Global Governance for Facilitating Access to Medicines: Role of World Health Organization

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Growing dissatisfaction with constant interference of trade regime with basic human right to health has necessitated the search for an alternative forum competent to take lead in the struggle for global access to affordable medicines, and thus it ended up with the World Health Organization. The WHO, in turn, recommended a Global Health R&D Treaty. Nevertheless, the clash between global health actors and the industry continues, occasionally affecting the WHO initiatives. Still, there is a room for hope.

Keywords: Global health R&D Treaty, Role of WHO, global access to affordable medicines

Conflict between Right to Health and Trade Interests

Right to health is a universal and inalienable right and it should take precedence over commercial interests and it is the duty of the government to ensure universal health coverage.1 The Committee on Economic, Social and Cultural Rights (CESCR), advertsing to the social function of intellectual property, has emphasized the duty of states to prevent unreasonably high costs of essential medicines.2 It has also emphasized the duty of State parties to prevent the use of scientific and technological progress for purposes contrary to human rights and dignity, including the rights to life and health.2 However, ensuring access to health, which is a fundamental human right, is a real challenge in the current market economy. Globalization of intellectual property and its incorporation into the global trade regime has considerably affected the States’ authority to set their health policies and priorities. It is a widely known fact that pharmaceutical industry has played an important role in the incorporation of intellectual property into the GATT agenda and subsequently into the TRIPS negotiations.

Paradoxically, TRIPS negotiations were initiated in the time of a major global health crisis resulting from the upsurge of HIV/AIDS epidemic. In the year TRIPS was adopted, it became evident that people in some low and middle income countries (LMICs) were doomed to die due to the unaffordability of HIV medicines that were saving the lives of North Americans.3 The post TRIPS era witnessed ruthless bargaining by pharmaceutical industry, supported by industrialized nations, for unrestrained enjoyment of intellectual property protection. With the help of governments, particularly the US government, the pharmaceutical industry is actively influencing the global health agenda at domestic and global level. Availability and affordability of preventive and curative pharmaceutical products are the two major problems encountered by developing countries. In addition, market-driven R&D initiatives totally ignore health needs of people having no purchasing power. Growing dissatisfaction with the existing system has raised the question about the possibility of a more politically sustainable way to distribute R&D costs across countries so that equitable access to medicines is ensured.4 It has also become essential to shift the focus of discourse from trade/commercial interests to fundamental human right to health. The most appropriate agency to take leadership in such an initiative is the World Health Organization (WHO), United Nations (UN) specialized agency for health, which has been the cornerstone of world health since its creation in 1948.

Role of WHO in the Global Governance for Access to Medicines

The global health arena is complex with multiple actors such as bilateral donors, UN agencies, global

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and regional funds, and global health initiatives, in addition to a number of aid organizations, religious missions, and volunteers. The near total absence of coordination has resulted in fragmentation, duplication and poor efficiency. Governments looking to tackle health problems find it very difficult to identify the global agency from which to elicit support. Health ministries often complain of the large amount of time spent writing proposals and reports for donors whose interests, activities, and processes sometimes overlap, but often differ. The proliferation of global health actors and their competing interests are compelling factors for seeking the right global health leadership.

The WHO is the most appropriate organization to take up the leadership of global governance for access to health and coordinate global health R&D financing, because of the broad normative power conferred on it by its Constitution ‘to act as the directing and coordinating authority on international health’. Moreover its foundational objective is to achieve the ‘attainment by all peoples of the highest possible level of health’. No other international organization has the normative or technical capacity or legitimacy to take leadership in the pursuit of solution to the global health issues. Immediately after the TRIPS Agreement came into effect, member states in the WHO discussed its potential impact on public health and requested the WHO Director-General ‘to report on the impact of the work of the World Trade Organization (WTO) with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate’.

A major development in this regard was the establishment of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPHI) and subsequent adoption of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPA-PHI). The GSPA-PHI as well as WHA61.21 required the WHO to ‘establish a results-oriented and time-limited expert working group under the auspices of WHO and link up with other relevant groups to examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate R&D directed at the specific needs of developing countries in relation to Type I diseases’. Two WHO expert working groups (the EWG and the CEWG) have examined the current financing and coordination of R&D, as well as proposals for new and innovative sources of financing to stimulate R&D directed at the specific needs of developing countries.

Significance of Global Health R&D Treaty

The Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG), in its report, recommended adoption of a binding agreement based on Article 19 of the Constitution of the WHO for providing effective financing and coordination mechanisms to promote R&D, focusing the health needs of developing countries. Though the content of the agreement was left to be determined by the Member States, the CEWG Report set out the principles and objectives for the purpose of supporting the negotiation process. It also expressed the view that the framework for a possible convention has already been agreed between Member States in paragraph 14 of the GSPA-PHI. The Report suggested that the objectives of the Convention could include: (i) implementing states’ obligations arising under international human rights instruments relating to health; (ii) promoting R&D addressing the health needs of developing countries by securing access and affordability through delinking R&D costs and the prices of the products; (iii) securing sustainable funding for identified R&D priorities in developing countries; (iv) improving coordination of public and private R&D; (v) enhancing the innovative capacity in developing countries and technology transfer to these countries; (vi) generating R&D outcomes as public goods, freely available for further research and production; (vii) improving priority-setting based on the public health needs of developing countries, and decision-making relying on governance structures which are transparent and giving developing countries a strong voice; and (viii) core elements under the convention should focus on development of health technologies for Type II and Type III diseases as well as the specific needs of developing countries in relation to Type I diseases.

The CEWG, recognizing that substantial additional funding was required to promote R&D capable of addressing the health needs of developing countries, required all member countries to commit to spend at least 0.01% of GDP on government-funded R&D
devoted to meet the health needs of developing countries in relation to product development for those types of diseases. This suggestion was meant to ensure systematic global funding. Such funding is expected to be used with the objectives such as to: (i) fund R&D in all sectors (public, private and public–private partnerships) to address identified health needs of developing countries in relation to the types of R&D defined in the CEWG mandate; (ii) fund all phases of R&D utilizing open approaches to R&D and prize funds, as well as the costs of late-stage development, including clinical trials; and (iii) help build R&D capacity in developing countries and promote technology transfer.  

The major challenges currently faced by global health R&D are sustainable funding, priority setting, equitable distribution of R&D funds depending upon priority, ensuring accountability, transparency and affordability of R&D outputs, coordination, continuous monitoring of all these etc. Currently, there is no reliable and sustainable mechanism to generate sufficient funding for research, and priority of R&D is most often set by those who invest in R&D. Therefore only a limited set of diseases are covered by such investments. The CEWG suggested a Global Health R&D Observatory and relevant advisory mechanisms under the auspices of WHO to monitor financial flows to R&D and to identify gaps and unnecessary duplication.  

The CEWG examined both the issues of inadequacy of R&D investment relating to diseases disproportionately affecting developing countries and access to affordable medicines. It systematically assessed various new approaches to improve the R&D system and found particularly promising open-access approaches that ‘de-link’ financing of R&D from the pricing of end products so that medicines can be sold near the cost of production. The principle of delinking is based on the principle that costs and risks associated with R&D should be rewarded, and incentives for R&D provided other than through the price of the product. In the existing patent-driven innovation system, the returns for investment in innovation are generally recouped from the price of products. In contrast, new and innovative finance mechanisms and initiatives aim not to finance the cost of R&D through the price of the end product, thus delinking the cost of research from the price of the product.  

A treaty alone could include binding obligations on governments to contribute to R&D, in a manner facilitating equitable sharing of burden of R&D. An international agreement is required to establish robust, sustainable, predictable, and sufficient financial flows for R&D and to set norms for priority decision making so as to decide which R&D investment has to be prioritized, taking into account the health needs, and to facilitate distribution of R&D funds and ensuring accountability, transparency and affordability. Market incentives, not health needs or public priorities largely drive private R&D investments. This could be changed only by open access R&D initiatives with incentives in the form of prizes rather than pushing the entire burden of R&D on to consumers. Currently, donors play a central role in financing the R&D dedicated to the specific needs of developing countries and this leaves priority-setting decision-making largely in their hands. A system which works on collective knowledge and financing by all countries is expected to be more equitable in governance arrangements, with stronger decision-making power vested in the hands of affected population. A delicate issue that is sure to crop up in future discussions will be the treaty’s relation with other binding agreements, particularly the TRIPS Agreement.  

Challenges of Global Governance for Access to Medicines  

Industry Interference in the WHO Decision Making  

In spite of the WHO taking leadership of global initiatives for access to health in many areas in a laudable manner, it was never free from criticisms. Allegations against the WHO and the committees or working groups appointed by them are always disappointing, especially so when they relate to taking sides with transnational pharmaceutical industry, disregarding public health interests. For example, much against the expectations that the Expert Working Group (EWG) would work on the basis of the elements of global strategy set out by the Global Strategy and Plan of Action (GSPOA) and the CIPHI report, it fell prey to undue influence of transnational pharmaceutical industry and was criticized for leaking out confidential EWG documents, including the draft final report, to IFPMA (an association of transnational pharmaceutical companies). A Member of the EWG, Cecilia Lopez Montano sent a letter to the EB Members, urging the Members to refuse endorsement
of the EWG’s report, on grounds such as not being participatory or transparent in its method of working, for the absence of terms of reference for the EWG and for the attempts in the EWG to avoid issues pertaining to intellectual property rights (IPRs).  

The EWG was criticized by many developing countries including India, Bangladesh, Bolivia, Thailand, Ecuador, and Kenya, for its inadequate discussion about IPRs and issues related to access to products of innovation, de-linking of the cost of R&D from the price of products, transfer of technology, mistreatment of proposals submitted by some developing countries; insufficient information about criteria used to assess R&D incentive proposals; as well as findings contradicting the CIPIH report and the GSPOA. It was also criticized for consulting industry rather than public interest groups. Meetings were held behind closed doors and civil society complained that they were being ignored by the experts while big pharma was being courted. No wonder the NGOs and some member states became suspicious of EWG and Viroj Tangcharoensathien, Director of Thailand’s International Health Policy Programme came out in the open accusing that the EWG lost all legitimacy and credibility.

When the report was tabled on the first day of the World Health Assembly (WHA), there was a real rich country versus poor country split, as per Katy Athersuch, a policy adviser for Médecins Sans Frontières (MSF). Developed countries wanted to fine tune the report and adopt it, she explained, whereas developing countries wanted to scrap it and start again. The 63rd WHA took note of the fact that there was divergence between expectations of Member States and output of the EWG. Recognizing the need to further explore and promote a range of incentive schemes for R&D addressing de-linkage of the costs of R&D and the price of health products, for example through the award of prizes, the WHA requested the Director General to establish a CEWG to take forward the work of EWG. Unlike EWG which, without any restraint, undertook its activities secretly, CEWG was mandated to have transparent management of potential conflicts of interest and to ensure full transparency by providing regular progress updates to member states, and by making available all the documentation used by CEWG at the conclusion of the process to Member States. The next round of controversy started when the WHO appointed a representative of Swiss industry to the newly created CEWG. Special safeguards were added to prevent undue influence, but questions remain for some about a conflict of interest.

When the CEWG report was placed before the Sixty Fifth World Health Assembly, again the discord between the developed and developing nations resurfaced. The CEWG recommendations for having intergovernmental negotiations for an R&D convention and for contribution of certain percentage of GDP to the global health fund were strongly resisted by the United States. In spite of the US being the single largest funder of neglected diseases research, its representatives stated in the WHA that it would not ‘support any proposal that would put in place a new financing mechanism that could be characterized as a globally collected tax’. Another recent move, very much criticized by NGOs and health action groups, was the outcome of an open-ended meeting on the CEWG recommendations which, the civil society is apprehensive of as pushing off the treaty discussions till 2016 (ref.19). A joint letter from different health action groups expressed the concern that the draft resolution negotiated by a small number of Member States under less than ideal conditions should not include such far-reaching recommendation to the Executive Board. The letter stated that such a move undermined the rights of Member States to have a full discussion at the WHA.

A major criticism against the global health system is that it often limits civil society participation. The experiences in the EWG and the open ended meeting etc., are being pointed out as the ill effects of shutting civil society out of both policy and decision-making processes. It is also indicated that a purely state-centric governance model is responsible for the fate of the R&D convention. A global governance system that enables the WHO to negotiate multiple and conflicting sovereign interests of Member States and that actively resists co-optation of the global health agenda by the private sector would open the way to a more effective leadership role. Such leadership, grounded in social justice and equity, would be able to drive progress towards a global agreement.

The Problem of Non-Communicable Diseases (NCDs)

Developing countries are increasingly suffering from double burden of disease because of the continuing onslaught of communicable, maternal, prenatal and nutritional diseases, combined with injuries and non-communicable diseases. The
problem facing poor countries is not simply insufficient financing, but also skewed priorities. Currently, a significant amount of funding is directed towards ‘specific diseases or narrowly perceived national security interests’ placed high on the global health agenda by a small number of wealthy donors and hence a few high-profile infectious diseases are prioritized. For example, WHO’s 2010-2011 extra budgetary funding was primarily for infectious diseases (65%), with negligible allocations for non-communicable diseases and injuries. According to the WHO Global Status Report on Non-Communicable Diseases, non-communicable diseases, principally cardio-vascular diseases, diabetes, cancer and chronic respiratory diseases, account for 63% of all deaths worldwide, and injuries account for 17% of the global burden of morbidity among adults. Almost 80% of NCD deaths occur in low and middle income countries (LMICs) and 85% of the world’s population lives in LMICs.

In 2001, the World Health Assembly’s Resolution 54.14 ‘Global health security: Epidemic alert and response’ linked health security concept to a global strategy for prevention of movement of communicable diseases across national borders. The concept of ‘health security’ is controversial since it tends to limit the scope of health security to communicable diseases and attach the concept to a global strategy for prevention of movement of communicable diseases across national borders. The introduction of a threat protection mentality, foreign policy agendas, military interests and bioterrorism concerns into global public health, under the concept of global public health security, have subtly altered the understanding of global public health. This trend reflects market justice rather than public health interests. For example, during the negotiations of the 2011 United Nations Political Declaration on NCDs (NCD Political Declaration), it has become evident that market justice continues to reign international negotiations. In the WHO Ministerial Conference in Moscow in April 2011, the issue of access to medicines for NCD patients was raised by a coalition of civil society groups. The Moscow Declaration included a specific mention of the need to ensure affordable access to NCD medicines. Based on the discussions that began at the Moscow meeting, delegates from LMICs included clear references to TRIPS and Doha in the draft Political Declaration. In the plenary speeches immediately after the Political Declaration was approved, the representative from Latin America stressed that each country had the right to use TRIPS flexibilities as confirmed by the Doha Declaration, especially LMICs had unreliable access to needed medicines and that health should be considered above trade interests. However, references to Doha were removed from the final text of the NCD Political Declaration and TRIPS references were diluted. By seeking to eliminate any references to the Doha Declaration, civil society commentators believed that the US might have been trying to assert that the access to medicines for all provisions in the Doha Declaration were not applicable to NCD medicines. The NCD process revealed once more that WHO was unable to show leadership strong enough to defeat political and economic agendas regarding access to essential medicines.

Conclusion

It is time for intensifying the struggle for an internationally binding agreement on global health R&D. In spite of all its weaknesses, the WHO alone can take leadership of such an initiative. The WHO has played a significant role in health research from the very beginning. Different departments of the WHO have already undertaken many research activities and have a good experience with priority setting. The WHO has an Advisory Committee on Medical Research and a Clinical Trials Registry. It has also recently developed a health strategy. The WHO Framework Convention on Tobacco Control (WHO FCTC) is the first treaty negotiated under the auspices of the WHO. The WHO’s work on FCTC implementation and protocol development exemplifies its ability to take leadership in the global health R&D Treaty. If there are proper mechanisms to collectively oversee the implementation of the agreement, unwarranted political as well as industrial interventions can be effectively averted. Different health activist groups have suggested diverse means to ensure transparency and accountability. Peer review method used by the UN Human Right Council and the WTO, whereby members monitor each other by filing formal complaints of non-compliance when it negatively affects them, is an effective monitoring mechanism. Monitoring by technical experts or by self-reporting etc., also helps promote transparency, mitigate informational asymmetries, facilitate reciprocity and encourage compliance. Peer review
may be the most procedurally legitimate mechanism, but expert review may be more accurate. Interventions from vigilant civil society contributors and a strong coalition of likeminded countries are equally important.

It is felt that the most controversial elements of the treaty are the concept of delinking price of the final product from the costs of R&D, open ended research model with alternative incentives and recommendation for contribution of a fixed percentage of GDP to the global health fund. Once consensus is reached on an internationally binding treaty, further issues relating to financing, constant monitoring and administering the R&D activities etc., will crop up. The WHO is expected to play a critical role in agenda setting, identifying treaty content, consensus building, promoting Member State ratification and implementation of the treaty. It is also hoped that it will take leadership in matters related to coordination, financing, monitoring of priority decision making related to R&D, ensuring affordability and transparency etc.

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13 The history of EWG is as follows: 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.
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