



Drugs for Neglected Diseases *initiative*

## Sixty-Eighth World Health Assembly – May 2015 Briefing Paper

### Agenda Item: 17.4 Follow-up of the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination

#### **Background**

Since the 67<sup>th</sup> World Health Assembly in 2014, several major developments in global health have converged to make headlines and command increased political attention from Member States, most notably the Ebola crisis in West Africa, but also the growing global threat of antimicrobial resistance (AMR), and the continuing challenge of neglected diseases. A consistent thread that runs throughout all these global health concerns is the dearth in innovation for new health tools – diagnostics, drugs, and vaccines – that respond to clearly identified and well-documented patient needs. Over a year into the crisis in West Africa, therapeutics and vaccines for Ebola remain experimental; the pipeline for new antibiotics remains stubbornly empty; and many diagnostics and therapeutics for a range of neglected diseases predominantly affecting low- and middle-income countries are archaic or non-existent.

#### **Coherent solutions and overarching framework needed for inter-connected crises of pharmaceutical market failure**

Partly as a result of these developments, there are today multiple initiatives being proposed – such as a global warning and response system for outbreaks that includes a component aimed at expanding investments into research and development (R&D)<sup>1</sup> and numerous initiatives aimed at strengthening surveillance and response capacity as well as new strategies for increasing R&D for new diagnostics and anti-infectives to tackle drug-resistant infections.<sup>2</sup> These proposed initiatives are being discussed at various fora and under different conceptual frameworks: the framework of global security and the framework of health. The framework adopted will have strong implications for the solutions to be chosen and we therefore urge the WHO and its Member States to assert the importance of addressing these crises from the perspective of public health.

They are also being discussed against the backdrop of – but largely divorced from – the ongoing follow up of the World Health Organization (WHO) Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, as well as the Consultative Expert Working Group (CEWG) on R&D: Financing and Coordination. There is a risk that the multiplication of proposed initiatives will further fragment, rather than reconcile, efforts to accelerate innovation and ensure equitable access to desperately needed new health technologies for a wide range of diseases.

Yet there is also a unique opportunity to build on the unprecedented recognition of the failures of our current biomedical R&D system as well as the convergence of attention, interest, and momentum in global health innovation and access, to connect these initiatives into a coherent framework. But this cannot be done on the basis of crisis management or within disease silos.

<sup>1</sup> Gates, Bill. *N Engl J Med* 2015; 372:1381-1384, [April 9, 2015](#). DOI: 10.1056/NEJMp1502918

<sup>2</sup> Such as the £195 million “Fleming Fund” launched by the UK government, Wellcome Trust, and other partners in March 2015; the National Action Plan for Combating Antibiotic-Resistant Bacteria, launched by the White House in March 2015; the 2014 Lancet Infectious Diseases Commission, which called for a “new sustainable global model for the discovery, development, and distribution of antibiotics;” Outterson K. *New Business Models for Sustainable Antibiotics*. Chatham House, London: Royal Institute of International Affairs, 2014; etc.

As the WHO leadership itself recognized in its recent statement on the Ebola response and WHO reforms:

**We have been reminded that market-based systems do not deliver on commodities for neglected diseases – endemic nor epidemic. Incentives are needed to encourage the development of new medical products for diseases that disproportionately affect the poor. The scientific community, the pharmaceutical industry, and regulators have come together in a collaborative effort to vastly compress the time needed to develop and approve Ebola vaccines, medicines, and rapid diagnostic tests. In future, this ad hoc emergency effort needs to be replaced by more routine procedures...**<sup>3</sup>

In looking towards solutions, we urge Member States to take a holistic approach that looks at the full implementation of the recommendations in the 2012 final CEWG report.

At the 136<sup>th</sup> Executive Board in January 2015, Member States were presented with a proposal to establish a voluntary pooled fund within the existing UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) structure as follow up to the CEWG process. We support moving forward with the further development of this fund as an important step, but it cannot be seen as the end of the process.

In terms of the scope of the proposed fund, we believe it is essential to ‘join the dots’ so that all disease areas where there is market failure are covered, whether they be classified as “type I, II or III” diseases. As such the pooled fund should, among other disease areas, cover R&D needs for emerging infectious diseases such as Ebola, AMR, as well as diseases that exclusively or predominantly affect developing countries.

The extent to which such a fund could meet ‘the need for a sustainable financial mechanism for health research and development’ depends on its governance and funding structures. The leadership role of developing countries will be crucial on both fronts. We are concerned that the current voluntary contribution models put forward will be inadequate for this task and urge Member States to consider mandatory contribution models as well as innovative financing mechanisms as part of the review in 2016.<sup>4</sup>

In addition, such a fund, as the report for the Executive Board noted, would need to be strongly linked to the priority-setting, monitoring, and coordination functions being explored, for example, in the establishment of a global health R&D observatory.

And perhaps most importantly, it is critical that any fund be underpinned by an umbrella framework that would ensure the core principles put forward in the CEWG report and endorsed by WHO Member States are adhered to, namely de-linkage of the delivery price from R&D costs, the use of open knowledge innovation, and licensing for access.<sup>5,6</sup>

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<sup>3</sup> WHO leadership statement on the Ebola response and WHO reforms, April 2015. Available at <http://www.who.int/csr/disease/ebola/joint-statement-ebola/en/>

<sup>4</sup> Whilst we note that the Secretariat has interpreted its mandate in resolution WHA 66.22, 4(6) to be limited to exploring only funding models based on ‘voluntary contributions’, and has taken this approach in the report it presents before this Executive Board, we would like to draw attention to the fact that this limitation is not required under any specific WHA resolution. Resolution WHA 66.22 says that the Director General should include ‘pooling resources and voluntary contributions’ in its exploration of potential funding options, but it does not exclude the possibility of mandatory contribution models or other financing models that can ensure long term, sustainable and sufficient funding. Resolution WHA 67.15 recognised the Secretariat has taken a narrow interpretation of this mandate. WHA 67.15 stresses that the assessment made by the Secretariat on a fund for voluntary contributions should be ‘without prejudice to future discussions in the context of recommendations of the Consultative Expert Working Group on Research and Development Financing and Coordination and actions on other sustainable mechanisms for financing health research and development.’

<sup>5</sup> Follow-up of the report on the Consultative Expert Working Group on Research and Development: financing and coordination. [http://apps.who.int/gb/ebwha/pdf\\_files/WHA67/A67\\_28Add1-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA67/A67_28Add1-en.pdf)

<sup>6</sup> Røttingen JA, Chamas C, Goyal LC, Harb H, Lagrada L, Mayosi BM. Securing the public good of health research and development for developing countries. *Bull World Health Organ* 2012; 90(5):398-400

**Médecins Sans Frontières (MSF) and the Drugs for Neglected Diseases initiative (DNDi) urge the WHO and its Member States to:**

- Join the dots: ensure that solutions to address the chronic under-investment in R&D for tools to combat emerging infectious diseases like Ebola, AMR, and diseases disproportionately affecting developing countries are coherent and coordinated.
- Support the proposal for a pooled fund to address developing country health R&D needs with the following conditions:
  - It is important that any fund created be linked strongly with not only monitoring and coordinating R&D flows but also identifying needs and gaps, setting priorities, and even determining target product profiles. WHO remains the best platform for this.
  - The proposed fund should be based on a model that ensures long-term, sustainable and sufficient funding contributions, ideally mandatory funding, from participating states in order to fulfil its mandate and ensures it is in line with resolution WHA 66.22 which noted that this is ‘a shared responsibility’ for Member States.<sup>7</sup>
  - The proposed fund should have a clear mandate that ensures that all calls for proposals are rooted in the innovation with access principles formulated in the CEWG report and summarized in WHA 66.22, ‘affordability, effectiveness, efficiency and equity’ and achieve the objective of ‘de-linkage of the cost of research and development from the price of health products.’<sup>8</sup>
- Elaborate further options for financing mechanisms that allow for managed and active coordination, including the feasibility and modalities of mandatory financial contributions in order to equip Member States to ‘continue discussions on the remaining issues in relation to monitoring, coordination and financing for health research and development’ during the ‘open-ended meeting of Member States prior to the 69<sup>th</sup> World Health Assembly in May 2016.’<sup>9</sup>
- Focus on the open-ended meeting of Member States to be held in 2016 and the need to agree on a sustainable framework to comprehensively address the persistent R&D challenges of diseases that primarily affect developing countries. As the CEWG report noted, finding solutions to the collective under-investment in R&D to meet developing country health needs is the responsibility of developed and developing countries alike in an inter-dependent world.

**What is needed is public leadership to effectively channel the efforts of all actors towards clearly defined goals for needs-driven innovation and equitable access. Rather than multiple new mechanisms and individual funds for each disease area, we need to move beyond an *ad hoc* patchwork of limited efforts with a narrow scope to a comprehensive, sustainable, and lasting solution that focuses on all public health priorities, that is tied to key principles aimed at ensuring access, and that enables the rapid development of effective and affordable health tools, which can ultimately improve the health and lives of populations under-served by the current global R&D system.**

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<sup>7</sup> Preamble, WHA66.22, [http://www.who.int/phi/resolution\\_WHA-66.22.pdf](http://www.who.int/phi/resolution_WHA-66.22.pdf)

<sup>8</sup> Preamble, WHA66.22, [http://www.who.int/phi/resolution\\_WHA-66.22.pdf](http://www.who.int/phi/resolution_WHA-66.22.pdf)

<sup>9</sup> Operative paragraph 4(7), WHA 66.22, [http://www.who.int/phi/resolution\\_WHA-66.22.pdf](http://www.who.int/phi/resolution_WHA-66.22.pdf)