Binding R&D convention put on hold

Hopes for an immediate decision to begin work on a binding research and development (R&D) convention to spur innovation of affordable and much-needed medicines for developing nations were deferred at the 65th annual meeting of the World Health Assembly.

Proponents of the convention had sought assembly support to begin crafting a global R&D framework in which innovation is driven by global health needs rather than potential for profit. It would have also compelled countries to spend at least 0.01% of their gross domestic products (GDPs) on medical research that meets the health needs of developing countries.

But the governing body of the World Health Organization (WHO) backed off immediate adoption of the convention, opting instead at its May 21–26 gathering in Geneva, Switzerland, to ask member states to conduct further national, regional and global consultations on the issue.

"The meeting will also take into account the results from national consultations and regional committee discussions and develop proposals or options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures, to be presented under a substantive item dedicated to follow up of the CEWG [Consultant Expert Working Group] report at the Sixty-sixth World Health Assembly," states the draft resolution, forwarded to *CMAJ* by WHO.

The main purposes of the convention would be to gather government support and financing to develop medicines in priority areas and to "de-link" the price of R&D from the cost of new medicines to make them affordable to people in developing nations. The convention was recommended in a WHO report released in April by the Consultative Expert Working Group on Research and Development: Financing and Coordination (www.who.int/phi/CEWG_Report_5_April_2012.pdf).

Advocates of a global health research convention argue that innovation can and should be driven by health needs rather than profit.

Along with calling for the creation of a global R&D framework, the report urged open approaches to R&D and innovation, pooled funds, direct grants to companies, milestone and end prizes, patent pools, an advisory committee and a global health research and development observatory.

But members appeared divided on the merits of a binding convention.

"There is quite a spectrum of opinions here from different ministries of health. Kenya put forward clear resolutions and is ready to start setting up and negotiating the convention. Then, on the other end, is the United States," says Dr. Tido von Schoen-Angerer, executive director of the Campaign for Access to Essential Medicines of Doctors Without Borders/Médecins Sans Frontières (MSF). "In the middle you have the position of Switzerland, asking for delays."

MSF chastised US and European Union delegations for "blocking efforts to move towards a binding convention" during discussion at the assembly (www.doctorswithoutborders.org/press/release.cfm?id=6043&cat=press-release). The medical humanitarian aid organization also "urged the US and European governments, who are leading the developed country effort, to stop obstructing a process that has been 10 years in the making and has broad support from developing countries."

But at least the notion of a binding R&D convention has not been completely scuttled, Michelle Childs, director of policy/advocacy for the Campaign for Access to Essential Medicines, indicated in a statement forwarded by MSF to *CMAJ*. "These were extremely tough negotiations with the US, the EU [European Union] — led by France — and Japan making every effort to block progress on what health experts agree should be the way forward to meet the medical needs of people in developing countries. While there's no doubt we are disappointed that there was not an immediate decision to move towards an R&D Convention, countries have agreed to a formal process for considering the report's recommendations and will bring these discussions back to the WHO in January."

A binding convention between

countries is essential "to make further progress," von Schoen-Angerer says. "There have been new initiatives over the past few years to address the big R&D gaps in areas like infectious diseases … and that's all good but it's still not filling the gaps sufficiently and there is stagnation in the contributions being made."

It would also provide three main benefits, he adds.

The first is priority setting, creating mechanisms to identify the greatest needs, von Schoen-Angerer says. "The commercial market is not driving that sufficiently in the right direction." The second benefit would be firm commitments from countries to dedicate at least 0.01% of their GDPs to medical R&D aimed at the needs of developing countries. Finally, it would create guidelines around accessing new medicines. "There is no point in having great innovations if they aren't affordable," he adds.

Other reasons to create a binding health R&D convention include spurring innovation for medicine for neglected diseases, encouraging cooperation between different research organizations and ensuring people in poorer nations benefit from medical innovations by separating medical research from the commercial market, says Suerie Moon, a doctoral research fellow with the Center for International Development at Harvard University's John F. Kennedy School of Government in Cambridge, Massachusetts. "Then you don't have to rely on high-priced products in order to recuperate the costs of R&D."

But this is not just another rich country versus poor country issue, Moon adds. "Now much of the debate is on emerging economies. They have financial capacity and clear public health needs," she says, citing China and India as examples. "If they have a desire to been seen as leaders in global health on an international stage, the moment is ripe for some of these middle-income countries to show leadership on this issue."

It is important that leadership on the issue be taken sooner rather than later, irrespective of who takes it, von Schoen-Angerer says. "There have been years of discussions and expert reports and global strategies. We have all of that. We don't need more of that," he says. "We need to create some obligations to move this thing forward." — Roger Collier, *CMAJ*

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