Health for All Now!
People's Health Movement

# Policy Briefs
## on Important Issues before WHA 69

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

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## Proposed Framework of Engagement with Non-State Actors (FENSA) [1]

We, the undersigned Civil Society Organisations (CSOs), believe that the independence, integrity and credibility of World Health Organization (WHO) are non-negotiable for the fulfilment of its constitutional functions. Actions of a few dominant donor countries, venture philanthropy foundations with large conflicted investments, private sector and private sector influenced NGOs and entities erode WHO's capacity to do its job.

The existing safeguards – to protect WHO from undue influence and to avoid or properly resolve conflicts of interest – are not sufficient and have been inconsistently enforced. That is why we, public interest advocates from civil society, stand ready to support the development of a robust effective framework to regulate relationships with non-state actors (NSAs). The on-going negotiations on the *Framework of Engagements with Non-State Actors* (FENSA) could have been an opportunity to adopt such a framework.

We fear that the upcoming FENSA negotiations during the World Health Assembly may be used by certain Member States (MS) to further dilute the existing policies regulating the engagements with the private sector and weaken stronger provisions that have been negotiated so far.

Compared to existing measures, the current draft FENSA does bring certain improvements. For example, proactive disclosure of financial contributions and the prohibition of secondments from the private sector. However, **major concerns are left unaddressed**:

1. FENSA, in its overarching section puts private sector entities on an equal footing with other NSAs, failing to recognize their fundamentally different nature and roles. It uses the principle of '*inclusiveness'* for all five *"types of interactions"* (resources, participation, evidence, advocacy and technical collaboration) to all NSAs. When applied to major transnational corporations, their business associations and philanthropic foundations, this categorization of interactions, combined with an alleged right to inclusiveness, will once and for all, legitimize the framing of public health problems and solutions in favor of the interests and agendas of those actors.

2. FENSA proposes technical collaboration with the private sector, including capacity building, with no adequate safeguards. Similarly, there is opposition from developed countries to a clause which would exclude provision of resources from the private sector for activities such as norms and policies development and standard setting. FENSA removes the existing minimum restrictions on accepting financial resources from the private sector to fund the salary of WHO staffs. If the WHO relies on funds from the private sector for *any* operational expenses, it risks showing favouritism toward those sectors in its standard-setting, expert-advisory, and other public health functions.

3. FENSA's proposal to expressly allow business interest groups to officially participate in WHO governance through *"Official Relations,"* will legitimize lobbying of business associations and philanthropic foundations at WHO governing bodies now under the

[1] This brief is informed by a civil society statement signed by several organisations that have an interest in maintaining WHO's independence and integrity

label of non-state actors, normalizing the inclusion of business agendas into public health decision-making. This seems in direct contradiction with FENSA's stated principles that any engagement must *"protect WHO from any undue influence, in particular on processes in setting and applying polices, norms and standards*"; and *"not compromise WHO's integrity, independence, credibility and reputation."*

4. Member States have so far failed to rectify FENSA's **flawed definitions and conceptualization of conflicts of interest.** Thus FENSA ignores the prime purpose of institutional conflict of interest policies that is to ensure that "*an institution's own financial interest"* and those of its senior officials do not *"pose risks to the integrity of the institution's primary interests and missions."* FENSA blurs the distinction between a conflict of interest, which is *within* an actor or institution, with *"conflicting or diverging interests" between* actors. The issue of conflicting interest is, of course, important. But it has to be dealt with through robust risk assessment measures and political debate. **Had the correct conceptualization been applied throughout the entire FENSA process, the document would have taken a different form.**

5. We fear that FENSA's poor conceptualization will be transferred to and felt at national level and that it will be used to redefine national rules, undermining any chance of effective safeguards.

6. Some Member States that resist the development of strict conflict of interest rules for WHO have developed relatively strict conflict of interest policies, e.g. to prevent industry from unduly influencing regulators and elected officials in their own jurisdictions. For example, OECD Member States have committed to follow the *OECD Guideline on Management Conflict of Interest in Public Service* at the domestic level are now obstructing the development of a WHO comprehensive conflict of interest policy. Similarly, the UK National Institute for Health and Care Excellence (NICE) prohibits involvement of any experts from the private sector, yet the UK delegation resists inclusion of such a provision in FENSA. Canada's Federal Government prohibits financial contributions by corporations to political parties and limits the amount of contributions by individuals and makes bribing government officials a criminal offense punishable by up to five years of imprisonment. **Member States must shed such double standards.**

7. Finally, we note that, referring to the 2030 Agenda for Sustainable Development, at the last minute some Member States inserted into the draft Resolution and the FENSA document, references to *"multi-stakeholder partnerships."* Yet the entire FENSA fails to address how WHO should appropriately approach public-private hybrid entities, which undoubtedly create avenues for undue influence on policy-making. The OECD Guidelines have highlighted public-private partnerships, sponsorships and lobbying as particular "at risk areas" for conflicts of interest.

We call on Member States to:

- **Not approve a faulty FENSA at WHA**: This process will define the role of our highest global authority in public health for years to come and needs to be done correctly.

- **Evaluate the process,** re-open transparent debate, clarify concepts, obtain missing evidence, including from WHO civil servants and public interest advocates, do an in-depth review of the adequacy of existing relevant WHO policies. WHO must emerge from this process as an agency able to fulfill its mandate.
- **Stop developing FENSA under two contradictory objectives:** both as an instrument to attract voluntary financial resources for WHO and, at the same time, as a safeguard to protect its mandate. It can't be done. If WHO is to fulfill its constitutional mandate, Member States must find other financial solutions. The freeze on assessed contributions must be lifted and Member States must increase their levels of funding. This would end WHO's dependency on voluntary, often earmarked and volatile contributions. It would resolve the most important – financial - institutional conflict of interest of WHO and at the same time prevent wasting resources on implementing an ill-conceived FENSA.
- **Strengthen rather than weaken the safeguards against undue influence from the private sector:** At the very least, FENSA should not dilute the existing WHO safeguards contained in policies regulating WHO's relations with NGOs and the private sector. FENSA should acknowledge the especially high risks posed by interacting with food, baby food, alcohol, pharmaceutical, medical technology, and tobacco industries in all WHO work.
- **Strengthen these safeguards by developing a comprehensive and effective conflict of interest policy**: If conflicts of interest had been effectively addressed, some of the recent public health emergencies would have been dealt with more efficiently, moreover also saving public resources.
- **Fully protect WHO from the undue influence of venture philanthropy and corporate funding:** WHO should be fully funded by Member States. In addition, FENSA should set out clear rules regarding acceptance of cash or in-kind contributions from these NSAs, recognizing that such forms of funding to WHO also risk unduly affecting WHO's integrity, independence and effectiveness in fulfilling its mandate.
- **Protect the Integrity of Official Relations:** Ensure that the Official Relations policy is adequately discussed after this WHA so that it becomes a safeguard against undue influence, not a wide open lobby channel to influence the work of WHO governing bodies.

# Human Resources for Health

## INTRODUCTION

Governments have the core responsibility for education and employment in the health sector and the ultimate accountability to ensure the human right to health through universal access to health care, founded on availability, affordability, acceptability and quality.

The Global health workforce crisis is evidenced by the shortage of human resource for health. It is estimated that by 2035, 107 countries will be affected by a cumulative deficit of about 12.9 million skilled health professionals.

Given the demands of achieving the Sustainable Development Goal of ensuring "healthy lives and promot(ing) well-being for all at all ages"(SDG3), work in health will require major transformations, including substantial increases in the numbers of healthcare workers. Notwithstanding technical advances, health care will remain a labour intensive sector. MS have committed to a target (under SDG3) to "Substantially increase health financing and the recruitment, development, training and retention of the health workforce in developing countries…".

The discussion under agenda item **16.1. Health workforce and services** occurs within this context. This policy brief makes specific proposals on two documents under this agenda item, namely the **Draft global strategy on human resources for health: workforce 2030** (document A69/38) and the **Framework on integrated people-centred health services** (document A69/39 and resolution EB138.R2). Please note that the having strong health systems and health workforces in place are interlinked with many items of the WHA agenda.

## A. DRAFT GLOBAL STRATEGY ON HUMAN RESOURCES FOR HEALTH: WORKFORCE 2030

### Best health outcomes are reached through public health systems

While more than half of document a69/38 addresses the 'current challenges and solutions'(paragraph 7 to 20), the document fails to address the crucial question of the nature of the health system in which health workers provide care. There is enough evidence to show that the best health outcomes are reached through investment in public health systems. We urge MS to demand that this be recognised, as well as included as an element of Objective 1 and included as a milestone that will guide priority setting, including in terms of access to health. We urge MS to promote equitable access to health care by investing especially in health workers at primary and community levels and in community structures to facilitate citizens' voices, under Objective 2.

### Intrinsic value of a competent health workforce

The draft global strategy is very weak on implementation. There is intrinsic value in a competent workforce in improving health outcomes, reducing health inequalities and assuring the right to health. In addition, HRH are a necessary component of the much debated global health security, as suggested by a recent editorial in The Lancet[2]. Despite the

2 The Lancet, No health workforce, no global health security, 21 May 2016, http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)30598-0/fulltext?elsca1=etoc

importance of training and retaining a competent workforce, the strategy does not propose a mechanism that would ensure that health workforce training and health system strengthening is guided by the commitment to implement the right to health and SDG3. Relying on an instrumentalist, utilitarian argument regarding the role of health workforce in economic growth and labour markets to drive implementation is a risky alternative. We urge MS to include an implementation mechanism in the strategy that does not leave the expansion and allocation of health workforce to the labour market but gives a clear role to the public sector in health workforce, education, development, distribution and management in health care provision'

**Importance of a binding instrument**

We believe that the strategy is at risk of non-implementation. There have too often been gaps between policies and their implementation and the experience of previous initiatives needs to be examined. For example, the fundamental shortcoming of the WHO Global Code of Practice on International Recruitment of Health Personnel are the lack of provision for financial compensation to sending countries and its status as a legally non-binding instrument. We urge MS to ensure that the **Global strategy on human resources for health: workforce 2030** is a binding instrument with a strong implementation mechanism.

**Adequate Financing**

The draft strategy proposes "adopting innovative financing mechanisms, allowing local and private entities to provide complementary funding to government subsidies to health worker training" (under Policy options to be considered in some countries, depending on context, page 6). The health workforce market has specific features that have to be taken into account in the process of increasing the health workforce and its financing. Despite the relative global scarcity of healthcare workers, employment conditions, especially wages, do not reflect this scarcity. Governments that are often major employers of healthcare workers are motivated to limit wage growth to reduce health budget growth[3]. This contradiction has to be considered.

The lack of public resources is often used as an argument in favour of privatization and PPPs. However, there is evidence that shows that PPPs lead to worse health outcomes, increased indebtedness, and compromises effective governance within the system. It is crucial that fiscal policies are no limitation to public sector expenditure in this field. The Right to Health is a right of all citizens and Member States, particularly better endowed states, have a duty to assist other governments, technically and/or financially to ensure its full realisation. We urge MS to ensure that economic governance arrangements and fiscal space enables the development of a strong national health workforce as a long-term investment in the wellbeing of the people and the economy of a country.

There is also growing recognition of the need to restructure the international taxation system to capture immense revenues from taxes that are systematically avoided and evaded. The implementation of global tax reforms could provide significant gains for government budgets. Health should be one of the highest priorities for the expenditure of

[3] See "Health workers wages: an overview from selected countries", Sigrid Dräger, Mario R. Dal Poz, David B. Evans. Geneva: World Health Organization, 2006, at http://www.who.int/hrh/documents/health_workers_wages.pdf

such revenues, given the benefit of investment in health and the associated returns to the economy, productivity and employment. Governments can, in any case, greatly increase financial resources for health by altering budgetary priorities and tolerating deficits amply repaid by consequent economic and fiscal gains. Overseas development assistance will continue to play a role in the least developed countries; this assistance should be earmarked, provided through budgetary allocation for health, and tracked accordingly. We urge MS to consider reforms of taxation systems that lead to increasing the contribution of those who have more (tax justice) and the prioritisation of public health.

**Migration**

Migration of health workers from developing to developed countries has a substantial financial cost to sending countries[4]. This decreases the incentive for receiving countries to invest in the education of health workforce. At the same time, it increases the burden on sending countries. This trade in a very expensive resource is unfair trade that has to be contained at the source of the problem. While the WHO Global Code of Practice on International Recruitment of Health Personnel attempts at addressing the symptoms a response that addresses the causes of the issue systematically is still needed. We welcome the creation of the Commission on Health Employment and Economic Growth under the leadership of WHO, OECD and ILO. In the current consensus, the Commission is looking at stopping the importation of health workers. We see this as a complementary processes in which the WHO is playing a key role and urge MS to demand that the WHO report on progress of the HEEG Commission, and integrate the findings. We also urge MS to request a universal review of certification. This will contribute to combatting the loss of human resources from developing countries, as well as avoid social dumping.

In addition, we urge MS to request guidelines on a global framework for compensation to sending countries for brain drain, including a mechanism for participation of trade unions of health workers in the use of this compensation in the receiving country in health system strengthening and/or health worker education.

**Conditions of employment and work for health workers**

Healthcare workers are systematically exposed to occupational health risks that are not only damaging to them, but also significantly threaten health outcomes. The occupational injuries and diseases of healthcare workers occur in all settings, but have been best observed in hospitals. These occupational risks include death, disease, violence and overwork, with resultant stress and musculo-skeletal disorders. Absenteeism is one manifestation of these systemic issues, which worsens healthcare worker overload and further lowers the quality of health services. Brain drain and migration of health workers from the developing world, in search of better working and living conditions, is the other side of the coin. The results for health outcomes are higher morbidity and mortality of patients. It has been shown that reduced ratios of patients to healthcare workers, or patient quotas greatly improve the working conditions of healthcare workers and resulting health outcomes for patients.

[4] For instance, in nine African source countries, the estimated government-subsidized cost of a doctor's education ranged from US$21,000 in Uganda to US$58,700 in South Africa. The overall estimated loss of returns from investment for all doctors currently working in the destination countries was US$2.17 billion, ranging from US$2.16 million for Malawi to US$1.41 billion for South Africa. The benefit to destination countries of recruiting trained doctors was largest for the United Kingdom (US$2.7 billion) and the United States (US$846 million) (Mills et al. 2011).

The strategy does not address the trends in worsening employment conditions, such as informalisation of terms of employment, as well as conditions of work. The strategy also does not address improvement of working conditions, including through patient / medical and support workers ratios.

We urge MS to improve investment in health workforce development, including salaries and social protection, and in national training institutions in order to rapidly increase numbers of HRH.

**B. FRAMEWORK ON INTEGRATED PEOPLE-CENTRED HEALTH SERVICES**

The proposed framework has several areas of weakness. We highlight here only a few.

**Include trade unions as a stakeholder**

Para No. 17 of document A69/39 lists stakeholders' responsibilities. It is of great concern that this section does not include trade unions. It does refer to professional associations and NGOs, but in a context of representation and information sharing, not negotiation. Collective bargaining is a fundamental right of public sector workers (ILO Convention 151, ILO Convention 98). However, these fundamental rights are too often denied. We urge MS to include trade unions and their role in paragraph 17 and ensure that their role as a bargaining agent is asserted.

## Health in the 2030 Agenda for Sustainable Development

The effort by the United Nations to formulate new global development targets in which the focus is on sustainable development needs to be commended. This move from the Millennium Development Goals which had a focus mainly on poverty reduction, from a public health perspective should bring the focus to other important determinants of health. We welcome the desire to reduce health disparities and transform the lives of all. The 17 goals and 169 targets are comprehensive and visionary. An inspiring vision can mobilise people to work together for change. However, false promises lead to disillusion and withdrawal.

We however have some concerns relating to some of the targets of the SDG's and their impact on population health and sustainability of the environment. As Member States acknowledge through the Social Determinants of Health framework there are structural and social factors that affect health and there is a need to place health first in all policies. Health and access to healthcare should be a priority in all SDG related goals and policies.

The Millennium Development Goals had poverty reduction as its first goal and that has been carried over in the SDGs. However, the proposed methods of poverty reduction continue to be premised on the same policies that have had a limited effect on poverty reduction. Poverty reduction should focus on reducing inequalities especially those relating to income. Encouraging an economic growth of 7% of GDP in developing countries in the current financial climate, where growth is dependent on increased consumption is not environmentally sustainable. International trade is being encouraged as a way of achieving economic growth, but until the impacts of unfair trading regimes are not addressed, it will only maintain the status quo. Tariff cuts attached to trade liberalisation have resulted in a loss of public revenues which reduces governments' capacities to fund health and social programmes. They also have an effect on a country's sovereignty by limiting the scope of national policies that governments can set to promote health. Bilateral and regional agreements can become barriers to equity in health. Some agreements have resulted in extensions of Intellectual Property rights for pharmaceuticals, thereby making drugs more expensive for longer periods and reduced access especially in low and middle income countries. Health ministries should be more involved in these trade talks so that the full national health implications of all trade agreements are considered.

As well as trade of goods, the extension of trade agreements to services, particularly the General Agreement on Trade in Services will have a profound impact on the health workforce in developing countries. In the global regime that promotes unrestrained mobility of health workers from poor countries to developed high income countries, health workers are seen as commodities that can be traded without any compensation paid to the countries that invest in the education and training of health workers. Under a voluntary code, now in operation, though countries are discouraged from recruiting healthcare workers from other countries, it is not mandatory and there are no enforceable penalties. As a consequence the current situation related to health worker migration to developed countries is set to continue.

Equity in access to health is a commendable goal. However Universal Health Coverage is not synonymous with equity in access and care. It can lead to different levels of care and differences in quality of care. It focusses on public financing whilst encouraging private

provision. This puts government at risk of inadequate coverage especially for public goods like public health projects for which there is no financial incentive for private providers. It may also result in Member States having to bear the extra costs of market failure, which history has shown happens regularly in the private provision of healthcare.

Capacity building and attainment of the health related SDGs can be achieved only if appropriate structures are in place. In those countries where there is no universal access, an overhaul and significant strengthening of the health system, including the availability of appropriate public structures and agencies are necessary. The WHO through its regional offices should support Member States to ensure that health systems are strengthened in a manner that they are developed and are adequate for the functions they will be required to perform.

While Member States try to achieve equitable universal access to healthcare, the WHO needs to support them through its functions which were set out in the Twelfth General Programme of Work 2014-2019. While putting health first in the SDGs, the WHO should support countries to generate necessary funding not just by working as a facilitator, but also as an advocate for the removal of unfair Trade practices which would increase government's fiscal space as well as allow them to develop health policies without fear of trade embargoes or legal action. The WHO while supporting member countries to promote cost effective interventions and delivery strategies, should advocate against the negative effects of higher standards of Intellectual Property protection which impact on cost and access of drugs. High standards of IP protection has increased the cost of drugs to a point where they are now prohibitively expensive, even for developed countries whose health systems also facing significant budgetary pressures.

## Reforms to Enhance WHO's Response Capacity in Emergencies

WHO reform is essential in the wake of the Ebola Virus Disease (EVD) crisis, which highlighted structural failings throughout the organisation. These are rooted in the weakness of the WHO's financing structures and its place in the wider architecture of Global Health.

### 14.1B Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response

Global public health is at the core of the International Health Regulations. However, this cannot be upheld without a WHO with the financial resources and stability to fulfil this and its many other disparate roles.

Even prior to the 2013 Ebola Virus Disease outbreak (EVD) the International Health Regulations were acknowledged to be unfit for purpose. The 2011 International Health Regulation Review Committee on H1N1 made six recommendations which, if they had been implemented rather than ignored, would have mitigated the devastating effects of the Ebola crisis. This painful lesson must be internalised when considering the 2016 Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response.

The 2016 Review Committee makes a series of constructive suggestions that should be supported, including a call for:

- A focus on wider health-system strengthening and acceptance that it is vital to improving the core capacities of nation states
- Reducing the reliance on self-assessment in the review of core capacities, instead shifting to a system of external assessments
- A demand for an intermediate level of emergency response to increase the WHOs flexibility in responding to emergency crises
- The use of WTO mechanisms to prevent the effective sanctioning of MS who are the targets of PHEIC pronouncements

These are strong suggestions and their implementation is vital to stabilizing the health of WHO. However, it must be remembered that the independence and effectiveness of WHO cannot be substantially improved with an increase in assessed contributions. The Review Committee unfortunately shies away from making an explicit recommendation in regards to this key point. We call on Member States to recognise that this move is fundamental to curing WHO of its current operational malaise.

**14.8B Options for strengthening information-sharing on diagnostic, preventive and therapeutic products and for enhancing WHO's capacity to facilitate access to these products, including the establishment of a global database, starting with haemorrhagic fevers**

The proposed R&D Blueprint touches upon crucial issues connected to adequate research efforts in emergency contexts. Recent commitments by major stakeholders including funders and publishers on Data Sharing in Public Health Emergencies suggest a paradigm shift encouraging all researchers to share data as quickly and widely as possible.

We request Member States to consider two key points when discussing this agenda point;

- While a welcome foray into improving the current state of the Research and Development (R&D) system, this agenda point does not exist in isolation - it should be considered in the context of the ongoing debate surrounding the follow-up to the Consultative Expert Working Group recommendations.
    - De-linkage of market price from R&D-costs, the use of open knowledge innovation and drug licensing conditions that favour access are core principles of both the CEWG and the Blueprint. These must be considered in conjunction as both are attempting to correct a failing R&D system in parallel to each other.
- A holistic approach that reformulates incentives in research towards rewarding much-needed Open Knowledge instead of publication in closed access journals should be the underlying principle of all health related research, not just in the context of emergencies. Moreover, recommendations alone will not solve this issue: For open science to become a reality, we must train researchers how to practice its principles of licensing and archiving data openly.
- Epidemic preparedness is more than vaccines, diagnostics and chemotherapies but includes strong and resilient health systems and other components of social and economic infrastructure (literacy, communications, transport). WHO should be participating actively in the implementation of the Sustainable Development Goals and emphasising in intersectoral communications the significance of the SDGs for epidemic preparedness.

While a strengthening of WHO's capacity appears to have been informed by the challenges the organisation faced in the wake of the 2014 Ebola epidemic, caution needs to be exercised that the WHO's primary role as a norm setting organisation does not get diluted. While developing WHO's capacity in emergency response, the need and logic of close collaboration with organisations such as the International Red Cross, who are specialised agencies with core capacity for emergency response, need to be kept in mind.

# Antimicrobial Resistance

The extensive use, misuse and overuse of antimicrobials in both humans and animals have increasingly raised levels of resistance in a wide range of pathogens (bacteria, viruses, fungi and parasites) in all countries and patients of all age groups. The growing global health threat of antimicrobial resistance jeopardizes our ability to treat conditions, ranging from common wound infections to complex medical procedures such as organ transplants and cancer treatments.

***As stated in the Antibiotic Resistance Coalition Declaration, public leadership is needed to enact new, needs driven research and development models, with open research and transparent data, which support rational use and equitable access to antibiotics.***

**INNOVATION**

There must be policy coherence among the various parallel processes addressing innovation and access including the United Nations High-Level Panel on Access to Medicines, Consultative Expert Working Group (CEWG) on R&D, as well as the United Nations High-Level Meeting on Antimicrobial Resistance. Different strategies to address the gap in R&D of antimicrobial drugs and other technologies have been put forward by the Consultative Expert Working Group (CEWG). WHO and Member States should insist on policy coherence between WHO and UN processes on R&D and apply the core principles enunciated by the CEWG of affordability, effectiveness, efficiency, equity and de-linkage. In line with the CEWG report, the Global Action Plan on Antibiotic Resistance (A69/24 Add.1 ) "emphasizes the principle of de-linking the cost of investment in research and development from price and sales volume". The Global Action Plan also argues that "If implemented, this principle [of de-linkage] would remove pressure on pharmaceutical companies to maximize prices and sales volumes, thereby facilitating the implementation of policies to expand access and ensure conservation". On the other hand the pharmaceutical industry tends to have a distorted view of the principle of de-linkage by proposing that de-linkage refers to an assured return for the industry irrespective of the value of a particular innovation in promoting public health goals.

**Assessing measures proposed to curb antimicrobial resistance**

Several measures are currently being proposed by different processes that seek to address antimicrobial resistance. However many of these proposals are not adequately aligned to real research constraints or the underlying reasons for antimicrobial resistance. A case in point relates to various proposals for financing antimicrobial innovation proposed by the United Kingdom Review on Antimicrobial Resistance. Included among its proposals is one that proposes a high "Market Entry Reward" of $1 billion per drug to incentivize pharmaceutical innovation of antimicrobials. The proposal fails to address the real bottleneck in antimicrobial innovation. In fact, pharmaceutical industry data shows that there is a mere 7 percent yield from screening promising antibiotic drug compounds, which is less than one tenth of the yield from screening promising drugs in all other therapeutic areas. This clearly indicates that the bottleneck lies well before the point of testing

promising drugs in clinical trials. To address this bottleneck incentive mechanisms should focus on early-stage R&D. Measures that would be useful to promote include the creation of a Global Innovation Fund, also put forward by the UK Review on AMR.

Another proposal in this document calls for financing of research on antimicrobials and other complementary technologies through a tax on antimicrobial use in animals. Such a tax might have a disproportionate impact on small farmers as well as on countries with developed livestock sectors. Additionally, as the base value of antimicrobials in many countries is low, a tax may have limited impact on curbing use and in providing sufficient funds for innovation. Consideration of the imposition of a tax on antibiotic use in animals, in order to be effective, needs to be accompanied by technological and fiscal measures to support poor farmers and low income countries to transition to sustainable methods of livestock farming that do not depend on inappropriate antibiotic use on animals.

Besides development of new antimicrobials, proposals should also ensure innovation of vaccines and diagnostics. Product-development partnerships such as WHO-DNDi Global Antibiotics R&D Facility should engage in R&D of new antimicrobials as well as these other complementary technologies. The proposal of a "diagnostic market stimulus" as recommended by the UK Review on AMR as a top-up payment for individual tests may drive manufacturers to patent both the diagnostic test and the underlying technology platform. Instead, diagnostics platforms should be developed as 'open source' innovations in order to ensure development of affordable, rapid, point-of-care diagnostics for resource-limited settings. Finally, proposals for lowering antimicrobial drug approval standards through "regulatory harmonization" of antimicrobials should be addressed with caution by the WHO and Member States. Proposed legislation in the United States and the European Union to hasten antimicrobial approval through expedited pathways, unless judiciously applied, could threaten patient safety. Further, such measures do not address the real bottleneck of antibiotic innovation.

**ACCESS, NOT EXCESS**

Antimicrobials, vaccines, and diagnostics should be considered global public goods – common resources requiring common stewardship. We would like to draw the attention of Member States to the Antibiotic Resistance Coalition's (ARC) strongly support for the development of a binding stewardship framework that would ensure access, not excess of new and existing therapies and technologies. Securing access for everyone in need is as vital as curbing overconsumption. Price should not be used as an instrument to ration use for humans. Limiting access leads to preventable suffering and death.

Effective regulation and control of antimicrobials must be exercised to secure affordable access to existing and new antibiotics are in all countries, while also curbing overuse or misuse. This calls for strengthening of public health systems in all countries. Resource-limited countries and vulnerable health systems need particular help from the international community to strengthen infection prevention and control. Development of sustained investments in health systems must be a common commitment. WHO needs to work together with those Member States that need assistance to strengthen their own capacities and system as part of implementation of the Global Action Plan on AMR.

While we welcome the inclusion of new antibiotics in the WHO Essential Medicines List (EML), this alone would not ensure equitable access to these drugs. As part of their national action plans, Member States will need to monitor not only resistance and stewardship, but also access to first- and second-line antimicrobials. Data for both human and non-human uses must be gathered and publicly disclosed in sufficient detail to enable effective action by civil society, medical professionals and governments. Indicators for monitoring the implementation of these plans must reflect availability as well as affordability and should be developed with broad engagement with all sections, including civil society. Member States must also reaffirm their right to use TRIPS flexibilities to ensure access to antimicrobials, vaccines, and diagnostics and trade agreements should not dilute the use of TRIPS flexibilities and hinder access.

**CONSERVATION**

Besides access to treatments, Member States and WHO, in collaboration with FAO and OIE should consider strategies to increase capacity of health care and veterinary professionals to ensure appropriate use of existing drugs. Activities to curb excessive use must include better training of health professionals through non-commercial, evidence-based programmes and sustained and targeted public education. Standard treatment guidelines should inform antibiotic administration. The preservation of effective antibiotics for human health should take priority over their use for commercial gain in food production. A disproportionately high amount of antibiotics is used in animals, particularly in industrial scale animal husbandry. Antibiotics should only be used for treating animals when indicated by a genuine therapeutic need and based on antibiotic therapeutic guidelines.

Moreover, antibiotic stewardship through optimal antibiotic drug regimens and appropriate duration of therapy and route of administration, as well as future effectiveness, should be incentivized, and unnecessary use should be disincentivized. For instance, promotion and advertising of antibiotics, including marketing for inappropriate uses or incentivising medical and veterinary professionals to overuse or inappropriately prescribe antibiotics, is harmful to health and should be prohibited. Instead, pharmaceutical companies should ensure appropriate packaging of antimicrobials and provide data for post-marketing surveillance of rational use.

The various initiatives by WHO and Member States to promote rational use of antibiotics to control the incidence and spread of infections are welcome and necessary. An overreliance on new antibiotics as the main solution should be avoided. Further research must also be coordinated to develop innovative conservation mechanisms rather than mere reliance on development of new therapies. While much attention has been placed on financing the innovation of novel antibiotics, particularly with incentives for the private sector, the WHO and relevant funding agencies should also work to ensure significantly increased financing for developing and piloting new approaches to conservation of antibiotics.

Farm practices such as overcrowding, unhygienic conditions, inappropriate diets, and early weaningmust be prohibited. Strong policy coherence among WHO, FAO and OIE to restrict use of critically important antimicrobials must be encouraged with broad stakeholder engagement. The urgency to do so is further evidenced by the recent emergence of resistance across Asia, Europe, and the Americas in food animals to colistin, a last-line antibiotic critical in human medicine. Moreover, aligned with objectives of the Global Action

Plan on AMR, Member States must work towards restricting non-therapeutic use of antimicrobials in food animal production.

**Towards the UN High-Level Meeting**

As AMR is a complex global development issue, WHO in coordination with OIE, FAO and other UN agencies must call for a priority setting mechanism to help guide Member States to address this threat across sectors. Such a mechanism should be publicly transparent and have the leverage to carry out priorities that would ensure funding for AMR is deployed with the greatest marginal gain and equitably across populations and targets in need. During the upcoming High-Level Meeting on AMR, Member States should put forward options for public financing to ensure implementation of the Global Action Plan on AMR, reaffirm core CEWG principles (affordability, effectiveness, efficiency, equity and de-linkage), and a commitment to monitor access, not just conservation efforts. Given the multisectoral nature of this issue, creation of an interagency task force across UN agencies with broad stakeholder engagement is necessary to effectively prevent and control the spread of resistance. Finally, the linkages between AMR and SDGs must be made clear so that the SDG indicators are aligned with those proposed by WHO, FAO, and OIE for national action plan implementation.

## Policy Follow-up to the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination[5]

***Context***

**Agenda item 16.2** addresses the long-standing discussion on how to find a solution to the failures of current research and development (R&D) incentives to provide for public health needs. In 1990 it was determined that, while an estimated 93% of the world's burden of preventable mortality occurs in the developing world, only 5% of the global investment in health research addressed health problems of developing countries (COHRED, Oxford University Press, 1990). With patent monopolies being the main current incentive to R&D, not only is access and affordability of medicines a rising issue in both developing and developed countries, but innovation is largely lagging behind and neglecting to address large global burdens of disease. 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).

Since the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) in 2003, discussions have been taking place at the WHO, culminating in the 2012 report by the Consultative Expert Working Group on Research and Development (CEWG): Financing and Coordination. The CEWG was established under Element 7 of the Global Strategy and Plan of Action on Ppublic Hhealth, 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 recommendations of the CEWG clearly called for a **global legally-binding framework to ensure sustainable funding and coordination of R&D**.

The Open Ended Meeting on the follow up to the CEWG report (2-4 May 2016) had the mandate to discuss the remaining issues in relation with the CEWG report including the discussion of an R&D Agreement. Unfortunately, a coherent and binding framework was not seriously addressed. Discussions did not conclude at the meeting and thus delegates are encouraged to finalise the drafted text during the 69th World Health Assembly. We are inspired by the emphasis in the draft resolution on the implementation of needs-driven and evidence-based health R&D, guided by the core CEWG principles of affordability, effectiveness, efficiency, and equity, and based on the principle of de-linkage and knowledge sharing approaches.

***We urge the resolution drafting group to consider the following:***

**Global Health R&D Observatory & Prioritization and coordination mechanism**

We welcome the progress made in monitoring health R&D efforts via the Observatory, and we see this monitoring as fundamental in tackling the lack of coordination of needs-driven health R&D. However, we do not see the Observatory as an aim in itself, but as one of several

[5] Developed by the Universities Allied for Essential Medicines (UAEM)

necessary tools to achieve the aim of providing access to affordable medicines to those in need. **We urge the resolution drafting group to emphasize that the Observatory will only fulfill its purpose if it is part of a wider framework. Furthermore we urge the resolution drafting group to include all diseases, including those for which there is a market failure, in the scope of health R&D prioritization**, regardless of geographical origin or level of income of the majority of the patient population.

### Pooled fund

Following up on CEWG, the 67th WHA asked the Director- General to explore the options for a pooled fund hosted by the Special Programme for Research and Training in Tropical Diseases (TDR). The currently proposed TDR fund, relying on voluntary contributions, is contrary to CEWG recommendations. The current budget gap of 88%—, that's $75 million dollars out of the estimated $85 million dollars estimated needed for the demonstration projects and the Global Health R&D Observatory—, shows that voluntary funding is clearly unsustainable. Creating an unsustainable fund does not align with the mandate of the GSPOA, the CEWG, nor resolution WHA66.22 in Operative Paragraph 1 which mandates to "ensure sustainable funding for health research and development". **We urge the resolution drafting group to include in the resolution a mechanism for mandatory financial contributions from Member States to be invested into health R&D in line with the CEWG recommendations, and in line with the GSPOA**.

### WHO policy coherence

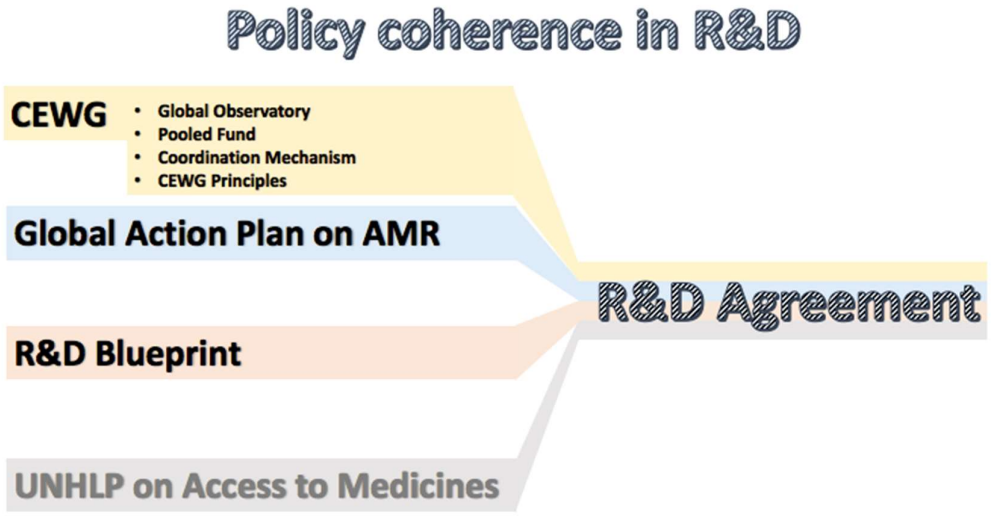
Since 2012, CEWG recommendations have only been partially implemented and in a fragmented manner. We welcome the progress made in the launch of the R&D Observatory, the Demonstration projects, and the exploration of a pooled fund hosted by TDR (Special Programme for Research and Training in Tropical Diseases). More recently, and in the context of the lack of a global coordinating framework, important advances have also occurred in fields such as like the R&D Blueprint for Emerging Pathogens, the AMR Global Action Plan, and an R&D fund for vaccines. It is of concern that some of these initiatives are not based on CEWG's analysis of innovative mechanisms to incentivise R&D. **We urge the resolution drafting group to ensure policy coherence between R&D activities within WHO by applying core CEWG principles of affordability, effectiveness, efficiency and equity, and de-linkage and open access, to the R&D Blueprint for Emerging Pathogens and to the AMR Global Action Plan. These initiatives need to be moved forward together**.

We believe that unless these currently 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 discussions that have not been resolved since the CIPIH (2004). The urgency to work towards full implementation of the CEWG recommendations is more evident than ever. We strongly believe that this inevitably requires the resolution drafting group to include in the resolution the possibility **to negotiate an internationally binding instrument on R&D, by convening an open-ended meeting or a meeting of an intergovernmental working group with the mandate to elaborate such an instrument. We believe in an Agreement based on meeting the health needs of patients and upholding CEWG principles.**

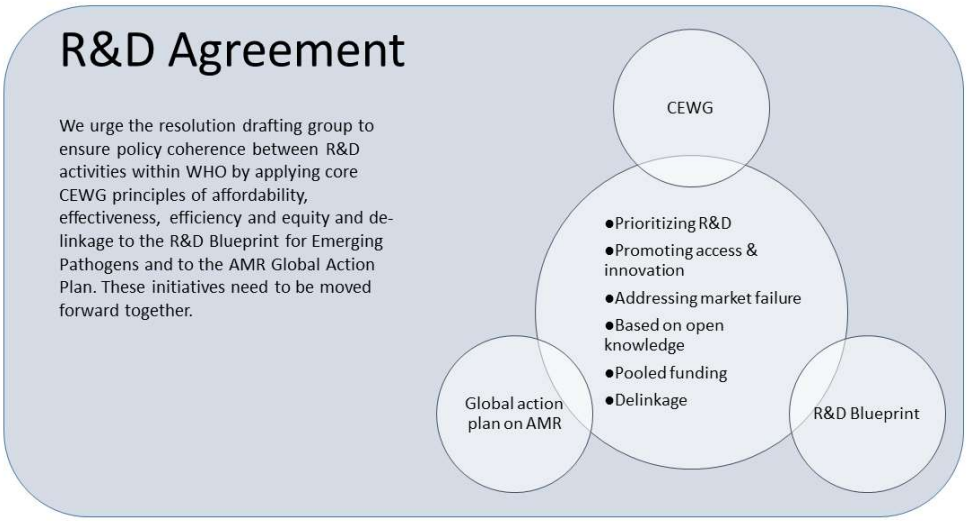
**Moving forward**

Efforts should be made to ensure that the process to implement the recommendations of the CEWG Report are sustained after the 69th World Health Assembly in accordance with the principle of **policy coherence on health innovation and access**, and of informing further governmental discussions on the follow up to the CEWG. **We support including in the resolution the convening of an open-ended meeting as recommended above, after the publication of the report of the UN Secretary General High-Level Panel on Access to Medicines and the UN High Level Meeting on Antimicrobial resistance.** This is necessary to ensure coherence between recommendations made by CEWG and by these two High-Level Panels, and to address the remaining issues and recommendations that were insufficiently addressed during the Open-Ended Meeting May 2-4 2016 (most importantly, but not limited to, a binding and coherent agreement on health R&D).

We urge the resolution drafting group to be mindful that restricted access to medicines due to high prices are affecting countries of all income levels, and is not only a public health issue relevant in low- and middle-income countries. High prices of medicines have been recognised as a barrier to access on domestic markets by the current presidency of the European Commission and Canadian Prime Minister and U.S Democratic presidential candidates. Promoting access and innovation are not two conflicting processes. The lack of access to high-priced medicines and the lack of innovation in diseases affecting poorer populations are consequences of an R&D model based on market incentives. Access and innovation should be addressed together, overcoming the falsely-widespread assumption that patent monopolies are necessary to incentivise innovation, and promoting alternative R&D mechanisms as analysed by the CEWG. Sustainable, systemic and global solutions for all types of diseases are needed now to address the root causes of the existing access and innovation crisis. We are convinced that a systemic and sustainable solution will be only achieved if the current initiatives come together under a unifying framework, as proposed by the CEWG, and thus it is fundamental that the **WHO moves forward with the discussions of an R&D Agreement or Convention in 2016**.




We urge member states to include in the resolution the affirmation of the right of any Member State to make use, to the fullest extent and without retaliation, of all current and future provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) and the Doha Declaration on the TRIPS Agreement and Public Health, which provide flexibilities for the protection of public health, and in particular to promote access to medicines for all. We encourage the resolution drafting group to include a framework for independent assistance to developing countries in this regard.



**Annexure**

**Make Medicines for People Not for Profit**

**Towards an Agreement on Biomedical Research and Development for the Public Benefit: Academia's Urgent Call to Action**

*(We present you this ask for a new R&D framework or R&D Agreement in the form of a letter signed by over 450 academics and over 2,000 other individuals, including four Nobel laureates: **Joseph E. Stiglitz, Sir John Sulston, Edvard Moser and May-Britt Moser**)*

As members of the international academic and scientific community, we call upon the member states of the World Health Organisation (WHO) to negotiate a much overdue global research and development (R&D) agreement to ensure innovation and access to affordable vaccines, medicines and life-saving technologies for all.

In an open letter in 2008, leading academics, researchers and scientists, including many of us, urged universities and research institutes to set policies for research and technology transfer that serve the public good, while calling on the WHO's Intergovernmental Working Group on Public Health, Innovation, and Intellectual Property to find new mechanisms to address a failing system of R&D on medicine and health technologies.

In 2012, the WHO's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) stated that the way to truly address the systemic issues causing the crisis in global health today would be to work towards a legally binding global biomedical R&D agreement. This recommendation was supported by many member states. However, opposition by a few led to the 66th World Health Assembly postponing the discussions of an agreement until 2016.

After over 10 years of debate at WHO, a number of initiatives have been developed and put into practice proving that a different way of implementing biomedical R&D is possible. Projects like the Drugs for Neglected Diseases Initiative have shown that patient-driven innovation is possible at affordable cost and show that claims that it takes $2.56 billion to produce a drug are a myth. The Medicines Patent Pool has shown that a collaborative approach to intellectual property can speed up the availability of affordable HIV medicines in resource poor settings.

Yet the current system continues to fail people. New Hepatitis C cures are marketed at an exorbitant $1,000 per pill. A generic drug treating toxoplasmosis saw a price increase of 5,000% overnight. Breast cancer patients in the UK are unable to access treatment and we

are proving unable to stimulate real innovation to combat antimicrobial resistance. The current biomedical R&D system is no longer just failing the poor, it is failing us all.

There is a lack of sufficient research funding for neglected tropical diseases (such as sleeping sickness, and Chagas' disease), chronic diseases, and diseases for which return on investment cannot be guaranteed (such as multi-drug resistant tuberculosis). The international system is going in the wrong direction by strengthening intellectual property rights - with the Trans Pacific Partnership Agreement as a lead example - that further advance corporate control over biomedical R&D. Preserving patent monopolies as the primary incentive for medical R&D results in exorbitant prices for medicines and medical technologies which endanger public health budgets and impoverish families.

Innovation has slowed as the overproduction of "me too" drugs has been incentivised, and legal restrictions have proliferated impeding the free flow of information for scientific progress. Patent monopolies increasingly enable rising drug prices, without any corresponding increase in innovation. We have witnessed stagnation in the face of public health emergencies. In the case of the tragic Ebola epidemic, governments and private companies allowed potential vaccines and treatments to remain in preclinical development for over a decade prior to the outbreak because there was no market incentive to invest in treatments for diseases limited to poor countries. As noted by the WHO-commissioned Report of the Ebola Interim Assessment Panel in July 2015, it was "a defining moment for the governance of the entire global health system."

A different system, based on principles of open access, open knowledge, open sharing and fair price, as well as incentives and mechanisms to encourage research and development of essential medicines according to needs of people worldwide, is possible. There are mechanisms being used that show great potential including prize funds, patent pools, and open collaborative approaches. However, the initiatives are fragmented and lack coherence. A global agreement for an equitable biomedical R&D system can provide a much needed structure. It can provide guiding principles which can move us to a system that incentivizes research and technology transfer based on global health needs and recognizes the human right to health.

Now, more than ever, we must act. As academics, researchers and scientists it is our responsibility to generate and transmit knowledge. We have a unique role to promote innovation in many fields and to ensure that our innovations are used to benefit the public. In no field are the moral imperatives to do so as clear as they are in medicine. At a time of huge progress in scientific research we are deeply concerned about the ability of the existing system to translate investment into better global health.

We are therefore calling on WHO member states to ensure the open-ended meeting of WHO member states on May 2-4, 2016 in Geneva seriously addresses this urgent situation. We believe 1 the meeting must include a broad range of civil society actors. The meeting should advance and inform member states discussions on an agreement that will support a coherent, sustainable and needs-driven agenda for a new approach to biomedical research and development for all.