



PHM Policy & Press brief compilation document for the 138th Session of the Executive Board of the World Health Organisation

Geneva: January 2016

The policy briefs set out below have been prepared by the People's Health Movement as a contribution to Member State deliberation during the 138th Session of the Executive Board meeting of the World Health Assembly.

PHM is a global network of organisations working locally, nationally and globally for Health for All. Our basic platform is articulated in the [People's Charter for Health](#) which was adopted at the first People's Health Assembly in Savar in Bangladesh in December 2000. More about PHM can be found at www.phmovement.org.

PHM is committed to a stronger WHO, adequately resourced, with appropriate powers and playing the leading role in global health governance. PHM follows closely the work of WHO, both through the Secretariat and the Governing Bodies. Across our networks we have many technical experts and grassroots organisations who are closely interested in the issues to be canvassed in the Eb138 debates.

PHM is part of a wider network of organisations committed to democratising global health governance and working through the WHO Watch project. More about WHO Watch at: www.ghwatch.org/who-watch.

PHM representatives are attending the Assembly and will be pleased to discuss with you the issues explored below.

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OPEN LETTER: Civil Society has no confidence in the stalled Framework for Engagement with Non State Actors process

Geneva, 25 January 2016

Dear Members of the Executive Board,

We the undersigned members of public interest non governmental organisations, civil society organisations and social movements wish to address you on the critical issue of the integrity, independence, and credibility of the World Health Organisation (WHO) and its ability to fulfill its constitutional mandate. We reaffirm and value WHO's unique role as the world's highest international public health authority, and over the past four years we have closely followed the deliberations of the WHO governing bodies related to what has become known as a Framework for Engagement with Non State Actors (FENSA).

We appreciate the efforts of Member States who were engaged in the negotiation process of the Open Ended Working Group who have tried to strengthen the document. However, the most recent draft of the Framework, instead of providing robust safeguards to protect WHO, legitimises undue influences by the corporate and venture philanthropic sector.

Principle of Inclusiveness

The principle of 'inclusiveness' when applied to major transnational corporations, their business associations and philanthropic foundations raises ethical issues including, but not limited to, conflicts of interest. Adoption of a principle of inclusiveness would reinforce the framing of public health problems and solutions that favour the interests and agenda of those actors.

Furthermore an inclusiveness principle poses a new and serious threat to WHO's independence and integrity. It contradicts the basis of all conflicts of interest policies which, in order to be effective, must consider which actor to exclude, when and why. This has made it impossible to reach agreement on the conflict of interest section. Conflict of Interest policies should be based on the principle of vigilance and arms length interactions, and do not preclude interactions between WHO and corporate actors, but would ensure they are appropriate.

The overarching Framework treats public interest actors, who are guided by a public health mission, and private entities, guided by market profit-making logic on an equal footing. This problem is one of FENSA's fundamental flaws and is at the heart of our concern.

Official Relations Policy

A related and equally serious concern is the inclusion of an Official Relations Policy which proposes wholesale admission of International Business Associations and philanthropic entities, with a highly problematic conditionality that such entities have a workplan with WHO. This builds in risks for undue influence.

The Way Forward

We call on you as EB members, who have an obligation to protect the right to health of people, to task the OEWG to:

- Do an in-depth review of the adequacy and implementation of existing relevant WHO policies. In particular the WHO Guidelines on Interaction with Commercial Enterprises and the 2010 policy on WHO's Engagement with Global Health Partnerships and Hosting arrangements in order to establish whether FENSA strengthens or weakens safeguards.

- Start work on a comprehensive and effective COI policy for WHO, including whistleblower protection, as well as other such essential safeguards addressing risks of secondments, and the ‘revolving door.’ Such a policy is a prerequisite, before any rules on interactions with any external actor are framed and developed.

Finally we ask all Member States to transparently evaluate the FENSA process and clarify its purpose. The WHO secretariat and some Member States seem to hope that FENSA will help address WHO’s financial constraints. This is a misplaced expectation. We stand united in calling on Member States to increase assessed contributions for WHO’s core work. This is an underlying determinant that FENSA can never address. This limitation has fuelled WHO dependency on earmarked voluntary contributions from major donor states, private sector and philanthropic entities. Member States must consider the legitimacy of corporate funding of WHO and the impact of this model on WHO’s constitutional mandate and functions.

Unless the concerns outlined above are taken on board, we are convinced that WHO will be relegated to play a subordinate and ineffective role in what is becoming a ‘stakeholderised’ global health architecture. It will fundamentally undermine the agency’s capacity to set norms, standards and regulations in the public interest.

This letter is endorsed by the following organisations:

- Anti Drug Abuse Association of Lesotho
- Association of Breastfeeding Mothers (UK)
- Associação Mama Mater/IBFAN Portugal
- Baby Milk Action IBFAN-UK
- Bangladesh Breastfeeding Foundation
- Blue Cross Norway
- Blue Cross Thaba Bosiu Centre
- Borstvoeding vzw (Belgium)
- Centre for Health Science and Law
- Centre for Science in the Public Interest (Canada)
- Centro Internazionale Crocevia (Italy)
- Corporate Accountability International
- Déclaration de Berne – Berne Declaration
- European Alliance of Lactation Consultants
- Feminist Center for Information and Action (Costa Rica)
- FIAN International
- First Steps Nutrition Trust (UK)
- Geneva Infant Feeding Association
- Health Action International
- Health Equalities Group (UK)
- IBFAN Italy
- IBFAN-Sumy group, Ukraine
- IFARMA Foundation (Colombia)
- INFACCT Canada/IBFAN North America
- Institute for Socioeconomic Studies INESC – Brazil
- Institute of Alcohol Studies (UK)

- International Baby Food Action Network
- International Blue Cross
- International Code Documentation Centre (Penang Malaysia)
- IOGT International
- Iniativ Liewensufank
- Lactation Consultants of Great Britain
- Medico International
- Medicus Mundi International
- Network Health for All
- Observatory for food and nutrition security policies (OPSAN/UNB) University of Brasilia
- Peoples Health Movement
- Proyecto Alimento – Mexico
- Reference Centre on Food and Nutrition Security (CERESAN), Rural Federal University of Rio de Janeiro, (Brazil)
- Royal College of General Practitioners (UK)
- SAAPA Lesotho
- Soul City Institute for Health and Development Communication, South Africa
- Society for International Development
- Southern African Alcohol Policy Alliance
- The East Africa Alcohol Policy Alliance
- Third World Network
- Transnational Institute, Amsterdam
- UK Health Forum
- UK Association of Milk Banks
- Wemos Foundation
- World Obesity Federation

10.3 Follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

This agenda item is addressing how to find a solution to the market failure in R&D. For many years discussions have been taking place in WHO to develop a R&D framework to address the unmet Health R&D needs of developing countries. The current patent driven R&D framework fails to attract R&D investment in diseases and conditions predominantly affecting poor populations, due to their lack of capability of paying exorbitant prices. The process discussed is a follow up to the **Commission into IPRs, Innovation and Public Health** (2006) and the **Global Strategy and Plan of Action on public health, Innovation and Intellectual Property** (GSPOA) in 2008. The Consultative Expert Working Group (CEWG) was established under Element 7 of GSPOA. The CEWG report on R&D Coordination and Financing made a set of recommendations with the objective of creating an R&D framework with sustainable and predictable financing to meet health R&D needs of developing countries. The report presented in 2012 contains the following recommendations: 1) all countries should commit to spending at least 0.01% of GDP on government funded R&D to meet the health needs of LMICs, 2) the establishment of an international legal instrument for supporting health need-driven R&D, 3) the establishment of an R&D observatory to monitor R&D efforts and identify gaps. The recommendations of the CEWG are relevant to address the market failure in health R&D.

An Open Ended Working Group was convened in 2012 which decided to implement part of the recommendations i.e establishment of an R&D Observatory. However, there was no consensus with regard to work towards the establishment of the international legal instrument. The Working Group recommended to WHA through EB to hold another open ended meeting prior to 2016 WHA. The WHA 66.22 provides the following mandate to the working open ended meeting: *“To convene another open-ended meeting of Member States prior to the Sixty-ninth World Health Assembly in May 2016, in order to assess progress and continue discussions on the **remaining issues in relation to monitoring, coordination and financing for health research and development**, taking into account all relevant analyses and reports, including the analysis of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination.”*

Thus the open ended meeting is to address the remaining issues in relation to **monitoring, coordination and financing for health research and development including CEWG recommendation on the internal legal instrument**. However, the proposed agenda of the open ended meeting prepared by the Secretariat (Annex of EB138/39) does not contain the second element of the mandate provided under WHA 66.22 i.e. remaining issues in relation to monitoring, coordination and financing for health research and development. **Therefore the member States are requested to demand the modification of the agenda to reflect the mandate provided under resolution 66.22. We believe the meeting must include civil society actors.** The Secretariat’s proposal to establish a pool fund based on voluntary contribution is not part of CEWG recommendations, and it is unsustainable and unpredictable. The underfunding of the demonstration projects clearly shows that voluntary funding cannot resolve the problem of sustainable and predictable R&D funding to address market failure in health R&D. The fragmentation of efforts into an Observatory, the R&D Blueprint and demonstration projects will not address market failure of R&D for health needs unless accompanied by an legal instrument or R&D framework and sustainable financing.

Annex - Progress made (EB138/39): Fragmentation of efforts and insufficient funding

Director General explored options for a pooled R&D fund (Para. 9) hosted by TDR. As reported in A68/34, the fund would finance R&D projects to address priority research gaps as identified by the Global Observatory and a coordination mechanism. We appreciate that the pooled fund would utilise an open approach, de-linkage mechanisms, and would ensure that health technologies would be accessible to those in need. However, the activities concerning the fund would be subject to the availability of new funding (EB138/39), and fundraising would be the responsibility of WHO (A68/34). Voluntary contributions as the currently proposed mechanism to finance the pooled fund will make it unsustainable and therefore render its principles meaningless. The current gap to finance the voluntarily funded observatory and demonstration projects stands at US\$ 75 million, of the US\$ 85 million financial requirement for 2014-2017 (Para. 8, EB138/39). Only three of the six demonstration projects selected received funding (Para. 6). The creation of an unsustainable fund within an existing UN programme does not align with the **original mandate of the GSPOA**, nor does it follow the **recommendation of the CEWG**. It does not comply either with **resolution WHA66.22** which endorsed a “strategic workplan to improve monitoring and coordination, and to ensure sustainable funding for health research and development”. **We urge Member States to consider mandatory contributions to finance the pooled fund for R&D.**

We thank and appreciate the **R&D blueprint for action to prevent epidemics**. However, we doubt that it is fit for purpose in its current state: without mandatory contributions and without taking into account CEWG recommendations. We hope the R&D blueprint does not deviate the attention from the evident need of a coherent global framework to address the health needs for which market incentives fail. These needs stretch far beyond the health technologies required in emergency response to epidemics. We thank and have hope in the **UN High Level Panel on Access to Medicines** convened by the UN Secretary General in November 2015 with the purpose “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.” We hope it reconciles the so far failed promise of the GSPOA of “developing and delivering affordable, effective and safe health products for which existing market mechanisms fail to provide incentives for health research and development”, which will only be made possible through the commitment to adequately funding a mandatory fund, free of conflicts of interest, coordinated through an R&D Agreement or framework.

Nevertheless, it is important to note that the **recommendations of the CEWG** are the result obtained after four working groups already 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 recommendations clearly propose an R&D Agreement as the way to truly address the roots of the access and innovation crises in global health that we are witnessing today. Whilst we welcome the progress made, unless these fragmented efforts come together under a binding R&D Agreement or Convention supported by mandatory contributions, the WHO will not achieve the goals set out by the GSPOA nor advance the discussion that has not been resolved since CIPH (2004). The need for an R&D Agreement has been stressed by over 300 academics so far including Nobel laureates: <https://uaem.wufoo.com/forms/make-medicines-for-people-not-for-profit/>

We hope Member States ensure the High Level Panel takes cognisance of the GSPOA and CEWG process. We urge Member States to address the root causes of the WHO discussions since 2004, which have now been extended to the UN, and advocate the recommendation of funding a mandatory fund through an R&D Agreement. We would like to remind Member States that **Article 19 of the Constitution of the WHO** states that “two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

10.2 - Comprehensive evaluation of the Global Strategy and plan of action (GSPoA) on public health, innovation and intellectual property, progress update

It is fundamental that we recall the **original goal of GSPoA**: the promotion of new thinking on innovation and access to medicines, and an enhanced and sustainable basis for **needs-driven** essential health research and development, relevant to diseases that disproportionately affect developing countries. It is also useful to recall that the GSPOA was initially prompted by the struggle on intellectual property (IP) and on the use of TRIPS flexibilities. GSPOA contains 8 elements: Prioritizing research and development needs, promoting research and development, building and improving innovative capacity, transfer of technology, applications and management of intellectual property to contribute to innovation and promote public health, improving delivery and access, promoting sustainable financing mechanism and establishing monitoring and reporting systems.

Furthermore, it is also important to recall a fundamental recommendation contained in the GSPOA: **to consider the adoption of an internationally binding instrument on health and biomedical Research and Development**, a recommendation also submitted by the CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health) and the CEWG (Consultative Expert Working Group) in order to address the current disruption of the R&D system.

According to the initial GSPoA project, an overall programme review has to be undertaken on its achievements, remaining challenges and recommendations (**WHA62.16**). The report on the overall programme review has been delayed until 2018 and the evaluation, which should have occurred after the completion of the first implementation period of GSPOA, has been prioritized. This has been explained in the report of the Secretariat (**EB133/7**), in which it proposed “*an approach of combining the evaluation and the overall programme review into a single instrument*”. In fact, this constitutes a delaying tactic: the evaluation and the overall programme review have not had the same scope: the evaluation, which will be conducted under the WHO Evaluation policy, is based on performance guidelines (funders targeted), when the review would have qualitative outcomes (level of implementation).

In line with resolution **WHA68.18**, the Secretariat submitted a report to EB (**EB138/38**). This report provides an update on progress made in relation to the evaluation and giving details of both the key points from the inception report and the response of the evaluation management group. It further develops the composition of this group and gives information on the nomination of the independent evaluator. There is also an additional short report, containing the key points from the inception report and comments from the ad hoc evaluation management group (**EB138/38 add. 1**).

An inclusive and transparent evaluation free from conflicts of interests

Neither the report (**EB138/38**) nor the addendum to the report (**EB138/38 add.1**) mention the identity of the “independent” evaluator. The evaluation and the overall programme review of the GSPoA must be done in a transparent manner. It is important to disclose the identity of the independent evaluator.

A comprehensive, transparent agenda and methodology

In order to ensure a transparent and comprehensive process, the Secretariat should provide further

information on the methodology used for the evaluation and the overall programme review, and clarify certain terms of references contained in resolution WHA68.18.

A broad evaluation as a fundamental step for effective implementation

The evaluation should be broad and focus on the implementation of GSPOA by WHO, at national, regional and global levels. Only such an evaluation can inform the Member States of the gaps and challenges in the implementation and strengthen the implementation in the coming years.

Action to be taken by Member States

Member States should:

- Ensure that the evaluation effectively addresses the implementation of Element 5 of the GSPoA, on the application and management of IP to contribute to innovation and promote public health;
- Call for a transparent and an inclusive process of evaluation of the GSPoA, free from conflicts of interests;
- Demand further information on the methodology used for the evaluation, clarify certain terms of references contained in resolution WHA68.18 and request for more details on the agenda of the overall programme review;
- Demand a broad evaluation and overall programme review (in accordance with the terms of the resolution WHA62.16), which would be focus on implementation at all levels and can inform Member States of the gaps and challenges in the implementation;

10.5 Addressing the global shortages of medicines, and the safety and accessibility of children's medication

The board is asked to consider EB138/41 which combines two distinct issues of “global shortage of medicines” and “safety and accessibility of children's medication”.

Scope and conflation of terms

In Paragraph 20, the use of the word “stockouts”, conflates issues related to stockouts and shortages. The two have very different causes and solutions. Stockouts are not absolute shortages but can represent a failure of healthcare and supply systems to deliver existing medicines to the populations in need. They can result from inadequately resourced health systems, inappropriate procurement policies, supply chain or management failures, as well as international sanctions imposed on countries.

Despite acknowledging that “High-income, middle-income and low-income countries all may have different reasons for shortages” later in the report, paragraph 1 is quick to detail the “common denominator” for these shortages using data purely from the United States. This scope is insufficient, and cannot be extrapolated to other countries which experience different causes for shortages. It paints a misleading view of the issue globally. Furthermore the analysis that shortages affects “mostly off-patent” medicines does not take into account the vast shortages of medicines typically caused by exorbitant prices of on-patent drugs.

Monopolies and competition

Although the report notes that “limiting competition can also result in problems with supply” it does not identify monopolies held by few pharmaceutical companies which collude to drive up price, as a cause of shortages of medicines. Another unidentified cause is the active creation of shortages by pharmaceutical companies to shift doctors and healthcare providers from prescribing a more affordable generic drug to using expensive branded versions at the expense of patients' health and financial sustainability of health systems. Shortages of off-patent medicines are also created by pharmaceutical companies to extend patents on a class of drugs by actively patenting small variations of the original drug (a practice that is known as ever-greening).

Advanced Purchase Commitment

With regards to suggestions of advanced purchase commitments we stress that these are only relevant in emergency situations and does not constitute sustainable procurement policy. Advance purchase commitments serve to perpetuate high monopoly prices and dis-incentive competition local generic manufacture. Such a measure which, in turn, hinders access and constitute use of “perverse incentives to use expensive products [which] may also lead to shortages of low-priced alternative treatments” (paragraph 5).

Also problematic is the suggestion in the document that shortages are a result of pricing policies. While this could be the case in a few situations, this is too sweeping a statement and could serve to have a chilling effect on the legitimate efforts in many countries – both HICs and LMICs – to impose price controls on essential medicines in order to reduce runaway increases in healthcare costs and to rein in profiteering by pharmaceutical companies.

Mandatory notification is an appropriate and necessary tool and manufacturers are, due to their position at the beginning of the supply chain, in the best position to notify of upcoming shortages. It is important to note that, whilst legal obligations to notify are necessary, these mechanisms only work if the penalties associated with non-compliance are high.

Children medication

The lack of transparency of the costs of biomedical research and development is a deep concern and we welcome the suggested “analysis and understanding of costs of research and development for medicines for uncommon diseases in children” so long as this is done by truly independent evaluators utilizing a transparent process. We urge MS to develop a comprehensive strategy in this regard, and not one limited to children medication. It is a concern that pharmaceutical companies use infant and child dosages to practice ever-greening and ensure higher prices under additional patents.

Local manufacturing

We are concerned by suggestion (e) as it does not specify what is meant by “centralized negotiation” and the terms “fair price” and “minimum volume” may easily be misused in negotiations with pharmaceutical manufacturers. WHO can provide valuable data and technical assistance to support local manufacturing, especially in developing countries, so that they can produce medicines and make medicines more affordable by promoting the registration of generic medicines. The support and creation of regional and sub-regional production hubs would allow local manufacturers to take advantage of economies of scale and this is an area where the WHO can play a supporting role.