

LONG-AWAITED STEPS TOWARDS AFFORDABLE ACCESS AND NEEDS-DRIVEN RESEARCH AND DEVELOPMENT



66TH WORLD HEALTH ASSEMBLY

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After a 10-year process, the World Health Organization (WHO) and its Member States have finally agreed on concrete steps to move towards needs-driven innovation. At the 66th World Health Assembly (WHA) in Geneva in May 2013, Member States adopted a much debated resolution on the follow-up of the report of the Consultative Expert Working Group on Research and Development (CEWG). This resolution was approved with an extra decision point unexpectedly introduced by the United States (US), which proposes a process for rapidly identifying research and development (R&D) demonstration projects. It recognises de-linking the price of the product from the cost of research, as well as open knowledge innovation, as guiding principles. This is promising because it will ensure that needs-driven innovation and affordable access to health products and knowledge sharing will be part of the design of these R&D initiatives. However, talks on a global framework for R&D should not be postponed any further.

Health Action International Europe (HAI Europe) cautiously welcomes the outcome of the 66th WHA discussions on the follow-up of the CEWG report. As the agenda point approached in the first week of the WHA, it seemed that the minimalist draft resolution resulting from the Open-ended Member States Meeting in November 2012 would be re-opened. HAI Europe previously criticised this draft resolution because it did not provide a clear agenda for a comprehensive solution. It also suffered from a lack of ambition to achieve structural change and a dearth of concreteness in its commitments. Both in the run-up to, and during, the WHA, it appeared that the US was pressuring countries not to change the draft resolution. The European Union (EU) also did not want the draft resolution changed.

However, when the post-CEWG process was discussed on Friday, 24 May, seemingly to everyone's surprise, the US proposed an extra decision point on this agenda item: to hold an advisory meeting on R&D demonstration projects as soon as possible while defining the norms and aims that should govern these projects. While the initial US proposal was promising, it was limited in scope and lacked clarity. Eventually, the decision point was greatly improved after Member States discussed it during a closed-door drafting group on Friday afternoon and Saturday morning.

STATEMENT



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In the decision points that were finally adopted, the Assembly requested a two to three day technical meeting be held with experts, open to all Member States, with the task of identifying demonstration projects.

Unfortunately, experts were invited solely by the WHO's Directorate-General, making the selection process less than democratic. Nonetheless, the decision points explicitly mentioned the need to safeguard public health from undue conflicts of interest. This is important because, when selecting and designing demonstration projects, the complex private interests of pharmaceutical companies, vaccine manufacturers, other industries with an interest in the health market, and private donors cannot—and should not—be underestimated. In addition, the future experts meeting will be consultative with Member States. This is crucial because, in such a politicised process with strong interests, the meeting needs to be inclusive and transparent. The mistakes made with the earlier expert working group in 2010, including poor transparency, conflicts of interest and unrepresentative engagement, should be avoided. The fact, however, that there is currently no role for non-governmental organisations (NGOs) in the experts meeting is problematic. HAI Europe sincerely hopes it will be an open meeting that NGOs can attend.

HAI Europe sees the final outcome of the WHA discussions as an opportunity to add clarity to the post-CEWG process. In particular the role of the demonstration projects, the norms that will govern them, and the ambition to move towards a comprehensive and sustainable solution are critical to addressing the lack of biomedical innovation and access. With these decision points, the Assembly has now firmly embraced the key principles, as identified in the CEWG report, and agree that de-linkage and open knowledge innovation are integral to improving global health.

Even though the resolution calling for an R&D observatory and demonstration projects has also been adopted, the focus appears to have shifted from the observatory championed by the EU and US in earlier discussions to concrete demonstration projects and steps towards sustainable funding. The US commented at the WHA that “it is now time to see if Member States will actually ‘put their money where their mouth was,’” and commit to funding these demonstration projects. To date, the US remains the biggest spender on biomedical innovation for global health.

At this year's WHA, two clear developments were noticeable: on one hand, the US has taken the initiative from developing countries, such as the Union of South American Nations (UNASUR), India and others that have driven this decade-long process to improve global health R&D. Although this is an important development, it remains unclear *why* the US did this and what will be the implications of its initiative. On the other hand, the EU has moved to the position of a passive player on the side lines with no vision other than not wanting to commit to a binding treaty. This is embarrassingly at odds with the ambitious commitments for the EU to be a leader in global health, as expressed in the Commission and Council's communications on global health in 2010.

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Hopefully, the EU will accept its responsibility soon because global health R&D is a policy area that can bring a great deal of knowledge and (financial) support to the table. Moreover, this comes at a time when EU health systems are under immense financial pressure; leadership by the EU in this global learning process to enhance needs-driven and affordable biomedical R&D could be very valuable for the EU Member States struggling with high medicine prices.

While the outcome seems promising, it is important that the agreed actions by the World Health Assembly provide steps towards a comprehensive solution in the form of a global framework for health R&D that addresses a broad range of diseases and conditions. HAI Europe will closely monitor the lead-up to the expert meeting at the end of 2013 and hopes discussions on a global framework for coordination, norm setting and financing for R&D will start as soon as possible.

Link to HAI intervention at WHA 66: <http://haieurope.org/wp-content/uploads/2013/06/Intervention-Stichting-Health-Action-International-item-17.2.pdf>

Link to decision points: <http://keionline.org/node/1730> - and draft resolution: http://apps.who.int/gb/ebwha/pdf_files/WHA66/A66_23-en.pdf -on the follow up of the CEWG report adopted at the WHA66

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