



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

Context

This agenda item is addressing the long-standing discussion on how to find a solution to the failures of the current biomedical research and development (R&D) model 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 low and middle income countries, only 5% of the global investment in health research addressed health problems of developing countries (COHRED, Oxford University Press, 1990). As financial gain is the primary incentive for biomedical R&D, access and affordability of medicines today is faltering in high, middle and low income countries, while innovation largely neglects major 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 in 2003 of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), 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 recommendations in the CEWG report are based on the results obtained from four working groups with 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). The recommendations of the CEWG called for a **global legally-binding framework to ensure sustainable funding and coordination of R&D**.

Attendees of the Open Ended Meeting on the follow up to the CEWG report (2-4 May 2016) were mandated to discuss the remaining issues in relation with the CEWG report, including the discussion of an R&D Agreement. Disappointingly, a coherent and binding framework was not sufficiently addressed. Discussions were not concluded at the meeting. The outcomes recommended that the Health Assembly set up a drafting group to develop a draft decision/resolution (A69/40). We urge a resolution to be reached that calls for a needs-driven and evidence-based R&D model, guided by the core CEWG principles of affordability, effectiveness, efficiency, and equity, and grounded in the concepts of de-linkage and knowledge sharing approaches.

We urge the resolution drafting group to consider the following:

A Global Health R&D Observatory & Prioritization and Coordination Mechanism

We welcome the progress made in monitoring R&D efforts in global health via the Observatory, and we see this monitoring as important for addressing the lack of coordination of needs-driven R&D for global health. However, we do not see the Observatory as an aim in itself, but as one of several 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% or \$75 million out of the estimated \$85 million 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 Global Strategy & Plan of Action on Public Health), 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 the R&D Blueprint for Emerging Pathogens, the AMR Global Action Plan, and an R&D fund for vaccines. Not all these initiatives uphold 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, as well as 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 supported by mandatory contributions, the WHO will not achieve the goals set out by the GSPOA nor advance the discussions that have been left unresolved since the CIPIH (2004). With patients left waiting while the discussions trail on, it is urgent to work towards full implementation of the CEWG recommendations. We strongly believe in the need **to negotiate an internationally binding instrument on R&D which upholds the CEWG principles and starts to address the needs of patients.** We strongly encourage the resolution drafting group to include convening an open-ended meeting or a meeting of an intergovernmental working group with the mandate to elaborate such an instrument.

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 in the follow up to the CEWG. **We support including in the resolution 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.** Such a meeting is necessary to ensure coherence between recommendations made by CEWG and those of the two High-Level Panels. It is also needed 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 R&D for global health.

We urge the resolution drafting group to recognise that barriers to accessing medicines due to high prices are affecting countries of all income levels, not only low- and middle-income countries. High prices of medicines have been recognised as a barrier to access in 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 mutually exclusive 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 profit. 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.**