by the CEWG Principles, including the AMR Development and Stewardship Framework (which is not mentioned in document **WHA70/21**). In its norm- and standard-setting mandate, the WHO should advocate for these Principles to be applied in R&D initiatives outside the Organization too.

12.2 Antimicrobial resistance (and sepsis)

Background

In May 2015, the Assembly adopted the **Global Action Plan on AMR (**WHA68.7). Objective 5 of the Plan deals with investment in new medicines, diagnostics, vaccines and other interventions. This objective is to be largely progressed at the global level, presumably through the **Global Development and Stewardship Framework**, which was endorsed in **WHA68.7**.

Document **A70/12** mentions a number of initiatives undertaken by the Secretariat including:

- the manual and tools to support the development of national action plans and new provisions for monitoring progress;
- awareness raising regarding AMR;
- continued development of the Global Antimicrobial Surveillance System including training for national participants in monitoring antibiotic consumption;
- the revision of the Critically Important Antimicrobials list;
- new guidelines on infection prevention and control and on antibiotic use;
- monitoring drug resistance in relation to HIV, TB and malaria; and
- prioritisation of R&D for particular diseases/infections including TB, malaria, gonorrhoea and neonatal sepsis.

Global attention has been drawn to the looming threat posed by antimicrobial resistance on public health goals across the world. One of the major issues emerging from discussions on AMR is the need to promote R&D incentives that delink the price of medicines from the cost of R&D.

Stewardship Framework

The delay in the roll-out of the "Global Development and Stewardship Framework" related to AMR is a matter of concern and the reasons for this delay merit attention**.** Despite multiple requests during EB140 for explanations of the delay in progress regarding the Framework, **WHA70/12** does not explain these delays. We are equally concerned that the issue of funding is a big shadow looming over all of the initiatives undertaken. There appears to be **a significant funding gap** of $2-3m per year for the global observatory and a minimum of $100m is required for the voluntary pooled fund.

Links to CEWG

We believe that the **CEWG principles should be included in all WHO R&D initiatives - including, and especially, in the AMR Stewardship Framework.** WHO, in its mandate to protect public health, **should also advocate their inclusion in initiatives outside the WHO** too, especially for AMR initiatives which may receive public funding. Such an approach would be critical to ensuring affordability of new treatments.

Applying the principles of the UN declaration on AMR

With the UN political declaration on AMR, WHO and Member States have adopted the principles of affordability, accessibility, efficiency, and equity. It has further been stated that this is best achieved by delinking the cost of investment from the price and volume of sales. It is now crucial that this is put to action. A number of laudable initiatives have been initiated to expand R&D in the area of AMR, such as CARB-X, DRIVE-AB and GARDP (the Global Antibiotic R&D Partnership). WHO and Member States need to ensure that these initiatives follow the suggestions of the Global Action Plan on Antimicrobial resistance and include 'delinkage' as a core principle so as to ensure affordable access to new health technologies. National Action Plans by Member States should also apply this principle.

Flawed approach of 'Health Security'

Co-ordinated action on AMR is an opportunity to strengthen international solidarity and cooperation. Actions on AMR should not be designed with a 'health security' lens and thereby blame or isolate

resource deprived countries that do not have the means to contribute to the global efforts to combat AMR. Instead better endowed countries should contribute by fulfilling their c**ommitments on technology transfer and strengthening the capacity of health systems in LMICs.**

Action on AMR needs to address current practices in animal husbandry and agriculture

One of the contributing factors to AMR is the industrial mode of food production and agriculture. The emergence of new pathogens can be traced to unsustainable industrial modes of animal husbandry. The gross misuse of antibiotics as growth promoters in animal husbandry contributes to the rapid emergence of resistant strains of pathogens. Agribusiness is also dramatically contributing to climate change, which in turn is promoting emergence of infections in new locations. There is therefore a need to address all the contributory factors of AMR, including those related to current practices in animal husbandry and agriculture.

13.4 Evaluation and review of the global strategy and plan of action on public health, innovation and intellectual property (GSPOA)

The report of the evaluation of GSPOA presented at EB140 is disappointing. The report does not provide any new valuable insights, but instead reiterates things that have been time and again reaffirmed several times in the past. The only major finding of the evaluation is its reporting of **the very weak engagement of most** Member States with this process, especially due to the **clear lack of awareness of GSPoA** and the **clear lack of funding for its implementation**. The underfunding is due to the fact that GSPoA is not funded by the core budget of WHO, but rather by tightly earmarked donations. This is an area where Member States and WHO need to collectively reflect as the evaluation appears to suggest that there has been virtually no progress in this area of work after almost decade long investment of time and resources in a multitude of intergovernmental processes, dating back to the setting up of the open ended Intergovernmental Working Group (IGWG) in 2008.

15.6 Cancer prevention and control in the context of an integrated approach

Background

The Secretariat report (A70/32) outlines the disease burden and trends in relation to cancer; reviews the current situation regarding national cancer control plans; reviews the main elements comprising cancer control (from prevention to palliative care) and summarises WHO's activities, and other international efforts, to meet the global challenge posed by cancer. The document lists a range of recommended actions for member states at the country level and actions for the Secretariat.
The Secretariat report provided to EB140 (EB140/31) included a draft resolution which urged member states to progress a wide range of national cancer control policy issues and urged the DG to provide appropriate support including publishing a world report on cancer. Several amendments were proposed to the draft resolution at the EB but member states at EB140 were not able to finalise an agreed text. A draft resolution, based on extensive negotiations, is to be discussed at the Assembly for adoption.

Gaps in Secretariat Report

Several gaps need to be addressed in the Secretariat Report (A70/32). There is no substantive discussion of the reference in the title of the paper to 'integrated care'. There are no references to

the institutional challenges of fostering networks of excellence in cancer prevention, diagnosis and care which are integrated within generic health systems including strong bidirectional referral pathways between primary health care services and more specialist services. There are no references to the challenges of monitoring standards of practice in relation to cancer prevention, diagnosis and care in such integrated health systems and in particular no reference to the regulatory challenges of quality assurance in relation to cancer care in private practice.

The currently market driven system of R&D, relying on IP-protected monopolies as the main incentive for R&D, is driving the prices of treatments for NCDs, including cancer, to prohibitive levels and even HICs are adversely affected. We urge Member States to support the Indian proposed amendment OP2.5ter which addresses the need for a fund for cancer R&D to progressively delink cancer R&D from product prices.

Missing discussion on biologics, biosimilars and regulatory barriers

Another major barrier of access to new cancer drugs is the regulatory regimes in place in different countries as regards introduction of biosimilars (that is follow on drugs similar to biologics introduced by innovator companies). A majority of the most expensive and new anti cancer medicines are biologics. Barriers to the introduction of low cost biosimilars relate not only to IPRs but more importantly to regulatory barriers to the introduction of biosimilars. While the WHO has been involved in co-ordinating efforts towards harmonised regulatory standards for biosimilars, there appears to be a reluctance to promote biosimilar use and their marketing approval. It is unfortunate that this issue has not been addressed in the Secretariat report or in the draft resolution

We urge WHO to form a commission for a comprehensive and systematic report to address the issue, creating a clear, integrated action plan as done by ECHO on ending childhood obesity.

Overall recommendations on Agenda Items Related to Access to Medicines

We urge the WHO:

- To seriously address the UNHLP recommendations and provide an opportunity in WHA70 for Member States to discuss the UNHLP report.
- To expeditiously roll out the stewardship framework on AMR and to effectively collaborate with FAO and OEM on issues related to animal husbandry and agricultural practices that contribute to AMR
- To support strengthening capacities of health systems in resource poor settings to effectively address emergence of AMR
- To convene an inclusive open-ended meeting in 2017, as proposed by resolution WHA69.23, where the negotiation of an R&D Convention must be discussed. Such binding international instrument should be based on de-linkage and principles promoting public health.
- To promote policy coherence, by advocating for the introduction of the CEWG Principles in all health R&D initiatives.
- To work towards increasing funding, but also knowledge and awareness of the GSPoA.

- To strengthen work on regulation of introduction of biosimilars with a view to abolition of unreasonable regulatory barriers to their introduction

We urge Member States to:

- Apply Intellectual Property Rights with a public health lens, for example, by making full use of TRIPS flexibilities.
- Create new incentives for R&D, beyond patent monopolies: coordinating and sustainably financing R&D through innovative models, thus de-linking the costs of R&D from the price of medicines.
- Ensuring transparency, accountability and governance in the R&D process, and link this to their regulatory approval processes
- Refrain from adopting FTAs that include provisions that impede Human Rights, especially the right to health and access to medicines and conduct pre and post impact assessment studies of FTAs.
- Register complaints against undue political and economic pressure, which includes taking punitive measures against offending WTO Members.

Nutrition, Childhood Obesity and Non-Communicable Diseases

Background

This brief refers to the following agenda items:

15.1: Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018

15.5: Report of the Commission on Ending Childhood Obesity: implementation plan

Nutrition is a basic human right which plays an important role in shaping population health. Globally, a large portion of the population is still affected by various forms of under-nutrition. On the other hand widespread consumption of unhealthy and obesogenic food, marketed as packaged commodities by the food and beverages industry around the world is driving an obesity epidemic. This double burden of malnutrition characterises the landscape of nutrition.

The scale of the problem can be discerned from the recent Joint Child Malnutrition Estimates (UNICEF 2017), which reports that 22.9 percent of the under 5 population of children are stunted, 7.7% experience wasting, and another 6 percent are overweight. The trend holds true not only for children, but adults as well who exhibit much higher and increasing rates of obesity. Globally, the burden of NCDs is increasing and poses a challenge for all countries in terms of not only its effect on population health but also as regards the growing fiscal strain on their health systems.

Issues related to malnutrition (both 'over' and under nutrition) and diet-related Non-communicable Diseases (NCDs) have their roots in the social determinants of health and vary across and within countries. Moreover, this burden is distributed unequally across populations based on socio-economic status. The drastic changes in the food systems, owing to the exploitative advances by the food & beverage industries, are a major cause of the problem, particularly in terms of the aggressive marketing and widespread availability of products that are high in calories but low in nutritional value.

While much of the focus of WHO's actions and interventions are aimed at individual risk factors such as smoking, alcohol, physical activity, and unhealthy diet, the underlying socio-economic factors responsible for NCDs and malnutrition are inadequately addressed. Below we address the recent developments on the agenda items on NCDs (15.1) and childhood obesity (15.5) by critically analysing WHO's proposals and present several recommendations for the WHO and Member States.

15.1: Preparation for the third High-level Meeting of the General Assembly on the Prevention and Control of Non-communicable Diseases, to be held in 2018

The WHO has made efforts to address the increase in NCDs globally in its preparation for the high level meeting of the assembly on the prevention and control of NCDs (Agenda item 15.1). Unfortunately many countries have shown inadequate progress in implementing commitments to reduce NCDs. During the EB140 the Secretariat reported (EB 140/27) on the status of the work proposed by the

Health Assembly and the UNGA in preparation for the third High level Meeting of the General Assembly on the Prevention and Control of NCDs, namely:

> (i) to update Appendix 3 of WHO's global action plan for the prevention and control of non-communicable diseases 2013–2020 (revising the list of interventions in the light of recent research; see Annex 1 of A70/27); and
>
> (ii) development of a draft approach (see Annex 2 of EB140/27) that can be used to register and publish contributions of the private sector, philanthropic entities, civil society and academic institutions to the achievement of the nine voluntary targets for the prevention and control of non-communicable diseases (as mandated in para 37 of UNGA68/300).

The Secretariat has also submitted for consideration a proposed workplan 2018−2019 (Annex 3 of A70/27) for the global coordination mechanism.

Policy recommendations to address NCDs

Annex 1 of A70/27 provides an updated version of Appendix 3 which is part of the global action plan for the prevention and control of non-communicable diseases 2013–2020. Appendix 3 has been updated at the request of Member States, to take into consideration the emergence of new evidence of cost-effectiveness and the issuance of new WHO recommendations since the adoption of the global action plan in 2013

The updated Appendix 3 consists of a menu of policy options and cost-effective interventions (marked in bold) to assist Member States in implementation, as appropriate for national context. Additionally Annex 1 of A70/27 also proposes that "*Cost-effectiveness analysis is a useful tool but it has limitations and should not be used as the sole basis for decision-making*". Critical non-financial considerations that may affect the feasibility of certain interventions in some settings are set out in a new column in the updated Appendix 3. This is a welcome addition.

While many of the policy recommendations in Appendix 3 are robust and need to be supported, there continues to be a strong focus on individual behaviour change. It is important that recommendations be expanded to better address the underlying social determinants of health and health system strengthening. Simultaneously, countries would benefit by choosing options that address the underlying social determinants of health in order to create enabling conditions for people to change their behaviour as well as options designed to enhance the capacity of health systems to address NCDs. **We also urge Member States to recommend the addition of specific policy tools for the regulation of trans-national corporate actors** linked to alcohol, food and beverage, and pharmaceutical industries within Appendix 3. Moreover, **we urge Member States to include collaboration with the Human Rights Council regarding their proposed binding agreement on transnational corporations as a strategy for curtailing health damaging corporate practice** in the GCM 2018-19 workplan.

Managing Conflict of Interest

WHO remains insufficiently protected from undue influence and conflict of interest. Para 37 of UNGA 68/300 (July 2014) called upon WHO to put in place a register which can be used to publicise the

'contributions' of private sector entities, philanthropies and civil society organisations to the achievement of the nine global NCD targets. This proposal is part of a wider push to reframe WHO programs and reconceptualise global governance in terms of 'multi-stakeholder partnerships', with the corporate sector recognised as a key player in such partnerships (see brief on FENSA).

PHM urges that the concept of 'contribution' be recognised as having *negative* as well as positive significance and that there should be scope for independent registrations of the negative contributions by private sector entities (PSEs) to the nine global targets. If a register of the 'contributions' of private sector entities (PSEs) were to make a contribution to public policy it would need to have some representative quality (in the sense of being a valid reflection of the field as a whole) to enable useful analysis rather than simply the wish of particular PSEs to be registered.

The global coordination mechanism for the NCDs should provide global guidance. It lacks provisions to prevent adverse influence from big food, alcohol, beverage, tobacco and pharma. We also urge the WHO to provide guidance to member states regarding the investment chapters of Free Trade Agreements (FTAs) to guard against the use of such provisions by corporations to protect their investments in third countries even when their operations run contrary to the interests of public health. We also urge Member States to ask the Secretariat to include a more active engagement with country and regional offices in the GCM workplan and better **articulate how GCM will coordinate with country/regional offices regarding technical assistance.**

15.5: Report of the Commission on Ending Childhood Obesity: implementation plan

PHM lauds the WHO and Member States for their efforts on the High-Level Commission on Ending Childhood Obesity (ECHO) and the comprehensive draft Implementation Plan. **We urge Member States to adopt the proposed plan and strengthen the interventions to address the problem of childhood obesity.** The document places the onus on governments to ensure children's right to health and reverse the trend of increasing childhood obesity.

The recommendations of the report of the Commission on Ending Childhood Obesity (ECHO) and Draft Implementation Plan address the root causes, appropriately situated within the context of larger issues of globalisation, agriculture, and trade. The document recognises the fact that current policies related to these sectors have insufficient protections for public health, which have a disproportionate impact on the poor and vulnerable. WHO's suggested interventions such as nutrient profiling, ban on advertisements, sugar tax, making facilities for physical activity accessible and dealing with obesogenic environments, both at home and school are appreciated. A sugar tax, however, needs to be accompanied by measures that provide alternative sources of affordable and nutritious foods so that the poor are not punished by the tax. The proceeds from a sugar tax should be ring fenced and used to subsidise foods that are nutritious.

Prevention of childhood obesity requires Member States to address the social determinants of health, as articulated via the "whole of country" and "whole of society" approach discussed in the draft Implementation Plan. As described in the document, efforts toward ending childhood obesity must start with the health of a mother through her life-course, including antenatal care through to exclusive breast-feeding. In regard to the child, the interventions need to be continuous as they grow, with

particular emphasis on the first 1000 days. These interventions, as outlined in the Implementation Plan, must deal with the internal as well as the external environment.

However, there are several concerns that PHM would like to bring to the notice of Member States on the issue of childhood obesity. **It is clear that the Draft Implementation Plan will only be able to achieve its aims and objectives if it is passed and recognised as a binding international treaty.** This would ensure that Member States have the necessary mandate to effectively ensure the implementation of interventions, providing a stronger position from which to enact policies and regulations in the face of opposition from commercial interests. In particular, nutrient profiling, food labelling, taxation of sugar-sweetened beverages, and other regulatory strategies need to be given treaty status globally to protect them from corporate challenge under trade agreements. A binding agreement would further enable the political will for in-country progress and empower civil society to hold governments to account for protection of their right to health. **In absence of such a treaty, implementation of the interventions proposed by WHO to solve the issue of childhood obesity will be hindered and progress will be slowed.**

Framework for Engagement with Non State Actors (FENSA)

23.3: Engagement with non-state actors

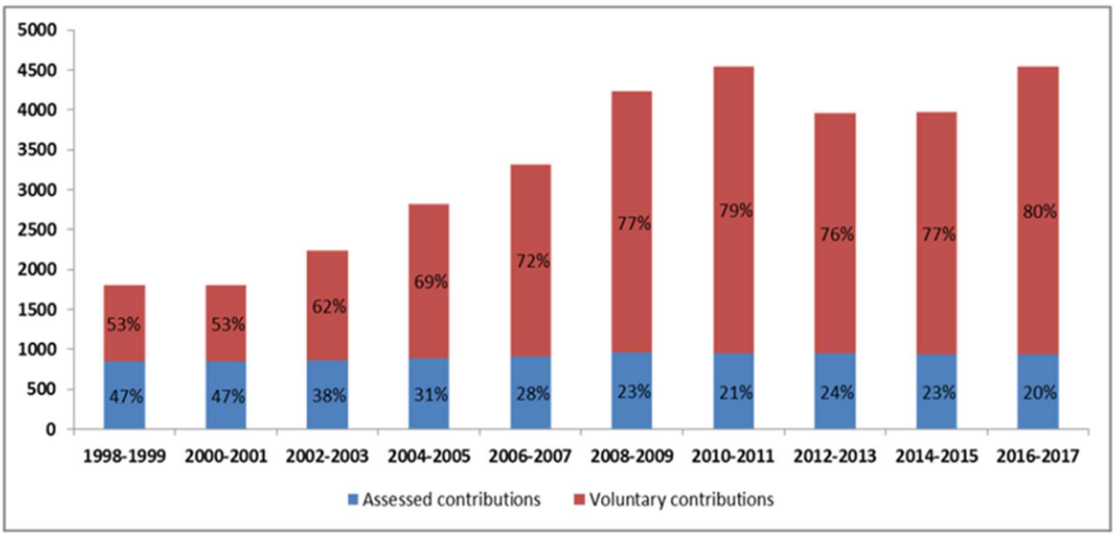
Summary

The Framework for Engagement with Non-State Actors (FENSA) emerged in recognition of the growing number and range of actors engaged in global health governance and the need for WHO to establish guidelines to ensure its autonomy and leadership role in this arena. In its current form unfortunately, FENSA legitimates the stakeholderization of global health governance and entrenches the view of WHO as only one of many actors within global health policy-making. FENSA has the potential to perpetuate the under-financing and under-investment in WHO (especially as regards untied flexible funding). Moreover, its provisions are inadequate in protecting WHO against the undue influence of non-state actors. WHO remains underfunded and overly reliant on voluntary contributions from Member States, private foundations and other entities. Public oversight of WHO decision-making processes can only be secured if assessed contributions from Member States are expanded.

Background

FENSA emerged from a broader agenda of WHO reform grounded on the premise that WHO was ineffective and inefficient. This contention was used as a politically expedient tool to justify under-investment in WHO as a public multilateral institution, exercised by a freeze on assessed contributions since the 1990s. Figure 1 demonstrates the proportional decrease in assessed, untied contributions to the WHO by Member States relative to the growth of the overall budget and voluntary contributions to targeted programs.

Figure 1. Trends in WHO financing, assessed contributions and voluntary contributions 1998–2017



WHO faces a funding shortfall in the present biennium of around US$ 400 million. This is so in spite of the fact that WHO's overall budget, given its broad constitutional budget, is very small. Its annual budget of approximately $2,200 million is around 30% of the annual budget of US CDC; 4% of Pfizer's turnover; 3% of Unilever's turnover; and around 10% of Big Pharma's annual advertising in the US. It is simply not enough for WHO to properly fulfil its responsibilities in global health.

There are significant risks associated with continuing stream of reforms directed to adapting to the dysfunctions associated with donor control as a consequence of WHO's funding crisisi. These risks arise in the increased use of short term and non-staff contracts, the mandatory mobility policy, and now a new focus on 'efficiency' and cost cutting. The Third Stage Evaluation reports a sharp deterioration in staff perceptions regarding the effectiveness of the Organisation and its impact on health outcomes and national health systems (A70/50 Add.1, p6) in the years since the Second Stage Evaluation.

Also of concern are the recommendations of the Third Stage Evaluation for improving efficiency and effectiveness. Instead of highlighting the inefficiencies and brakes on effectiveness consequent upon the pressure to mobilise funds the evaluators call for increased professionalisation in funds mobilisation. Even while commenting on WHO's fragmentation the evaluators call for outsourcing of 'technical functions'.

The neglect of WHO's finances by Member States is typified by the rolling back of the earlier proposal of the DG to solicit for a 10% increase in this year's WHA to 3%. If endorsed this would net an additional $28 million, paltry even in contrast to the projected shortfall this year of $400 million. This inadequate financing of WHO has opened the door for legitimizing the engagement of private donors and a multi-stakeholder agenda. This process of stakeholderization has undermined WHO's central role in global health governance, positioning it as only one of many actors within global health and contributing to reducing its authority around the world. It has also led to dependence on donor funding and capture of the WHO's agenda by financial contributors.

Hotly debated for 4 years, the framework was finalized at WHA69 and is currently in the process of being implemented. While it held the potential to establish clear rules and guidelines for protections against conflict of interest and preservation of WHO's autonomy, in its final form FENSA entrenches the stakeholderization of WHO and explicitly formalises the participation in global health governance of private sector entities whose interests may not align with WHO's public health goals.

Analysis

The framework normalises financial contributions from Private Sector Entities (PSEs) in projects in which they have direct or indirect commercial interests. The provisions regulating contributions from PSEs can be found in the Annex on **WHO Policy and Operational Procedures on Engagement with Private Sector Entities**. The provisions are written in a way that allows PSEs to participate in processes in which they have direct or indirect commercial interests.

For example, the regulations governing contributions from PSEs that have a direct commercial interest in collaborating with the WHO is allowed, provided this contributes to public interest. Paragraph 36 of the Annex reads,

> "*WHO may collaborate with PSEs in the research and development of health related technologies that contribute to increasing access to quality, safe, efficacious and affordable medical products. Collaborative research and development should, as a general rule, be undertaken only if WHO and the private sector entity have concluded an agreement which ensures that the final product will ultimately be widely available, including to the public sector of developing countries at a preferential price. If such an agreement is concluded, financing may be accepted from the private sector entity for a trial arranged by WHO on the product in question, on the basis that contractual commitments obtained from the private sector entity outweigh any potential conflict of interest in accepting such financing*."

The annex contains no information about precisely how this conflict of interest assessment will be made. The general procedure for managing actual or potential conflicts of interests with PSEs is described in paragraphs 21-45 of WHA69.10. No guarantee is given that the WHO will publish detailed, case-by-case reports on these oversight procedures. Paragraph 37 only asserts that the

> "*WHO's interaction with non-State actors is managed transparently*" and that it "*provides an annual report to the governing bodies on its engagement with non-State actors, including summary information on due diligence, risk assessment and risk management undertaken by the Secretariat. WHO also makes publicly available appropriate information on its engagement with non-State actors*."

It is not clear which institution or official has the discretion to decide what goes into the summary report, what standards should be used to identify "appropriate information" on WHO engagement with PSEs, and how officials and/or institutions tasked with this responsibility will be held accountable for their decisions.

The provisions governing contributions from PSEs that have an indirect commercial interest in WHO work are equally problematic. Paragraph 13(d) of the annex states that,

> "*Caution should be exercised in accepting financial contributions from private sector entities that have even an indirect interest in the outcome of the project (i.e. the activity is related to the entities' field of interest, without there being a conflict as referred to above). In such an event, other commercial enterprises having a similar indirect interest should be invited to contribute, and the reason clearly described if this does not prove possible. The larger the proportion of the contribution from any one source, the greater the care that should be taken to avoid the possibility of a conflict of interest or appearance of an inappropriate association with one contributor*."

In this instance, exercising caution thus involves increasing the number of PSEs that participate in decision-making processes in which they admittedly have a commercial interest!

FENSA also allows for entering into official relations between philanthropic foundations and WHO, and for allowing foundations to make contributions to WHO. However it fails to acknowledge that many philanthropic foundations are funded by PSEs which invest in industries that have an adverse impact on health. Paragraph 45 of FENSA says that

"*WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and other non-State actors whose policies or activities are negatively affecting human health and are not in line with WHO's policies, norms and standards, in particular those related to noncommunicable diseases and their determinants*." Paragraph 42 states that *"… Member States have electronic access to a summary report on due diligence of each non-State actor and their respective risk assessment and risk management on engagement*."

Despite these provisions, FENSA provides very little information about how detailed and pro-active WHO investigations into foundations' financing are. It provides no information on the criteria that are used to decide that foundations may enter into official relations with WHO - even when they are financed by PSEs known to invest in industries that are harmful to health.

It is troubling, for example, that the Bill and Melinda Gates Foundation has been admitted into official relations with the WHO despite admitting the fact that it has engagements with industries such as the food, beverage, and alcohol industries, healthcare industry, and the pharmaceutical industry. These industries have a commercial interest in preventing regulations that limit the availability and profitability of health-impeding commodities, and in defending a market-driven model for providing health care. The Foundation's financial statement in the NSA pilot register contains only two entries of total assets and revenue without any further details. It is unclear how the risk assessment, risk management, conflict of interest evaluations, and due diligence procedures took these contradictions into account in deciding that the Foundation should be admitted into official relations with WHO.

The issue of financing should also be given more attention in the rules governing secondment. Paragraph 47 of FENSA states that "*WHO does not accept secondments from private sector entities*". This does not take into account the fact that the work of some private foundations and NGOs may be financed by PSEs that invest in health-impeding industries. The rule presumes that a clear distinction can be drawn between philanthropic foundations and NGOs, and the private sector organisations that control their purse strings.

Key Issues and Recommendations

- Documentation related to financial reports, conflicts of interest, due diligence and risk assessment, such as the summary reports available to Member States, should be made available to the wider public. These reports should also be more detailed than they currently are. **Transparency with respect to these documents is necessary in order for global civil society, the public that will ultimately be affected by WHO policies and programs, to be able to monitor crucial decision-making processes within WHO, a public multilateral body.**

- FENSA **fails to shut the "revolving doors" between government, the private sector, and philanthropic foundations.** There are several instances where individuals who have worked in industries that undermine public health, such as the pharmaceutical, food, beverage, alcohol, tobacco, or medical technologies industries, join the WHO in senior positions. **Such individuals should be subjected to a "cooling-period" where they wait at least three years before joining WHO.**

- **When NGOs, philanthropic foundations, and other institutions are heavily financed by the private sector, secondments from them should be prohibited.**

- The framework **only regulates the Secretariat's engagements with NSAs, but leaves Member States free to advance the interests of private sector entities** through the governing bodies, financing dialogues, and behind closed doors. **FENSA should include regulations that prevent public officials from being captured by private interests and sanction instances where this occurs. FENSA needs to extend to a scrutiny of officials from Member States who are engaged in negotiating norm setting activities of WHO.**

- **We urge Member States to support the 3% increase in assessed contributions proposed by the Director General (document A70_INF2). Recognizing that this is insufficient to challenge the current donor capture of WHO, we further call on Member States to fulfil their responsibilities as members of WHO as a multilateral institution with adequate flexible untied financing.**