

The Relevance of Global Convention on Health Research and Development

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The Background

In the face of the rapid-growing science and technology, paradoxically, there are only scant initiatives in R&D that address the high disease burden of developing countries.² This curious situation is attributable to the patents based incentive model on which the current R&D system is functioning.³ The Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) reveals lack of incentives to invest in the research on pharmaceutical products, including preventive, diagnostic and curative interventions in Type II and III diseases and specific research and development needs of developing countries in relation to Type I diseases⁴. This suggests that the existing patents based incentive model is quite insufficient to motivate R&D addressing developing country health concerns as such a model is directed to the market demands rather than the public health needs of developing countries. Therefore the CIPIH draws the inference that “market alone, and the incentives that propel it, such as patent protection, cannot themselves address the health needs of developing countries”⁵.

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² The developing countries are suffering from the double burden of disease because along with diseases that disproportionately affecting the developing countries such as communicable diseases, maternal, perinatal and nutritional diseases, they are also affected increasingly by non-communicable diseases and injuries. Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPH Report), p.3

³ As mentioned in the CIPIH Report at p. 16, the Commission on Macroeconomics and Health (WHO) has suggested that, left to market forces, there will be an inadequate volume of research on diseases that disproportionately affect the developing countries.

⁴ The CIPIH Report points to one interesting data showing that developing countries which account for more than 80% of the world’s population are responsible for only 10% of global sales of pharmaceutical products because of two reasons; lack of effective demand (not need), and lack of supply. CIPIH, pp. 15, 16. Even the trend among the developing country pharmaceutical industries is not different as they too address the market demand rather than the health needs of developing countries. For evidences from India read Paul Wilson and Arathi Rao, *India’s Role in Global Health R&D*, Center for Global Health R&D Policy Assessment, Results for Development Institute, Washington DC, 2012 available at <http://healthresearchpolicy.org/assessments/india%E2%80%99s-role-global-health-rd> visited on 20.08.2012.

⁵ CIPIH Report, p. 17. The CIPIH Report has categorically stated that “where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to markets. See p. 22. Also read Tim Hubbard and James Love, “A New Trade Framework for Global Healthcare R&D”, (February 2004) Volume 2 PLoS Biology 147 available at <http://biology.plosjournals.org> visited on 27.07.2012

Another major drawback of the current incentive based R&D model is that the price of the products of innovation is attributed to the cost of R&D for which generally no evidence is procured. Right to health is a universal and inalienable right and it should take precedence over commercial interests and it is the duty of governments to ensure universal health coverage.⁶ The problems with the existing system extend far beyond the narrow notion of neglected diseases⁷. It extends to affordability⁸ and accessibility of pharmaceutical products⁹ for diseases with global incidence such as diabetes and cancer.

In this context it becomes relevant to think about alternative models which, while promoting R&D addressing developing country health concerns, ensure affordability and accessibility of the products of R&D. While pursuing such a model, the major hurdles that come up are locating adequate funds for R&D initiatives¹⁰, coordination of R&D ensuring transparency and sustainability. The alternative model should also delink the cost of R&D from product prices for ensuring affordability and in the long run equip the developing countries with innovative capacity by transfer of technology. A binding Treaty/Convention at the international level, thus, becomes highly relevant.

The most appropriate forum for such an initiative is WHO, the Constitution of which states that “the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition” and the objective of which is “the attainment by all peoples of the highest possible level of health”¹¹. Moreover, the constitution of the WHO authorizes the Health Assembly to “adopt conventions or agreements with respect to any matter within the competence of the

⁶ German Velasquez and Xavier Seuba, “Rethinking Global Health: A Binding Convention for R&D for Pharmaceutical Products” Research Papers 42, South Centre, December 2011

⁷ Suerie Moon, Jorge Bermudez, Ellen ‘t Hoen, “Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?” (May 2012) 9 PLoS Medicine, available at <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001218> visited on 20.06.2012. The authors say that the challenge should be best understood as one of “neglected populations” ensuring that global R&D system should benefit all (meets the needs of all), especially of the poorest and most vulnerable populations.

⁸ The high costs of pharmaceutical products are usually attributed to the high cost in R&D, which is a disputed fact. Despite the high cost and risk, pharmaceutical industry was the most profitable one in the U.S. during 1995-2002. Read CEWG report, at p. 18

⁹ Apart from medicines, they include antibiotics, vaccines, diagnostics, and medical devices.

¹⁰ The CEWG report reviewed EWG’s proposal on resources of finance and was reluctant to evaluate the proposal by Brazil for ‘taxation of repatriated pharmaceutical industry profits’ and discarded, as it felt that the proposal needed specific expertise and knowledge, which is not available with the CEWG. It felt that the ‘voluntary contribution schemes’ is unrealistic and the ‘new direct taxes’ option is a more realistic one, which it felt, should be further speculated and determined at the national level. These could include taxes on activities harmful to health such as tobacco and sweet or fatty foods, arms trade, airline travel, internet traffic or financial transaction etc. See pp. 64-75

¹¹ Article 1, The Constitution of the World Health Organization

Organization”¹². The WHA resolution 59.24 decided to establish an inter governmental working group open to all members to draw up a global strategy and plan of action in order to provide a medium-term framework based on the recommendations of the Commission on Intellectual Property Rights, Innovation and Public Health, and by resolution WHA 61.21 adopted the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). The GSPA-PHI, in turn, resolved to establish an expert working Group under the auspices of WHO to examine current financing and coordination of research and development as well as proposals for new and innovative sources of funding to stimulate R&D related to Type II and Type III diseases and the specific R&D needs of developing countries in relation to Type I diseases. The final outcome of all these is the Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). One major recommendation of the CEWG is to have an international treaty on R&D.

Objectives of the Global R&D Treaty

The main objectives of the treaty will be to set up a transparent, participative and effective governing structure for needs assessment of R&D gaps; to set priorities; to identify innovative sources of sustainable financing to stimulate R&D initiatives directed to the developing country health concerns; to share the burden of R&D by all member countries according to their ability; to coordinate the functioning of such mechanism; to ensure that exclusivity based incentives are not used to promote the new model of R&D; to identify alternative models; to ensure transfer technology to developing countries enabling capacity building in developing countries for initiating R&D of their own choice and priorities. Another very important objective, along with organizing R&D, is to ensure affordability and accessibility of pharmaceutical products to all the people in need of them, especially from developing countries, failing which the new initiative will become futile. De-linking cost of R&D from the prices of the products of such R&D is a major measure in ensuring universal affordability of pharmaceutical products.

Sustainable financing

Since research and development in pharmaceutical sector is a costly affair and the pharmaceutical industry, generally, is reluctant to invest in R&D for pharmaceutical products addressing the developing country concerns, it is essential to mobilize funds for promoting R&D in this area. This has to come mainly from the governments,¹³ but private participation in investment

¹² Article 19, The Constitution of the World Health Organization

¹³ CEWG Report, Executive Summary, p. 10, 11. The four sources of financing considered by CEWG are new direct taxes, voluntary contributions from business and consumers, tax on repatriated pharmaceutical

is equally important. The CEWG Report suggests that the proposed R&D Convention/ Treaty has to stipulate that each country has to contribute minimum 0.01% of their GDP to R&D initiatives for meeting developing country health needs.¹⁴ What is envisaged in most of the proposals is a centralized mechanism to be established under the Convention, to which the countries/governments are supposed to make their contributions with regional centers all over the world¹⁵.

Coordination of R&D

Proper coordination of R&D by continuous monitoring and evaluation and by ensuring transparency alone will ensure the success of the new model¹⁶. In the absence of a binding Convention, the priorities will be set by who finance the particular projects.¹⁷ Since the big pharmaceutical industries have started collaborating with governments, the convention has become a necessity to ensure government control in the information and research products and their accessibility. Therefore, coordination involves identification of research priority of unmet health needs of developing countries, providing advice and setting standards, mechanism ensuring collective decision making, regular systematic reviews, monitoring and evaluation of research, reducing overlap and waste in research by ensuring collaboration rather than competition among different groups doing research in the same field, managing and allocation of funds, ensuring that ethical standards are met in clinical trials, etc. A centralized agency under the auspices of WHO, with regional centers in all countries who form part of the Convention should be entrusted with the coordination. Already existing initiatives in different developing countries should be made use of for this purpose. These measures will ensure transparency in the coordination of R&D.

The three stages of R&D need to be properly coordinated. In the drug discovery stage, different developing countries have already developed different mechanisms like the Open Source Drug Discovery (OSDD) in India or the African Network for Drugs and Diagnostics Innovation

industry profits, and new donor funds for health research and development and regarding taxes to be imposed, the CEWG concludes that it should be left for the national governments to determine the taxable areas, but suggest two possible taxes – the Financial Transaction Tax and the Tobacco Solidarity Contribution in addition to the airline taxes imposed by some countries

¹⁴ CWEG Report, pp. 84, 110,111. In addition it proposed that developing countries with a potential research capacity should aim to commit 0.05-0.1% of GDP and the developed countries should commit 0.15-2% of GDP to government funded health research of all kinds.

¹⁵ CWEG Report, p. 123. The Report suggests a contribution of 20-50% of the total funding obligation of countries to a pooled funding mechanism.

¹⁶ The OSDD Model of collaborate, discover and share appears to be worth emulating. Please see <http://www.osdd.net/about-us>

¹⁷ Unni Krishnan Karunakara in an interview given to Naren karunakaran, “India to benefit much from convention on health R&D”, July 16, 2012, *The economic Times*, available at http://articles.economictimes.indiatimes.com/2012-07-16/news/32698526_1_affordable-treatments-india-benefit-initiatives

(ANDI) in Africa. These existing initiatives should be made use of for ensuring better coordination in the regional level.

In the drug development stage, regulation plays an important role in the development of new medicines, vaccines and diagnostics, setting standards of clinical research and providing a scientific assessment of product safety, efficacy and quality. The regulatory capacity in most developing countries, including India, remains very weak¹⁸. The major problem they encounter is with respect to executing clinical trials. Most of the developing countries are lacking infrastructure for clinical trials including health facilities, clinicians, technicians etc. Apart from the deficiencies in infrastructure and requisite skills needed, there are other problems relating to ethical regulatory issues. Ensuring informed consent in clinical trials, lack of capacity in local ethical review committees and adequate mechanisms to ensure that the participants of clinical trials are properly treated once the trial is completed etc., also are serious challenges faced by developing countries. This weakness of the developing countries raises serious concerns when externally sponsored clinical trials are conducted in these countries.

In the drug delivery stage the major problems are proper functioning of primary and secondary health care systems, lack of proper drug delivery infrastructure etc. An interesting method adopted by OSDD in India is to make the developed drug available for any industrial player with appropriate manufacturing practices to distribute the drug so that the market competition will ensure accessibility and affordability. This will enable the use of existing infrastructure which, in turn, will reduce the cost of drug delivery.

De-linking cost of R&D from Product Price

One of the major challenges in the context of the new initiative for R&D promotion is to find viable business models for drug development in the absence of marketing monopoly incentives.¹⁹ Different models suggested by different sources are listed out in the CEWG report. It is felt that since the funding is largely from public sector and the objective is universal access to pharmaceutical products, open access model²⁰ with prize fund incentive could be an effective alternative to the existing model. Free dissemination of knowledge, enabling competitive and

¹⁸ CIPIH, p. 79

¹⁹ Tim Hubbard and James Love A New Trade Framework for Global Healthcare R&D (February 2004) Volume 2 PLoS Biology 147 available at <http://biology.plosjournals.org>, at p. 148.

²⁰ An Indian example of open source model is Open Source Drug Discovery initiative (OSDD) led by Council for Industrial and Scientific Research (CSIR). For details read ““Open Source Drug Discovery” An Open Collaborative Drug Discovery Model For Tuberculosis” proposal submitted before the WHO Expert Working Group on R&D Financing by Project Director, OSDD, CSIR, Government of India available at http://www.who.int/phi/public_hearings/second/contributions/ZakirThomasCouncilofScientificIndustrialResearch.pdf. Please visit the OSDD website www.osdd.net for more details.

follow on research, should be an important feature of the new R&D model.²¹ Open collaborative research through public-private participation appears to be a good option provided it is based on the philosophy of delinking the cost of R&D from the price of the pharmaceutical product.²² An objective of the de-linking model is to eliminate monopoly in the final product of R&D and to reward R&D efforts that bring out good results in terms of advancements in science and technology and public health. Such a model will promote competition by permitting generic production with immediate effect. However, patent could be used to prevent misappropriation with the clear understanding that it will never be used for blocking follow on research and innovation or for avoiding competition.

Facilitating transfer of technology

The long-term objective of the Treaty will be to ensure transfer of technology to developing countries and to build innovative capacity in developing countries for enabling them to be self-sufficient in ensuring universal access to medicine. The collaborative open model of R&D will be so designed that it will ultimately lead to transfer of technology and thus facilitate building and improving innovative capacity for research and development in developing countries.

Conclusion

It is high time that public health be freed from the constraints of trade regime and discussed and decided in a forum the concern of which is universal health coverage. We are already late in launching an international instrument addressing the health concerns of those who are unable to pay, as health is a fundamental human right. Therefore, it is quite disheartening that in the 65th World Health Assembly no resolution was made for the Global Health Treaty.²³ A ray of hope still remains as the WHA resolution 65.22 has requested the Director-General “to hold an open-ended meeting of Member States that will thoroughly analyse the report and the feasibility of the recommendations proposed by the CEWG, taking into account related studies as well as the results from national consultations and regional committee discussions, and will develop proposals or

²¹ However, the CEWG Report is cautious to state that the Convention is not seen as a replacement for the existing Intellectual Property system but as a supplementary instrument where the current system does not function. CWEG Report, p. 122.

²² James Love and Tim Hubberd, “The Big Idea: Prizes to Stimulate R&D for New Medicines” 82 *Chicago-Kent Law Review* 1519, at p.1528. This is the model followed by the OSDD initiative in India

²³ The U.S delegation has objected to almost all the proposals by the CEWG, especially the one for establishing a single pooled financing mechanism. The statement to the World Health Assembly by Nils Daulaire, who was leading negotiations for the US, was reproduced in “Obama Administration Blocks Global health Fund to Fight Diseases in Developing Nations” available at www.huffingtonpost.com/2012/05/25/global-health-fund-obama-administration-n-1544399.html

options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures” to be presented in the 66th World Health Assembly. In accordance with this resolution, national consultations and regional committee discussions are going on.²⁴ Further discussions and studies are also going on under the auspices of the World Health Organization seeking better methods for identifying disease burden by attempting to define the types of diseases more precisely so that specific priority areas for the R&D agenda could be decided more effectively.²⁵ Besides the WHO’s Department of Public Health, Innovation and Intellectual Property (PHI) has prepared factsheets on 18 international and regional funding and research mechanisms in the area of health, environment and agriculture as well as the WHO Framework Convention on Tobacco Control so as to serve as background information to assist Member States in developing proposals or options relating to (1) research coordination, (2) financing and (3) monitoring of R&D expenditures as referred to in WHA 65.22.²⁶ The open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination held at Geneva during 26–28 November 2012 has prepared a draft resolution to be submitted to the Sixty-sixth World Health Assembly for its consideration.²⁷ The draft resolution, *inter alia*, requested the Director General to develop norms and standards for classification of health R&D; to support Member States in their endeavour to establish or strengthen health R&D capacities; to establish a global health R&D observatory within WHO’s Secretariat; to facilitate through regional consultations; to review existing mechanisms to assess their suitability to perform the coordination function of health R&D; to explore and evaluate existing mechanisms for contributions to health R&D and, if there is no suitable mechanism, to develop a proposal for effective mechanisms, including pooling resources; etc. All these developments are definitely positive and optimistic.

²⁴ Report of the regional committee discussions by the Director-General, A/CEWG/2, 7 November 2012 available at http://apps.who.int/gb/CEWG/pdf/A_CEWG_2-en.pdf

²⁵ *Defining Disease Types I, II And III*, Background document provided by the WHO Secretariat, 14 November 2012 available at http://www.who.int/phi/3-background_cewg_agenda_item5_disease_types_final.pdf

²⁶ *Factsheets on Funding and Research Mechanisms*, Background document provided by the WHO Secretariat, 14 November, 2012 available http://www.who.int/phi/2-funding_mechanism_factsheets_6nov12.pdf

²⁷ Report of the open-ended meeting of Member States on the follow-up of the report of the Consultative Expert Working Group on Research and Development: Financing and Coordination, Geneva, 26–28 November 2012 available at http://apps.who.int/gb/cewg/pdf/A_CEWG_4-en.pdf