Towards a new model for pharmaceutical research

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Despite considerable investments in research and development (R&D) and the availability of powerful scientific and technological tools, innovation in the pharmaceutical industry has declined drastically in the last decade. In addition, most of the new molecules introduced into the market do not entail genuine therapeutic innovations or target the diseases that prevail in developing countries. Most importantly, the prices charged for new pharmaceutical products are unaffordable to the poor and, increasingly, to patients and social security systems, even in developed countries.

The lack of appropriate treatments for many of the diseases afflicting developing countries leads to millions of deaths per year.[1] Governments have the responsibility to provide effective solutions to this problem.[2] They have an ethical imperative to do so, but also the duty to see that the right to health, recognized under international law and many national constitutions, is guaranteed.

On 26 May 2012, the World Health Assembly adopted a resolution that could mark the beginning of a needed change in the current model of pharmaceutical R&D. The resolution calls for an inter-governmental meeting (scheduled for November 2012) to examine in depth the proposals made in April in the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG),[3] established by the World Health Assembly in 2010 under Resolution WHA63.23. Such proposals included open approaches to R&D, pooled funds, direct grants to companies in developing countries, prizes for milestones and end products, and patent pools. The main recommendation of the CEWG was, however, more far-reaching: to start multilateral negotiations for the possible adoption of a binding convention on health R&D.[3] This is quite momentous, since the only binding convention adopted so far by the World Health Organization (WHO) has been the Framework Convention on Tobacco Control.[2]

The concept of a new convention rests on four main premises. First, the current R&D model, based on patents and market-oriented research, fails to generate new health technologies to face the global challenges arising from existing health needs, particularly in developing countries. Second, it is crucial not only to enhance the innovation of relevant products, but also to secure product access and affordability by *de-linking* R&D costs from the prices of the products. Third, the efficiency of health research can be improved through better monitoring, priority-setting and international coordination of R&D. Fourth, voluntary financing cannot be the main or unique source of funding; a better, more sustainable and predictable financing model is needed.

The following are some of the possible objectives of a binding convention as spelled out by the CEWG report:

- Improving the coordination of public and private R&D;
- enhancing innovative capacity in developing countries and technology transfer to these countries;
- generating R&D outcomes as public goods, freely available for further research and production;
- improving priority-setting based on the public health needs of developing countries and making decisions through governance structures that are transparent and give developing countries a strong voice.

However, the objectives, elements and mechanisms of a possible instrument will be defined at the discretion of the governments that eventually participate in a negotiating process. For instance, the CEWG report recommended that all countries dedicate at least 0.01% of their gross domestic product (GDP) to R&D of relevance for meeting the health needs of developing countries.[3] This is certainly a desirable target; however, it will be the governments' decision, if negotiations on a convention take place, to determine the level and kind of contributions they should make. There is a wide range of options, such as spending on domestic R&D programmes or contributing to an internationally agreed financing mechanism. Hence, the percentages recommended by the CEWG should not be considered as a "take it or leave it" option, nor should they be a reason for countries with a large GDP to fear that the proposed convention would entail extraordinarily large financial contributions.

The basic objective of the convention proposal is to put in place a new model of R&D that would lead to a reduction of R&D costs and increase innovation through a more focused, health-driven research agenda and through improved monitoring, cooperation and sharing of research results. This would lead, in turn, to much more affordable, accessible treatments. Although this model will probably generate, in particular, new products targeting the neglected health needs of developing countries, it may help to mitigate the impact of high pharmaceutical prices on stretched public health budgets in developed countries as well.

The elaboration and adoption of an international mechanism capable of delivering new and affordable treatments is a milestone event. Through such a mechanism, WHO's Member States have an unprecedented opportunity to contribute to "the attainment by all peoples of the highest possible level of health".[4] ■

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References

Available at: http://www.who.int/bulletin/volumes/90/11/12-113712

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References

1. *Measuring medicine prices, availability, affordability and price components*. 2nd ed. Geneva; World Health Organization & Health Action; 2008. Available from: http://www.who.int/medicines/areas/access/medicines_prices08 [accessed 4 October 2012].
2. *WHO Framework Convention on Tobacco Control*. Geneva: World Health Organization; 2003. Available from: http://www.who.int/fctc/text_download [accessed 4 October 2012].
3. Consultative Expert Working Group on Research and Development. Financing and Coordination. *Research and development to meet health needs in developing countries: strengthening global financing and coordination*. Geneva: World Health Organization; 2012. Available from: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf [accessed 4 October 2012].
4. *ConstitutionWHO*. Geneva: World Health Organization; 1946. Available from: http://www.who.int/governance/eb/constitutionl [accessed 4 October 2012].

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