GHTC
global health technologies coalition

advancing innovation to save lives

The 69th World Health Assembly:

Background and outcomes

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About the Global Health Technologies Coalition

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 tools that bring healthy lives within reach for all people. GHTC is housed at PATH and funded by the Bill & Melinda Gates Foundation and our members.

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Introduction

The World Health Assembly (WHA), the ultimate governance body for the World Health Organization (WHO), is held in May every year. The decisions made at WHA have profound impacts on global health programs around the world through WHO's myriad offices. WHA's actual functions, decision-making, and relationships to other governance bodies within WHO can be remarkably opaque, even to long-time WHO watchers. This report provides a brief overview of these items as context for a discussion of the key debates and events at WHA this year.

What is WHA, and how does it operate?

As the supreme decision-making body for WHO, WHA is empowered to make decisions that affect WHO's operations globally. As specified in the WHO charter, "The Health Assembly appoints the Director-General, supervises the financial policies of the Organization, and reviews and approves the Proposed programme budget. It similarly considers reports of the Executive Board, which it instructs in regard to matters upon which further action, study, investigation or report may be required."[1] Within this mandate, each WHA session divides its work into three different committees: the Plenary, Committee A, and Committee B.

Plenary

Plenary sessions are formal meetings of all member states in which senior government representatives such as heads of state or ministers of health make a series of carefully-prepared formal statements laying out their domestic health commitments and calling in general terms for other member states to support their priorities. Although the Plenary has the ability to pass resolutions and make decisions, in practice it only does so symbolically. The Plenary is an opportunity for delegations to make a statement without risk of another speaker directly arguing the point. As such, speakers frequently use the Plenary to make statements intended for domestic media consumption in their home countries, while leaving the substantive negotiating to other representatives in Committees A and B.

Committees A and B

Committees A and B are the formal policymaking sub-assemblies of WHA. They are each committees of the whole, and any of the 194 member states can participate in their debates. Generally, Committee A covers the programmatic policy decisions, while Committee B has responsibility for budget and administrative matters. Despite this general division, if schedules require it, agenda items can be shifted from one committee to the other at very short notice to ensure that everything is covered prior to the end of WHA. For example, the Consultative Expert Working Group's report at this past WHA was shifted from A to B to balance out the committees' workloads.[2] Although decisions in the committees can theoretically be taken by roll-call vote, member states collectively decided that decisions should be made by consensus and have therefore instituted the informal closed drafting group system to ensure that this is possible.

Drafting groups

In addition to the formal committees, member states have adopted the practice of referring contentious resolutions to "drafting groups" where delegates can negotiate line-by-line edits to the text without causing the entire committee's agenda to grind to a halt. Although not formally part of the WHO governance structure, these drafting groups are held behind closed doors (member state delegations only) with the full support of the WHO Secretariat, including translation and interpretation. For particularly difficult resolutions, these groups can require dozens of hours of meeting time as various sections of text are negotiated, closed, re-opened, and then finally resolved. In addition, meeting behind closed doors lessens the public pressure to adopt hardline positions that many delegations face from constituents at home. If the resolution coming out of a drafting group is presented as a consensus compromise, no individual state can be held accountable for a particular edit. As a result, these groups have proven to be an effective tool to keep WHO's agenda moving, even if some advocates feel that they reduce the transparency of WHO's governance.

Non-State actor participation

Non-State actors (NSAs, any organization other than a member state government) who have entered into a formal relationship with WHO are accorded observer status at the Plenary, and courtesy speaking status at Committees A and B, though they do not have the right to vote. Most importantly, they are not included in the drafting group sessions. This means that NSAs do not have the ability to make meaningful statements to help shape contentious resolutions when those agenda items are moved to a drafting group (typically without any open debate on the floor). The only option open to NSAs is to work with sympathetic member state delegations to ensure that the drafting group is aware of the NSA's concerns.

Policy issues this year

This year's agenda was the most extensive in the 69-year history of WHA, with 77 formal agenda items and 27 decisions or resolutions across Committees A and B. Given the extent of the agenda, speakers were asked to adhere to a strict three-minute time limit for their statements. Despite this, both committees had to make liberal use of drafting groups to make progress, and many important resolutions did not reach the committee floors as consensus documents until late in the week.

GHTC held a panel discussion and briefing session in collaboration with the Geneva Centre for Security Policy examining the key research and development (R&D) points that would be discussed at WHA.[3] The panel included: David Kaslow, vice president of Product Development, PATH; Marie-Paule Kieny, assistant director-general for Health Systems and Innovation, WHO; Suerie Moon, co-director, Project on Innovation and Access to Technologies for Sustainable Development, Harvard Kennedy School of Government; Ambassador Guilherme Patriota, Permanent Mission of Brazil to the United Nations in Geneva; and Bernard Pécoul, executive director, Drugs for Neglected Diseases *initiative*. Kieny opened the session with the observation, "Of course the World Health Assembly is looking at many other agenda items… but as soon as you talk about medicines, and many items [talk] about medicines, then immediately the issue of R&D comes forward."

In a wide-ranging discussion, the panel touched on a number of key issues both for WHA and global health R&D more broadly:

1. *WHO's role in R&D*: The panel unanimously agreed that WHO has and will continue to have a vital role to play in R&D. Ambassador Patriota noted that the mission to "conduct and promote" R&D is explicitly stated in the WHO constitution. Panelists stressed that WHO's normative function is unique and vital to a coordinated global effort.
2. *Antimicrobial resistance (AMR)*: AMR featured highly on the WHA agenda, and all of the panelists agreed addressing it is vital, but there were differing opinions on how to do so. Moon noted that AMR needed to be viewed as a "social justice" issue rather than simply as a security issue, while Patriota noted the inherent conflict between the health security and health development perspectives when it comes to conserving new antibiotics by treating them as the new antibiotics of last resort. Kieny, however, noted that if security concerns resulted in more funding, "Well, fine. Let's take the investment because it will benefit everybody."
3. *Models to support R&D*: The panel enjoyed a spirited discussion on the ways in which various actors engage in and support health R&D. Kieny noted that no one organization can do everything, and thus partnerships are necessary. Ambassador Patriota, however, emphasized the importance of public R&D institutions such as the National Institutes of Health and Institute Pasteur. Kieny, Kaslow, and Pécoul saw much more space for the private sector, and Kieny noted, "You can really have good and equitable partnerships with industry…" Moon added that public funding is always welcome, but that it must be matched with adequate public return on investment in order to be sustained. Ultimately, the panel agreed that where there is public investment, there should be commensurate public benefit.

Framework of engagement with non-State actors[4]

In 2011, at the direction of the 64th WHA, WHO began a comprehensive reform process covering all aspects of the organization. As the Secretariat underwent external assessments of its operational engagement with NSAs, it became clear that there was no consistent approach to evaluating possible reputational risks or perceptions of undue influence that might arise from engaging with outside parties. There was similarly no uniform process for documenting these engagements for later review. To that end, the 67th WHA (in May 2014) authorized the creation of a drafting group of member states to develop a new approach to evaluating, managing, and documenting WHO's engagement with NSAs, which would become known over time as the Framework of engagement with non-State actors (FENSA). The drafting group worked to reach consensus over the intervening years, but still arrived at the 69th WHA deadlocked over a few key final points.

After intense negotiations spanning the entirety of WHA, the group finally reached agreement on the last day of the Assembly.

The two key sticking points for negotiators at WHA were:

1. *Documentation of NSA engagement*: Advocates for increased documentation requirements on WHO's engagements with NSAs argued that it would provide more transparency and reduce the danger of undue, unseen influence. Other delegations were concerned that requiring WHO to

document every meeting with outside groups was an untenable solution given the staff burden it would create.

2. *Private-sector engagement*: A number of delegations expressed serious concern that WHO has become too dependent on a few voluntary donors and private-sector partners, and that the organization is in danger of losing its reputation as an independent agency. These groups argued strongly for sweeping restrictions on WHO's involvement with the private sector, as well as for restrictions on staff secondments. Other groups argued that WHO should be able to engage with the private sector given the vital role it plays in global health. In addition, many groups expressed concern that such sweeping restrictions had the very real danger of unintentionally excluding organizations that partnered closely with the private sector.

The group reached a compromise and the resolution mandates that all non-State actors who engage with WHO register in an online database and that WHO staff conduct due diligence on the outside organization and proposed engagement. As a result of the compromise, however, the final resolution includes several critical language changes, including:

1. Emphasizing that FENSA should be interpreted in ways that enhance, not limit WHO's ability to engage with non-State actors.
2. Allowing for exemptions from rigorous registration requirements for routine, low-risk engagements that are substantively similar to ones that have already been evaluated.
3. Establishing an evaluation process to ascertain the impact of FENSA on WHO's operations.
4. Specifying that WHO's current risk management policies will apply under the new FENSA implementation (rather than calling for the creation of new norms), and directing the director-general to develop guidance documents directing staff on how to interpret them.

At the end of this process, although none of the delegations felt they had achieved everything they wanted, it was clear that an honest compromise had been achieved. As the representative of the Netherlands, speaking on behalf of the European Union (EU), said on the Assembly floor,

> *"The EU would like to thank the chair of the FENSA process for his unfaltering commitment to taking this complicated process forward to the finish line. During this process we have all tried to improve the set of rules governing WHO's engagement with non-State actors, albeit that our emphases and perspectives have been varied... Mr. Chair, to conclude, we applaud the hard-earned consensus that was reached after lengthy negotiations, and express our support for the draft resolution."*

Consultative Expert Working Group on Research and Development: Financing and Coordination[5]

The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) is the latest group to carry forward a process that dates back to 2003, when the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was created to address ways in which intellectual property rights might be limiting access to medicines. Since then, the process begun by the

CIPIH went through many iterations and name changes, ultimately resulting in the establishment of the CEWG.

A large part of the reason for this lengthy process has been the negotiation and evolution of its goals. The initial recommendation was to implement an international treaty that imposed a mandatory tax on some form of international financial transactions (the exact type and mechanism were never fully developed). The proceeds raised through this tax would then be used to fund an R&D mechanism that "delinked" the cost of R&D from the final cost of drugs. After significant resistance to mandatory funding models by member states, the principle of delinkage and improving access to medicines remained, but within the context of a voluntary funding mechanism that now contained a prioritization or coordination function.

With this background, the 66th WHA directed the director-general to convene a meeting of member states prior to this year's WHA to finalize concrete proposals in line with the CEWG principles. To that end, the director-general directed the Special Programme for Research and Training in Tropical Diseases (TDR) to conduct an analysis of how TDR could possibly constitute and structure a pooled fund and R&D observatory. As part of this analysis a small number of demonstration projects were set up to illustrate the financial and operational mechanisms TDR might use for the full fund. TDR presented the results of their analysis less than a month before WHA, and stakeholders immediately raised a number of concerns, including:

1. *Availability of resources*: With major global health donors such as the United States expressing that no additional funding would be available for the pooled fund, delegates raised concern that new donors might not be able to provide sufficient resources.
2. *Politicization of funding decisions and earmarking*: Member states noted that one of the key advantages of an independent observatory affiliated with WHO would be its ability to recommend global priorities for global health R&D. This normative function would be severely undercut if donors were allowed to earmark funding for specific projects or if the project became too dependent on a limited number of donors.
3. *Scope of the pooled fund*: A number of western donor governments expressed concern at broadening the scope of the fund and diluting its impact. The US in particular advocated prior to WHA for antimicrobial resistance to be excluded from the pooled fund and addressed through other mechanisms (though the US delegation later ceded this point during negotiations). Other nations, including current donors to the demonstration projects, argued for a truly global health R&D fund to replace private-sector pharmaceutical companies in R&D for the public interest.

As a result of the short time between TDR's presentation and the WHA, and the concerns expressed by parts of the global health community, there was no consensus on a resolution fully operationalizing the pooled fund and observatory. The Assembly did, however, reach consensus to support the CEWG principles and agreed to a resolution authorizing the development of concrete implementation plans for the observatory and pooled fund. Specifically, the Assembly agreed to these points:

1. *Sustainable financing*: The Assembly called upon all member states to provide both funding for R&D as well as support to the director-general in developing new mechanisms to provide sustainable financing.

2. *Global health R&D observatory*: WHO should expedite further development of costed workplans and terms of reference for the observatory for approval at the next WHA, as well as undertaking outreach and advocacy efforts to encourage all stakeholders to share R&D data.
3. *Expert committee on health R&D*: An expert committee should be convened to provide technical guidance on how to prioritize health R&D for type II and type III diseases, in addition to type I diseases in developing countries.
4. *Voluntary pooled fund*: The Secretariat should, based on the work already completed by TDR, produce a proposal and operational plan for a pooled fund for health R&D, including how the fund would coordinate with the expert committee, the observatory, and other R&D stakeholders to promote mechanisms that support delinkage.

Launch of the Global Antibiotic Research and Development Partnership[6]

One of the key priorities of the Global Action Plan on Antimicrobial Resistance is the development of novel antibiotics to replace current drugs that are becoming less effective. WHO began exploring innovative partnership models to pursue drug development in late 2014, resulting in the launch of the Global Antibiotic Research and Development (GARD) Partnership at this year's WHA.
GARD is a partnership between the Drugs for Neglected Diseases *initiative* and WHO that will develop novel antibiotics using the following principles:

1. The antibiotic must address global public health needs or the specific requirements of low- and middle-income countries.
2. A focus where industry will likely not develop the product due to lack of profitability or other barriers.
3. GARD will pilot the use of alternative incentive mechanisms to delink the cost of R&D from volume-based sales and high pricing of antibiotics, in support of appropriate conservation of antibiotics.
4. Antibiotics developed by GARD will be affordable to all in need.

The partnership will be incubated in its initial stages at Drugs for Neglected Diseases *initiative*, prior to spinning off into a separate organization. The founding executive director will be Dr. Manica Balasegaram who will be responsible for overseeing the development of a business plan, additional fundraising, standing up a scientific advisory group and steering committee, and preparing the organization for the transition to independence. WHO will provide support in priority-setting, stewardship guidance, and promoting access. In addition, WHO will assist in ensuring close coordination both with member states as well as with the various technical departments within WHO.

The initial seed funding for GARD was provided by donors, including: Germany, the Netherlands, South Africa, the United Kingdom, and Médecins Sans Frontières. To date, EUR 2 million of the projected incubation period cost of EUR 3 million has been raised.

In his remarks at the May 24th launch event, Dr. Balasegaram noted that GARD would initially focus on "short-term wins" through repurposing relatively simple antibiotics, while laying the groundwork for longer-term fully novel drug development. He commented that GARD's goal is to have two projects ready to commence by the end of 2016, followed by another two in 2017. The ultimate vision is for

GARD to pursue a diversified portfolio of projects, consisting of short- medium- and long-term projects that are similarly diverse in their risk profiles and complexity.

Conclusion

This year's WHA saw a robust discussion of how WHO can best support global health R&D, as well as what R&D mechanisms should look like. In the FENSA decision, WHO moderated its language and acknowledged the role of non-State actors in WHO's work, which is vital for R&D. Although the CEWG resolution did not result in a full approval, the WHA did offer tacit support for the observatory and pooled fund by requesting more developed proposals rather than rejecting the resolution entirely. In the launch of GARD, one sees an exciting new partnership between WHO, Drugs for Neglected Diseases *initiative,* and member state governments directed squarely at one of the greatest threats to health of our times. Put together, these outcomes paint an encouraging picture of what is to come in R&D at WHO. WHO will engage with novel partners, develop concrete proposals for an R&D coordination and funding mechanism, and support a partnership to directly address the specter of AMR by developing new antibiotics. Given that all of these processes will be lengthy and filled with critical decisions that will shape WHO's engagement with R&D, GHTC will remain engaged on behalf of its members to support policies that advance global health R&D.

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