

## Research and development at the 69<sup>th</sup> World Health Assembly

Each year in May the global health community gathers for the World Health Organization's (WHO) governing board meeting, the World Health Assembly (WHA). At the meeting, the 194 member countries set the policy and funding priorities for WHO for the coming year and use the collective legitimacy of the international community to set global norms in health-related issues. This year at the 69<sup>th</sup> WHA there are a number of agenda items directly related to global health research and development (R&D). Agenda items fall into two categories: decision points—resolutions approved by a vote of the full assembly and containing concrete policies or directions to the WHO secretariat—and information points—progress updates provided to the WHA pursuant to previous decision points.

### Agenda item 11.3: Framework of engagement with non-State actors (Decision)

That WHO engages with non-State actors (NSAs—any institution other than a member state) is well-recognized and supported. Some, however, have argued that WHO's current ad-hoc approach to managing those engagements leads to a lack of transparency and accountability that endangers WHO's independence and impartiality. The proposed Framework of engagement with non-State actors (FENSA) would require the WHO secretariat to implement a publicly-available database containing detailed information on WHO's engagements with NSAs as well as in-depth information on each of the NSAs. It would also create distinct categories of organization (for-profit, nongovernmental organization, academic, philanthropic, etc.), each of which would be subject to a different set of rules in their engagements with WHO. The current draft FENSA could be problematic for product development partnerships (PDPs) when there is a close partnership with a for-profit company. In some cases, the PDP could be deemed to be a for-profit organization itself and thus barred from any official

engagement with WHO. GHTC calls on WHO to put in place a guidance that does not disenfranchise PDPs that have been so critical to global health R&D progress over the past decade.

### Agenda item 13.2: Health in the 2030 Agenda for Sustainable Development (Info)

In September 2015, the United Nations General Assembly agreed and adopted 17 Sustainable Development Goals (SDGs) to succeed the Millennium Development Goals (MDGs). Goal 3 is "Ensure healthy lives and promote well-being for all at all ages," and includes sub-goal 3.b "Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines..." In planning how best to implement the SDGs, WHO has concluded that R&D will play a critical role in achieving Goal 3 and that "...partners will aim to uncover the most cost-effective and impact-oriented technologies and innovations..." WHO also states that there is a clear need for a systematic international R&D coordination mechanism to ensure that R&D gaps are addressed. GHTC welcomes WHO's commitment to R&D, and supports efforts to define and quantify unmet R&D needs.

### Agenda item 14.4: Global action plan on antimicrobial resistance (Info)

The 68<sup>th</sup> WHA adopted the global action plan on antimicrobial resistance (AMR) in May 2015. One of its key objectives is "develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions." This item is an options paper on WHO's efforts to develop a global framework supporting the development, control, distribution, and appropriate use of new antimicrobial

drugs, diagnostics, and other tools. Of particular note, WHO is seeking member states' input on methods to de-link R&D costs from sale price, as well as to manage intellectual property rights to support access. In addition, WHO lays out a number of options for developing a prioritization framework and mechanism within the unique requirements of AMR. GHTC fully supports efforts to ensure that new antimicrobials are developed and accessible in an appropriate context to those who need them.

### Agenda item 16.2: Follow-up to the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (Report of the open-ended meeting of Member States (Decision))

The Consultative Expert Working Group (CEWG) is the result of a decade-long process examining how best to coordinate and support global health R&D. The current proposal is to create an R&D observatory and a pooled R&D fund. The observatory, which is currently online<sup>1</sup> in trial form, will house a database of all global health R&D activities, funding streams, and target product profiles. This data would then be used to determine where there are unmet needs, as well as to ensure that there is no duplication of effort. The pooled fund would operate similarly to the Global Fund or other multilateral financing institutions, and would fund research into needs identified by the observatory. While additional funding for R&D is needed, there are several

potential concerns with the current proposal. First, it is unclear how much additional funding is actually available, and as such, how much of the pooled fund's financing would come at the expense of existing R&D programs. Second, there may be tension between the imperative to fundraise for the fund and the observatory's ability to maintain credibility and independence in its priority-setting. A particularly large donor, for example, could sway what should be technical decisions. Finally, the demonstration projects from the first pilot phase of the fund have not shown any significant advantages over existing funding mechanisms. GHTC supports the drive to catalog and coordinate global health R&D, but maintains some concerns about how the current proposals would be implemented.

### Agenda item 17: Progress reports (Info)

In addition to the other ad-hoc information points on specific special initiatives or programs, the WHO secretariat presents each WHA with a compiled set of progress reports on long-term programs and activities that WHO is pursuing. Three updates are relevant to R&D this year:

1. **Item G:** Access to essential medicines
2. **Item H:** Access to biotherapeutic products, including similar biotherapeutic products, and ensuring their quality, safety and efficacy
3. **Item I:** WHO strategy on research for health

The full progress update report text is available online from WHO.<sup>2</sup>

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<sup>1</sup> WHO Global Observatory on Health Research and Development (R&D) page. Global Observatory on Health Research & Development website. Available at: [gohrd.azurewebsites.net](http://gohrd.azurewebsites.net). Accessed May 13, 2016.

<sup>2</sup> Sixty-Ninth World Health Assembly Provisional Agenda item 17: Progress reports: Report by the Secretariat. World Health Organization. Available at: [http://apps.who.int/gb/ebwaha/pdf\\_files/WHA69/A69\\_43-en.pdf](http://apps.who.int/gb/ebwaha/pdf_files/WHA69/A69_43-en.pdf). Accessed May 13, 2016.

The Global Health Technologies Coalition (GHTC) works to save and improve lives by encouraging the research and development of essential health technologies. We are a coalition of more than 25 nonprofit organizations advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools that bring healthy lives within reach for all people. GHTC is housed at PATH and funded in part by the Bill & Melinda Gates Foundation.

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