

## Joint Letter to the 66<sup>th</sup> World Health Assembly: Follow-up of the report of the CEWG

Distinguished Delegate,

We urge the World Health Organization (WHO) and its Member States to exercise leadership, ambition and innovative thinking in developing new paradigms to take forward the work of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) in reconciling the objectives of stimulating medical innovation and ensuring access for all.

At the open-ended meeting (26-28 November 2012) on the follow-up of the report of the CEWG, an outcome document containing a draft report and draft resolution was produced. This meeting was convened to provide Member States with the opportunity to develop a work plan for taking forward the recommendations of the CEWG report. This report was part of the implementation of the WHO's Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA). The objective of the GSPOA is to secure "an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries". The CEWG identified the concept of de-linkage as the over-arching principle in which to secure this objective by de-coupling the cost of R&D from the price of health technologies including medicines, vaccines and diagnostic tools. The central recommendation of the CEWG report that Member States were asked to consider was the development of a legally binding global convention to address the unmet R&D needs of developing countries.

Such a global framework is needed to establish a process for identifying R&D needs, setting priorities, monitoring R&D flows, coordinating R&D efforts, securing sustainable financing, promoting new incentives and managing research outputs in a way that ensures both innovation and access. Given the WHO's role as the directing and co-ordinating authority in global public health and its constitutional mandate, it is uniquely placed to be the forum for such an instrument.

Despite the clear roadmap set out by the Expert Group, the outcome document produced at the open-ended meeting postpones discussion of an R&D Convention at the WHO, and does not provide a clear agenda for addressing these pressing unmet R&D needs. The commitments that are made are unclear and too limited. For example, the establishment of an R&D Observatory could be a positive first step, but only if the scope of its tasks includes the definition of R&D priorities in consultation with Member States in addition to simply monitoring what little is currently being done.

Whether this R&D observatory will receive adequate financing to operate effectively is also an unanswered question.

Similarly, with respect to the demonstration projects referred to in operative paragraph 4(4) of the draft resolution, more clarity is needed to provide assurances that these demonstration projects are predicated upon the principles outlined in the CEWG report, including de-linking the cost of R&D from the price of health products. The CEWG has evaluated and recommended five concrete proposals that best incorporate these principles and we would expect to see exactly these proposals to be operationalized through these pilot projects. As with the R&D observatory, these demonstration projects require adequate financing.

The outcome of the November 2012 open-ended meeting precipitated a rich and heated discussion<sup>1</sup> at EB132 in which many Member States shared our concerns on content and process in relation to CEWG follow-up. At EB 132, the WHO Legal Counsel stated, “the WHA remains free to further discuss the Director-General's report and the draft resolution” thus confirming the possibility that WHA66 can provide further amendments to the draft resolution contained in A66/23. As noted by A66/23, the Board “agreed that the comments made thereon by Member States would be brought to the attention of the Health Assembly” and provided in the “summary record of the eleventh meeting of the Executive Board at its 132nd session, section 2.”<sup>2</sup>

Against this background, we call upon WHO Member States to provide greater clarity and detail to ensure that document A66/23 is aligned with the spirit of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. WHO and her Member States need to exhibit leadership in fulfilling the aim of the Global Strategy which states:

*“The global strategy on public health, innovation and intellectual property aims to promote new thinking on innovation and access to medicines, as well as, based on the recommendations of the CIPIH report, provide a medium-term framework for securing an enhanced and sustainable basis for needs driven essential health research and development relevant to diseases which disproportionately affect developing countries, proposing clear objectives and priorities for R&D, and estimating funding needs in this area.”*

Finally, we request WHO Member States to consider the CEWG recommendations holistically including the central recommendation of the CEWG report which recommended to Member States that “formal intergovernmental negotiations should begin for a binding global instrument for R&D and innovation for health”.

## **Organizations**

All India Drug Action Network  
AISLAC  
AIS - Nicaragua  
Asia Pacific network of people living with HIV (APN+)  
American Medical Student Association  
Center for Health, Human Rights and Development (CEHURD), Kampala-Uganda  
Center for Technology and Society, Fundação Getulio Vargas  
Farmamundi  
IFARMA  
Health Action International  
Health Gap  
Knowledge Ecology International  
Misión Salud  
Médecins Sans Frontières- Access Campaign  
Oxfam  
Peoples' Health Movement  
Salud por Derecho  
SECTION27  
The Berne Declaration  
Third World Network  
Treatment Action Campaign

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<sup>1</sup> <http://keionline.org/node/1643>

<sup>2</sup> A66/23, [http://apps.who.int/gb/ebwha/pdf\\_files/WHA66/A66\\_23-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_23-en.pdf)

Universities Allied for Essential Medicines

**Individuals**

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Winner of 2002 Nobel Prize for Physiology or Medicine