Policy Brief

A binding biomedical R&D convention: a structural solution for systemic failure

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Background

The current financing structure and incentive model based on Intellectual Property Rights (IPRs) for biomedical Research and Development (R&D) and innovation has failed to deliver (a) adequate resources for R&D that addresses global health priorities, and in particular the needs of developing countries, and (b) new medical products that are suitable, widely accessible and affordable to people in developing countries once they are developed. This has resulted in a lack of access to suitable and affordable medicines in developing countries.[i]

This systemic failure - and the need to come up with a structural solution – has been widely recognized: in the 2006 World Health Organization (WHO) CIPIH report, by WHO Member States in 2008 in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual property, and in 2010 by European Union (EU) Member States in the Council Conclusions on the EU role in Global Health.[ii]

Despite this widespread recognition of a systemic failure in addressing priority global health needs, solutions have resulted in an *ad hoc* patchwork of publicly-funded and philanthropic initiatives. Sadly, this falls short of a politically and financially sustainable institutional arrangement which would ensure sufficient investment in medical global R&D, fair arrangements for burden sharing, efficient knowledge sharing that enables scientific progress, and equitable access to the fruits of scientific innovation.

Member States have looked to the WHO to promote the seismic shift that clearly needs to me made. The Consultative Expert Working Group (CEWG) established specifically for this purpose has now singled out a *binding biomedical R&D convention* as the politically and financially sustainable institutional arrangement that will ensure a realistic structural change in how R&D for priority health needs is financed, prioritised and incentivized.[iii]

Recommendations

Health Action International (HAI) and the Alianza LAC-Global (Alianza) commend the CEWG for its clear and realistic vision and support the CEWG recommendation that negotiations begin on a binding biomedical R&D convention. As a minimum, it should include the following elements:

Adequate, predictable and equitable funding of R&D for priority global health needs

Sustainable and predictable sources of financing are crucial for biomedical R&D. Current funding commitments are, however, dependent on political will of donor countries, private donors and some corporate social responsibility policies. Member states should therefore commit to a binding level of public funding for R&D relevant to global health priorities, based on the principle of fair and equitable burden sharing. The CEWG recommends a commitment to a threshold of at least 0,01% of GDP government-funded R&D, devoted to meeting the health needs of poor countries.[iv] The Alianza and HAI would like to draw attention to the importance of appropriate safeguards to prevent Member States from meeting this binding commitment by simply diverting resources from other domestic health priorities.

Coordination of R&D: improve priority setting based on global health needs

The biomedical R&D convention should further develop inclusive and transparent coordination mechanisms to identify and establish priority areas of needs-driven R&D and funding needs. Within this framework, HAI and the Alianza propose that the scope of diseases should be comprehensive and cover all priority global health needs and at least include Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases.[v]

In respect of allocation of R&D financing, HAI and the Alianza propose giving Member States the opportunity to (partially) allocate their R&D contributions in their own countries or to different pooled funds: provided that such funding is at all times consistent with global R&D priorities and the norms and policies governing publicly funded R&D under the R&D convention.[vi]

Within an R&D coordination framework, sufficient consideration should be given to adequate transparency and the management of conflicts of interest. There must be a clear policy and systematic approach to transparency and conflict of interest declarations to ensure that those representing commercial interests are not part of policy formation and norm–setting.[vii]

Norm-setting instrument

New approaches to innovation are needed because although IPRs can provide an incentive for innovation, it is widely acknowledged this this incentive is insufficient to address the majority of global health priorities in developing countries.[viii] These norms and policies can be complementary to the existing system and a variety of them are already being explored by governments, private funders and industry.[ix]

An R&D convention would provide the framework to consolidate existing and innovative approaches and include criteria to govern publicly funded R&D that ensure (a) more transparent, efficient and needs-driven R&D, and (b) medical products that are widely accessible and affordable to people in developing countries once they are developed. The Alianza and HAI recognize that such norms and policies should at least include measures that:

Encourage R&D guided by an open knowledge innovation approach. A crucial element of this approach is that R&D costs are delinked from medical product prices to replace the traditional

incentive expectations of high monopoly medicines prices through patents.[x] Examples of such models are open source innovation and prize funds.

Ensure the broadest possible dissemination and use of R&D results by acknowledging that publicly funded R&D outputs – including clinical trial data - are a global public good and should be in the public domain, or made available through appropriate open licensing approaches.

Ensure overall transparency of global medical innovation by requiring data on costs of R&D, other resource flows used to support R&D, and on medicines prices and revenues to be made publicly available.[xi]

How to proceed

We consider a *binding* agreement to be necessary to overcome the collective action problems inherent to the global public good element of global biomedical knowledge.[xii]
Because a binding R&D convention can be an instrument that benefits high, middle and low income countries, reaching such a binding multilateral agreement is also a feasible outcome. Moreover, the alternative of non-binding recommendations is not by definition easier to negotiate and the result, even if achieved, may also be considerably weaker and would not secure the necessary changes.

Negotiating and administering a binding biomedical R&D convention falls clearly within the WHO mandate.
This process can further strengthen the WHO's mandate in the ongoing WHO reform program.

Parties can and should now agree on the need for a systemic solution in the form of a binding R&D convention.
We recognize the need for countries to continue analyzing in detail all technical and practical implications of the different elements of the proposed biomedical R&D convention. This does not justify, however, postponing discussing the commitment to start negotiating a binding convention. There is an international consensus on the failures of the current R&D system and the CEWG recommendation to start negotiating a binding R&D convention brings to a close a more than 10 year effort by the international community to formulate a structural solution to a systemic failure in R&D meeting global health needs.[xiii] This solution can no longer be postponed.

Notes

[i] WHO (2006) 'WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health' (CIPIH Report). p. 171. Available at: http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf; WHO (2004). 'The Global Medicines Situation Report, 2004'.p 19. Available at: http://ebookbrowse.com/world-medicines-situation-2004-pdf-d50566214; WHO (2012) 'Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination'. Report of the CEWG on Research and Development: Financing and Coordination (CEWG Report). April 2012. p. 24-26. Available at: http://www.who.int/phi/CEWG_Report_5_April_2012.pdf.

[ii] WHO (2006) CIPIH Report; WHO (2008).'Global strategy and plan of action on public health, innovation and intellectual property'.*WHA61/2008/REC/1.* Available at: http://apps.who.int/gb/ebwha/pdf_files/WHA61-REC1/A61_Rec1-part2-en.pdf; Council of the European Union (2010). 'Council conclusions on the EU role in global health'.*3011th Foreign Affairs Council meeting*.Brussels. Available at: http://www.consilium.europa.eu/uedocs/cms_Data/docs/pressdata/EN/foraff/114352.

[iii] WHO (2012) CEWG Report: p. 120-125.

[iv] WHO(2012), p. 110-111.

[v] WHO (2012) CEWG Report, p. 122.

[vi] This could include existing Product Development Partnerships (PDPs) or for example regional or sub regional funds. See also: HAI (2011). 'Submission to the Consultative Expert Working Group on Research and Development: Financing and coordination (CEWG)'. June 2011. Available at: http://www.who.int/phi/news/phi_17_health_action_int_sub_en.pdf; James Love, Knowledge Ecology International (KEI)(2012). 'Is the WHO CEWG proposal for the R&D treaty "too small"?'. 4 May 2012. Available at : http://keionline.org/node/1405.

[vii] HAI supports a coordinated and comprehensive approach to handling personal conflicts of interest by:

i) Adopting a common definition of conflict of interest among relevant bodies ii) Instituting the mandatory declaration of the details regarding the activities of experts and decision makers in relation to any of the following: employment, strategic advisory roles, consultancy, representation, financial interests, ownership of a patent or product, researcher, employment or involvement at an institution receiving a grant or other funding. iii) Mandating the relevant bodies to publish all declaration of interest forms iv) Creating a procedure to identify and resolve any competing interest. In some cases, impartiality could be achieved by limiting the advisor's involvement in the decision making process. HAI Europe et.al.(2011). 'NGO letter on Conflicts of Interest, Future Financing, Reform and governance of the WHO'. 24 May 2011. Available at: http://haieurope.org/wp-content/uploads/2011/05/24-May-2011-NGO-letter-on-Conflicts-of-Interest.pdf.

[viii] ibid. footnote (i).

[ix] More information and an overview of current public and private initiatives can be found in: TACD/HAI Europe (2012) Policy Paper: 'Time for the EU to lead on innovation: EU policy opportunities in biomedical innovation and the creation of public knowledge goods', p. 20-26. Available at: http://haieurope.org/wp-content/uploads/2012/04/HAI-Europe_TACD-EU-Innovation-Paper.pdf. James Love, KEI (2012), mentions in this respect: "For example, the head of the European Federation of Pharmaceutical Industries and Associations (EFIPA) recently endorsed the use of prizes to reward the development of new antibiotic drugs, and the US Senate HELP committee is asking the US National Academies to study various models for de-linkage for

HIV/AIDS, antibiotics and other products. As another sign of the changing times, the Gates Foundation, which normally is closely aligned with big PhRMA companies, has recently invested the design of new innovation inducement prizes for diagnostic devices and other R&D targets.”

[x] This will not only make medicines more affordable, it will also stimulate generic competition and ensure sustainable access. Removing IP barriers to entry into the market will allow more players – also in developing countries - to take part in the process of production and innovation. This is not only a desirable situation from the point of view of the right of development but also the most effective way to ensure a sustainable supply of medicines. Generic competition has proven to be the most effective way to lower the price of medicines and ensure affordability:

[xi] Information on financial and other resource flows to R&D is essential to effectively identify research gaps and priorities in the existing landscape (WHO (2012) CEWG, p. 102). Unlike other products, medicine prices have fundamental implications for public health, since they determine access to necessary medical care. (HAI (2009).‘Response to the Expert Working Group on Alternative Financing’. http://www.haiweb.org/16042009/15%20Apr%202009%20HAI%20Response%20to%20EWG%20on%20Alternative%20Financing.pdf.

[xii] Joseph E. Stiglitz (1999). ‘Knowledge as a Global Public Good’. In: Kaul I, Grunberg I, Sern MA, editors. *Global public goods: international cooperation in the 21st century*. New York: Oxford University Press 1999; John-Arne Røttingen et.al. (2012). ‘Securing the public good of health research and development for developing countries’. *Bull World Health Organisation* 2012:90, p. 398.

[xiii] John-Arne Røttingen et.al. (2012), p. 399.