Policy Briefs
on Important Issues before EB 140

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CONTENTS

UN High Level Panel on Access to Medicines and related Access to Medicines agenda items

UN High Level Panel on Access to Medicines (UNHLP)

Policy incoherence is a problem affecting all countries

Today, access to medicines issues affect all countries worldwide. Since the harmonisation of patent law with the TRIPS Agreement in 1995, and the persistent challenge to make full use of the TRIPS flexibilities for public health protection in many countries, millions of people have died because of the unaffordability of the medicines they need. Despite developing countries still bearing the biggest burden of access to medicines problem, this is an increasing problem in western countries too. The current regulation on pharmaceutical products has enabled a 55-fold price increase on a 62-year-old toxoplasmosis drug in the US. Treating all Hepatitis C patients with new medicines in some European countries requires the entire national health care budget. Drug rationing is already taking place in countries like the UK.

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. Diagnostics, vaccines and medicines are missing for many diseases affecting patients in both developing and developed countries. The past 10 years have shown that only 25% of new medicines approved on the market provide a therapeutic benefit for patients (Revue Prescrire, 2015). The current crisis of antimicrobial resistance is but one example highlighting the inadequacy of the current R&D system in producing necessary innovation. A patient-driven approach to R&D is needed to address public health needs.

The UN High Level Panel on Access to Medicines (UNHLP)

In November 2015, the 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 represents the consensus reached by the members of the panel, formed by a wide array of experts coming from industry, academics, governments, and NGO backgrounds.

The panel drew upon existing mandates at the WHO and WHO discussions that have been ongoing for over 15 years and are not yet concluded (see CEWG section below). The panel received input from a variety of groups, including governments, industry, academia, civil society and patient groups. In November 2016, the 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.

Key differences between the UNHLP and the GSPOA-CEWG process are: the scope of the UNHLP includes all countries and diseases (instead of focusing on diseases affecting mainly developing countries), and the UNHLP recommendations affect more than one UN body (not only the WHO).

Necessary leadership by the WHO on access to medicines

The UNHLP report is of paramount importance to the work of the WHO and its Member States. Yet, after over 15 years of discussions at the WHO, patients still die without access to necessary medicines. There has not been a dignified Member State discussion of the UNHLP report and its implications at the WHO. The Executive Board rejected SEARO's proposal to include the UNHLP as a separate agenda item in its 140th meeting. Meanwhile, the UNHLP has been addressed at the WTO Trips Council, the WIPO Standing Patents Committee, the UNAIDS Programme Coordinating Board meeting, and it will be addressed at a panel discussion in the UN Human Rights Council in March 2017.

The WHO is the primary global agency responsible for health worldwide and it should therefore see the UNHLP work and its recommendations as an opportunity to revive and facilitate WHO's work on public health, innovation and access. As the eminent jurist Michael Kirby recently 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."*

We urge the WHO to implement the recommendations of the UNHLP and endorse it. We urge Member States to advocate for inclusion of an agenda item in the next WHA for discussion of the UNHLP report.

UNHLP Recommendations

- **Utilising public health-sensitive Intellectual Property Rights**. For example, countries making full use of TRIPS flexibilities, and using licensing agreements that ensure public health returns for publicly-funded research (e.g. non-exclusive licensing, donation of IPR, data sharing, etc).
- **Creating new incentives for R&D,** beyond patent monopolies: coordinating and sustainably financing R&D through innovative models such as milestone and end stone prizes, thus de-linking the costs of R&D from the price of medicines.
- **Negotiating a binding R&D Convention or Agreement**, based on de-linkage and other principles promoting public health, to implements the efforts listed above.
- Ensuring transparency, accountability and governance in the R&D process.

The UNHLP suggests a series of actions for countries, International Organizations, UN agencies and other stakeholders to implement this recommendations. The report was met with hostility by some powerful high-income countries before it was even published. Denying the current imbalance and policy incoherence is the cause of the neglect that is killing millions of patients worldwide. By upholding the current R&D system without addressing its faults, we are neglecting those lives even further. Some countries embrace the report and echo some of its recommendations[1].

We urge Member States to act on the recommendations made by the UNHLP, starting by making full use of TRIPS flexibilities and negotiating an R&D Agreement or Convention. We also urge Member States to undertake a debate at the national level to implement the recommendations.

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

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

Context
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 after from 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.

A key recommendation by the UN High Level Panel on Access to Medicines (UNHLP) report is the negotiation of an R&D Convention or Agreement. This was also the key recommendation of the CEWG report (2012), and it had already been put forth by the reports of the Commission on Intellectual Property Rights, Innovation and Public Health (2006) and the GSPOA (2008).

This recommendation has not been yet addressed. Discussions on the R&D Agreement 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 "remaining issues" in the follow-up to the CEWG report. Despite the R&D Agreement being the main issue remaining, this was again not discussed in the meeting. Equally and unfortunately, there was no mention of this recommendation in resolution **WHA69.23** (2016). Candidates to WHO Director General have provided their vision on moving forward with the R&D Agreement discussion[2].

WHO has a central role in setting norms and standards for public health. However, most of the regulations on health Research and Development are enshrined in trade agreements, such as the WTO Agreement on Trade-Related aspects of Intellectual Property Rights (TRIPs), rather than in health agreements. Moreover, there is a troubling trend with the adoption of so called TRIPs + provisions that undermine the ability of States to adopt and make full use of TRIPS flexibilities to promote public health and access to medicines.

We urge Member States and the 140th WHO Executive Board to convene a meeting in 2017, as proposed by resolution WHA69.23, where the negotiation of an R&D Convention is discussed.

An issue that was not addressed by this various panels of experts but that is raised by the UNHLP report is government's regulation of the way prices of medicines are fixed, including off-patent medicines. **We strongly encourage Member States to adopt regulations that would strengthen their capacity to negotiate affordable prices of medicines.**

Documents EB140/21 and EB140/22
In document EB140/21 the WHO Director General reports on the progress made on 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:

[2]www.thelancet.com/who-dg

- The development of WHO's Global Observatory on Health Research and Development.
- 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.

We welcome the progress made on the items listed above. As EB140/21 outlines, the gap in funding of all these initiatives is over 85% of the required budget. This means that progress has been slow and that not all Demonstration projects have received funding. This lack of funding is a proof that mandatory contributions are needed for sustainable financing, and that designing a pooled fund based on voluntary contributions is a prospect for systematic underfinancing.

While focusing on these initiatives, attention has been drawn away from the key tenet of the CEWG process: the need for a sustainable new way of incentivising, coordinating, financing and regulating Research and Development, not dependent on market incentives, and protecting public health by the legally-binding nature of an R&D Agreement. Insofar as these initiatives do not encourage a paradigm shift, the aims behind establishing the GSPOA and the CEWG will not be fulfilled.

In resolution WHA69.23, Member States agreed on some important propositions that the report by the WHO Director General (EB140/22) has fallen somewhat short in addressing:

- 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 **140/21**). 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.

We urge Member States to promote policy coherence, by advocating for the introduction of the CEWG Principles in all health R&D initiatives, informed by the UNHLP report.

8.1. Human Resources for Health and implementation of the outcomes of the United Nations' High-Level Commission of Health Employment and Economic Growth

Introduction

Agenda item 8.1 titled "Human Resources for Health and implementation of the outcomes of the United Nations' High Level Commission on Health Employment and Economic Growth" is a summary of the Commission's report, with ten recommendations and five immediate actions to be taken for the creation of jobs within the health and social sector. The Commission, chaired by the Presidents of France and South Africa with the heads of ILO, OECD and WHO as Vice-Chairs, submitted its report "Working for health and growth: investing in the health workforce" to the United Nations Secretary-General on 20 September, 2016.

Although the report advances the links between health employment and health systems, its proposals promote the perspective of an investment model rather than a social model where health and access to healthcare is viewed as a fundamental human right. The report makes the case for investment in health work force development due to its perceived contribution to economic growth. While this could be a tactic to encourage more investment on health workforce development, especially by Ministries of Finance, it is unfortunate that the advancement of health is viewed through the narrow lens of economic growth rather than as a social necessity and a fundamental right.

Strong public health systems are critical to ensuring that countries are able to provide quality health care and are positioned to cope with health emergencies. There is clear evidence that better health outcomes are linked to strong public health systems and these require the availability of a range og well trained and resourced health workers. However, globally, there is a continued shortage of health workers which is most marked in Low and Middle Income Countries (LMICs). For countries to be able to cope with health emergencies, strong health systems with appropriate facilities and adequately trained health workers are essential, as was apparent during the Ebola epidemic.

It is a matter of concern that the challenge of addressing the shortage of health workers, and the urgent need to train a variety of health workers, is increasingly sought to be addressed through market mechanisms. Unregulated privatisation of health workforce training can lead to compromised quality of skills and technical competencies of health workers.

While a commitment to stimulating the creation of decent jobs is important, there is also a critical need to guard against the commodification of health employment. There is a trend towards outsourcing and tendering of employment, resulting in precarious conditions of employment with its associated job and financial insecurities. Unfortunately, measures such as contractual mechanisms and outsourcing of health workforce is often advanced as a key recommendation directed at controlling public expenditure on health. It is to be noted that such recommendations have neither been able to bring about better health outcomes in the population nor have improved the conditions of work of the health workforce. **This policy brief makes specific proposals on the recommendations of the UNComHEEG and necessary steps towards implementing these.**

Job creation, job security and working conditions

We welcome the commitment to stimulate the creation of decent jobs. As noted in the introduction, there is however a crucial need to take concrete steps against the commodification of health employment which has resulted in a proliferation of unfair practices, including different forms of contract staffing and outsourcing. Implementing Recommendation 1 of the commission's report therefore requires that governments put in place mechanisms designed towards curbing and indeed eradicating the informalisation of labour relations in the health sector, such as zero hour contracts.

The report underlines the need to ensure the safety and security of health workers in humanitarian and conflict situations, which is important to address. The report also addresses issues such as gender equality and rights, which need to be important considerations. We urge Member States to take cognizance of the UNComHEEG report's recommendation to promote a more holistic approach towards combating workplace violence which is built into a composite strategy for growth of health worker employment.

The lack of regulation of health worker training in most countries is a matter of deep concern. It is important that country governments pay attention to the regulation of health worker training, which is currently being imparted by a variety of actors, including a large number of private for-profit entities. The oversight on health worker training should extend to the training and deployment of Community Health Workers (CHWs). CHWs have different names and roles in different countries. From available evidence it is clear that CHWs are involved in many important public health functions especially in the context of the HRH crisis and, in many situations, are associated with better health outcomes, such as in maternal health, in several LMICs. However in most cases CHWs are not viewed as workers but as volunteers which is exploitative of CHWs and leads to conflicts between paid health workers and volunteer CHWs. We urge the WHO to address issues related to training, deployment and compensation of CHWs and to provide guidance in this respect to Member States.

Health worker migration

The contentious issue of health workers' migration remains a major issue which undermines the development of public health systems in developing countries. The investment by LMICs in the training of health workers with limited local resources may be negated by internal migration resulting in an over-supply of health workers in larger cities and a deficit in more remote locations. This situation is compounded by the steady and often increasing migration of health workers from LMICs to High Income countries (HICs). Consequently some destination high income countries have reduced their investment into training of health workers and are able to source health workers from LMICs. Source countries are thus unable to retain even the workers they invest in training, resulting in a huge loss of public investment, high financial burden and additional stress for HWs who choose to continue to serve in their own countries. Destination countries benefiting significantly by saving on training costs[2]. This phenomenon represents a reverse subsidy of health worker training costs for high income countries, paid by LMICs. There is a clear rationale in LMICs demanding financial compensation from

[2] Global Health Watch 4 B9: The Global Health Workforce Crisis www.ghwatch.org

destination countries for loss of public investment[3]. Governance and financing steps towards addressing this crisis should include[4]:

- Bilateral agreements which integrate cost sharing and reimbursements of countries of origin or through a Global Health Resource Fund (GHRF);

- Sustainable funding mechanism through negotiated taxation which goes into training, recruitment and retaining health workers and strengthening of public health systems.

Funds from these mechanisms could go to support decent working conditions for health workers, including adequate remunerations and improved working conditions in countries of origin to encourage health workers to stay back in their countries of origin; and towards strengthening of public health systems.

Financial and fiscal space

We would like to draw attention of Member States to the Report (p.45) where it says:

"Creating a strong health workforce requires governments to invest in more and better health worker education, lifelong learning and the creation of decent jobs. Such investments, mostly from domestic sources, are achievable in many different country contexts. However, structural reforms including progressive fiscal policies may be needed…. Taxation and governance reforms could potentially stem over US$ 50 billion lost annually from countries in Africa through illicit financial outflows…"

Expanding the financial and fiscal space for countries to invest in the health workforce requires restructuring the international taxation system to capture revenues from taxes that are systematically avoided and evaded. The implementation of tax reforms could significantly provide revenues for government and the health sector should be prioritised for such revenues. These funds could be deployed for investments in health employment and strengthening the public health system as a whole.

The WHO Code of Practice on International Recruitment of Health Personnel

We would like to remind MS of the current state of implementation of the WHO Code of Practice on International Recruitment of Health Personnel. The continued brain drain from LMICs and destabilized public health systems is an indication of the costs of inaction and raise the question whether the voluntary codes have effectively addressed this issue. The voluntary nature of the WHO Code is a concern and as stated in the commission's report, while the code is "maturing" it is not being implemented in most places (weak uptake)[5]. The implementation of the code is critical as a key

[3] Barria, S., Bourgeauli, I L., Labonte, R., Sanders, D. & Van de Pas, R. A Proposal to Optimise the Benefits and Reduce the Harms arising from the International Migration of health workers.

[4] Agwu K & Llewelyn M (2009) Compensation for the brain drain from developing countries. The Lancet, 373 (9676), 1665-166 as cited by Remco van de Pas & Delphine in the consultation of the Commission

[5] MMI PHM Statement at the WHA 68 for agenda item 7.2 on the WHO Code of Practice on the International Recruitment of Health Personnel and WHA 67, Agenda item 15.8 Follow up of the Recife Political Declaration on Human Resources for Health

instrument of governance for health worker migration and MS should institute urgent measures to implement the code. The code is however deficient because of its voluntary nature and its refusal to propose financial compensation to source countries. We urge Member States to make use of the opportunity provided within the Code in article 9.5 ("The World Health Assembly should periodically review the relevance and effectiveness of the code. The code should be considered a dynamic text that should be brought up to date as required"[6]) to commence discussion on compensation and fiscal policies.

Five year implementation plan and uptake of the recommendations

In December 14-15, 2016, a Five-Year Implementation Plan for Health Employment and Economic Growth was formulated in line with the recommendations of the Commission. **The outcomes should ideally be the subject of discussion at the EB-140.** Related to this are the statements of commitments already made (during, for example, the High-Level Ministerial meeting in December 2016). There have been a number of extant commitments made over the years by Member States internationally and regionally. There is the need, thus, for reinforcing mechanisms for accountability to previous commitments as well as the need for generating commitment to the Five-Year Implementation Plan. Most countries especially in LMICs are unaware of the process of the commission and it is a necessary to make it visible at country level. It is important therefore to consider a mechanism for awareness and implementation of recommendations and actions at country level.

We request WHO and Member States to establish necessary mechanisms for ensuring that the Five-Year Implementation Plan is rigorously pursued.

[6] World Health Organisation, WHO global code of practice on the international recruitment of health personnel. Geneva: World Health Organisation: 2010

10.1 Preparation for the third high level meeting (HLM) of the UN General Assembly (UN GA) on NCDs in 2018

Background

The Secretariat report EB140/27 provides an update regarding the lack of implementation of previous commitments regarding NCDs ("In 2015, 138 Member States had shown very poor or no progress towards implementing the four time-bound national commitments for 2015 and 2016)

In EB140/27 the Secretariat also reports on the status of its work on two outstanding assignments given 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) a draft updated Appendix 3 of WHO's global action plan for the prevention and control of non-communicable diseases 2013–2020; and (ii) development of a draft approach 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. The Secretariat also submits for Board consideration a proposed work-plan 2018−2019 for the global coordina on mechanism.

PHM's Comments for Member states to consider

The global governance of non-communicable disease (NCD) prevention and control is characterized by a complex and fragmented institutional landscape and insufficient clarity regarding protections against conflicts of interest. Overlapping mandates and forums complicate global policy- and decision-making in this area. Moreover, the proposed workplan for the Global Coordination Mechanism (GCM) on the Prevention and Control of NCDs for the period 2018–2019 does not sufficiently explain the role of country and regional offices in providing technical assistance. To address this problem, **the Peoples' Health Movement (PHM) urges 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.**

Moreover, as it is inadequately addressed in the workplan, **we call upon Member States to request a formal procedure to ensure that recommendations of the Working Groups are reported to the governing bodies of the WHO.**

In addition to institutional complexity, the ongoing underfunding of WHO's work in NCDs under the Financing Dialogue signifies a lack of interest in and commitment to this issue among donors. In reporting on its governance and technical assistance activities, the Secretariat does not refer to this continued underfunding, obscuring this issue. Additionally, agenda item 10.5 providing a Report by the Secretariat on Cancer prevention and control in the context of an integrated approach clearly depicts the gap in financing for control and prevention between high-income and low-income countries. The report states that only 5% of global resources for cancer prevention and control are spent in low- and middle-income countries, despite most preventable deaths occurring in these countries. However, the report does not articulate required actions for addressing this issue through

sustainable financing and strengthening of health systems by adopting the principle of comprehensive primary health care.

Undue Influence of Private Sector Entities

The role of corporate practices in the harmful health effects of unhealthy commodities (such as tobacco, alcohol, and soft drinks and processed foods that are high in salt, fat, and sugar) have been recognized in the academic literature[7]. Large multinational pharmaceutical companies have also influenced the diagnosis and treatment of NCDs by successfully lobbying to set treatment thresholds so low that people with mild problems or modest risks are exposed to the harms and costs of treatment with little or no benefit[8].

The Secretariat states that the GCM workplan for 2018-2019 aims to safeguard WHO and public health from any undue influence by any form of real, perceived or potential conflicts of interest. Despite this, the GCM workplan does not address the influence of the powerful trans-national corporate actors within the alcohol, food, and beverage industries on WHO and UN policy-making regarding NCDs. Indeed, within agenda item 10.4 on the Implementation plan for the recommendations of the Commission on Ending Childhood Obesity there is a call for 'constructive engagement' with the private sector, without the articulation of clear and explicit guidelines for the prevention of undue influence through that engagement. We urge Member States to request that the GCM be tasked with monitoring potential conflicts of interest in the policy processes associated with the Global Action Plan (GAP) for the prevention and control of NCDs 2013–2020 and related policy areas, as well as advising the DG where conflicts of interest may lead to improper influence in such policy processes. In particular, we urge Member States to request guidance articulating procedures for this monitoring process, taking into account the WHO's framework of engagement with non-State actors (FENSA).

In the context of the potential for undue influence, there is a concerning lack of transparency surrounding the selection of a 'representative group of stakeholders' (paragraph 16 of EB140/27), as well as process and criteria used for the mid-point evaluation of progress on the implementation of the GAP. We urge Member States to request additional information and consider potential conflicts of interest in this process.

Registration of non-State actor (NSA) 'contributions'

In the draft of the approach that can be used to register and publish the contributions of NSAs to the achievement of the nine voluntary targets for NCDs (Annex 2 of document EB140/27), we welcome the stated need for 'protection from vested interests', 'detailed guidelines', 'quality criteria', and 'quantifiable output indicators'. However, in order to protect against undue influence and ensure

[7] Moodie R, Stuckler D, Monteiro C, et al. 2013. Profits and pandemics: prevention of harmful effects of tobacco, alcohol, and ultra-processed food and drink industries. The Lancet. 381 (9867): 670-679.;Stuckler D, McKee M, Ebrahim S, Basu S. 2012. Manufacturing Epidemics: The Role of Global Producers in Increased Consumption of Unhealthy Commodities Including Processed Foods, Alcohol, and Tobacco. PLOS Medicine.

[8] Moynihan, R. (2011) 'A new deal on disease definition', British Medical Journal, 342:d2548.

transparency and accountability, this approach should take into account all contributions of NSAs, including both negative and positive contributions. Moreover, there should be scope for independent registration of contributions. In order to serve as a tool for true accountability and contribute to public policy, registration of contributions should also be comprehensively assessed in order to represent the relevant field as a whole. **Overall, we recommend that Member States assign a very low priority to progressing the development of the self-reporting tool (regarding 'contributions') and the internet platform (for publishing such 'contributions'). If the draft approach is developed further it should be designed to include all contributions, to permit independent registration of contributions, and to provide a comprehensive assessment of a relevant field as a whole.**

Menu of Policy Options and Interventions: Appendix 3 to the Global Action Plan for the Prevention and Control of NCDs (2013-2020)

While we welcome the support for population-based interventions over individual interventions in terms of implications for equality (paragraph 6 of Annex 1 to EB140/27), overall Appendix 3 exhibits an emphasis on behavioural and lifestyle-related risk factors. **We encourage Member States to urge the Secretariat to revise the approach to the prevention and control of NCDs via the policy options and interventions outlined in Appendix 3 and to include interventions regarding the fundamental social determinants of health, robust health systems for continuity of care, and strong regulation of TNCs.**

The addition of taxation measures on alcohol and sugar-sweetened beverages in Appendix 3 are welcome, however we recognize that they may have negative consequences in terms of disproportionate impacts on the poor, in turn exacerbating inequalities. This is also relevant to the policy prescription for the taxation of sugar-sweetened beverages discussed in agenda item 10.4 on the Implementation plan for the recommendations of the Commission on Ending Childhood Obesity. Therefore, these measures should be conditional on the understanding that revenues from these taxes should be allocated to subsidising healthy foods (as recommended in the 'Unhealthy Diet' section of Objective 3 on Risk Factors within Appendix 3), and that they should be accompanied by the regulation of unhealthy food commodities. Moreover, to be consistent with taxation of alcohol and sugar-sweetened beverages, **we encourage Member States to request the addition of a recommendation for taxation of unhealthy food commodities should be added to Appendix 3.**

Currently there is no reference to the regulation of transnational corporations (other than tobacco) within Appendix 3 and in agenda items 10.4 on Ending Childhood Obesity and 10.5 on Cancer prevention and control, which is an essential mechanism for improving health outcomes based on evidence cited above of the detrimental health impacts of their practices. **We encourage Member States to recommend the addition of specific policy tools for the regulation of trans-national corporate actors within the alcohol, food, and beverage industries within Appendix 3, of a mandate to support this regulation for the GCM, and inclusion of these measures in the policy agenda outlined for specific NCD areas such as obesity and cancer. 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.**

Finally, considering the impacts of powerful corporate actors on NCDs, there is an important need to build capacity for protecting health during the negotiation of trade agreements, in particular through guidelines for health impact assessment and the abolishment of ISDS mechanisms within trade agreements which compromise state regulatory functions. Moreover, capacity-building is needed for the full utilisation of TRIPS flexibilities to ensure access to NCD medications, such as costly cancer drugs. Therefore we urge the Secretariat to examine trade and health policy coherence and the development of trade and health policy capacity in further revising Appendix 3.

Framework for Engagement with non-state actors (FENSA)

The FENSA discussion started with a focus on WHO playing a more proactive role in global health governance, and in particular, helping to coordinate the anarchy of multiple 'global health initiatives' providing 'development assistance for health.' It is unfortunate that this element of the WHO reform project has been so completely extinguished. This vision has been completely lost as the focus of the debate narrowed to the Secretariat's relationship with private sector entities. The finalized FENSA framework is long and complicated, and it remains to be seen how it will work in practice; indeed whether it can be fully operationalized in practical terms. The current FENSA framework represents something of a truce between the proponents and opponents of the private sector having a 'seat at the table' of global health governance. The FENSA framework has not provided an excellent security to protect WHO; instead, it legislates undue influence by the corporate and philanthropic sector. The biggest flaw in the FENSA arrangements is that they only deal with the Secretariat's engagement with non-state actors. Member states remain free to advance the interests of private sector entities through the governing bodies, through the financing dialogue, and behind closed doors, with no provisions for public accountability. The issue of "revolving doors" is not addressed at all in FENSA or the current proposed executive board documents.

Concerns on implementation of FENSA

Within the flawed FENSA framework, we have some concerns about the implementation, the structure, and procedures associated with the NSA register (EB140/41). The information deficit on NSAs in Official Relations with WHO (EB140/42); the provisions regarding secondments (EB140/47, listed for discussion under Item 15.3), and the joint action work programs are also major areas of concern. Other areas of concerns are the due diligence and risks assessment and risks management and classification of NSA. The discussion of the arrangements for 'pooled funding from the private sector', which was controversial during the negotiation of FENSA, is not mentioned in EB140/41.

Even though the pilot register is an active development, we note that there is no provision in the pilot entry to display the programs of cooperation, which are crucial to the idea of official relations. If FENSA seeks to provide clarity and transparency information should be made available on how decisions were made to include NSAs in official relations. There is also a lack of information and transparency available about the procedures taken by the Secretariat to address conflicts of interest and risk assessment and risk management and due diligence. Paragraph 45 of FENSA states "WHO will exercise particular caution, especially while conducting due diligence, risk assessment and risk management, when engaging with private sector entities and NSA 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 non-communicable diseases and their determinants." The same document states in paragraph 42 that "the Member States will have electronic access to a summary report on due diligence of each NSA and their respective risk assessment and risk management on engagement." Information on due diligence risks assessment and risks management are important indicators or evidence that the principles and rules set out in FENSA were followed, and so we call for transparency on these issues.

The lack of information on the joint action work plan raises concern and we urge Member States to address this issue. Under the FENSA framework, the joint action work plan for collaboration between WHO and the entity applying for official relations is fundamental for entering into official relations. The joint action work plan for the collaboration between WHO and the entity applying for official relations is a crucial condition and accordingly needs to be assessed by the Member States because a joint work plan bears the risk of drawing up a work program that involves conflicts of interest or is against the provisions of FENSA. In the past, joint work plans have shown conflicts of interest, and activities involving norms and standard setting. Paragraph 5 of FENSA lists the overarching principles of engagement. One of these is to "protect WHO from any undue influence, in particular on the processes in setting and applying policies, norms, and standards." Even though the secretariat has acknowledged its mistakes and has agreed to release the information on the joint action work plan, it leaves member state with a very short period for critical analysis of the document.[9]

NSAs in Official Relations: Current proposals

The Executive Board have decided to admit into official relations with WHO the following NSAs: Bill & Melinda Gates Foundation; Grand Challenges Canada; International Rescue Committee; Knowledge Ecology International; and The Fred Hollows Foundation. It will discontinue official relations with Inclusion International; Inter-African Committee on Traditional Practices Affecting the Health of Women and Children; International Centre for Trade and Sustainable Development; World Association for Psychosocial Rehabilitation; and World Association for Sexual Health. The Board also decided to maintain official relations with 58 NSA, the plans for collaboration is yet to be agreed. The Board has also decided to defer the review of relations of other entities until the 142nd session of the Board in January 2018, at which time reports should be presented to the Board on the agreed plans for collaboration and the status of relations.

In agreement with FENSA, the Board through PBAC shall consider collaboration with each non-State actor official relations every three years and shall decide on the desirability of maintaining official relations or defer the decision on the review of the following year.

The Board's report shall be spread over a three-year period with one-third of the entities reviewed each year. The Board may discontinue official relations if it considers that such relationships are no longer appropriate or necessary in the light of changing programs or other circumstances. The board may also suspend official relations if an organization no longer meets the criteria that applied at the time of the establishment of such ties, fails to update its information and report on the collaboration in the register. During 2014-2016, the Secretariat has reviewed 74 non-State actors and WHO's collaboration.

Currently, there are five NSA applying for officials relations and 58 others which are proposed for renew relationships, and importantly the joint collaborative work program state that WHO should not be in commercial relations. Alarming and controversial are some organizations applying or are in officials associations are involved in business activities, a public-private partnership. There are other

[9] TWN Info Service on Health Issues, 19 January 2017, Third World Network, http://www.twn.my/title2/health.info/2017/hi170102.htm

issues on disclosure of financial resources and declaration of interests. Some NSA engagement with the nutrition and pharmaceutical industries and private for-profit entities raises the alarm. What is stated in the FENSA framework should not be bypassed.

Concerns regarding approval to Gates Foundation to be in official relation with WHO

The joint work plans for NSA currently seeking official relations with WHO raise some concerns. One example is the Bill and Melinda Gates Foundation. Bill and Melinda Gates Foundation is the leading actor in global health, it spends extensive resources on global health programs and has a significant agenda setting power in global health governance. This foundation is the largest non-state founder of the WHO and the second largest donor after the USA; they are also the driving force behind public-private partnerships (PPP). Their primary focus is biomedical solutions, vaccines to the rescue: a quick-win solution to global health challenges such as malaria, HIV/AIDS, and tuberculosis.[10] Intriguingly, the Gates Foundation financial statement in the NSA pilot register contains only two entries of total assets and revenue without any further details.

The level of information provided is in contrast with many other entities found in the WHO's Register of NSAs. Bill & Melinda Gates Foundation states in the NGO registry that it has engagements with the food and beverages industry, health care industry and pharmaceutical industry. Concerning food and drinks industry the Gates Foundation has invested heavily in modern technology to boost food production. The increased use of genetically modified seeds on the African continent has raised a lot of concerns and criticism from different quarters. The Gates Foundation also receives revenue from equity in Coca-Cola, a product that has direct conflict with the notion of nutrition.

EB 140/47 states that there should not be secondments for higher positions or "sensitive posts," but this is not defined. Clarifications are necessary regarding what the definition of a 'sensitive position' and regarding what constitutes a managerial positions. FENSA states that there should not be secondments from the private sector. When NGOs, philanthropic foundations, etc. are classified as private sector due to their funding, there should also not be any secondments from them. There are also issues with former pharmaceutical officials joining the WHO in senior position. There should be at least a three-year period 'cooling period' between working in the private sector and holding a key position in the WHO.

When a flawed framework is used to assess something as crucial as WHO relations with non-state actors, there's a substantial risk of not being able to manage conflicts of interest adequately. The adoption of FENSA accomplished the political task of instituting the concept of 'multi-stakeholderisation' within the functioning of the WHO by bringing in private entities as part of the governance mechanisms of WHO. Instances of private sector influence on WHO's norm setting work was already in vogue before the adoption of FENSA. FENSA, unfortunately, has legitimized this practice. We urge the WHO to develop a robust framework for an agreement with private actors to protect the organization from conflict of interest. The framework should ensure that donations go to WHO programs goals rather than in shaping programs to meet donor's interest. The framework should also oversee how philanthropic foundation operates and how they meet the long-terms goals of WHO.

[10] Martens, J et al. (2015). Philanthropic power and development, who shapes the agenda? Published by Misereor, GPF, and Brot.