Editorial

The Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) - The way ahead

There is increasing recognition of the growing global disease burden and conditions that disproportionately affect the poor, especially women and children; over 50 per cent of infections occur in developing countries where about a half survive on US$2 day\(^1\). To compound the problem, along with Types II and III diseases the in Type I diseases* are threatening to overtake the infections in developing economies\(^2\). By 2015, chronic non-communicable diseases will be the leading cause of deaths in the developing world\(^3\).

Recognizing, and reiterating that (i) very few products are being developed for tropical diseases as developing and least developed countries account for less than 10 per cent of global drug sales; (ii) over 90 per cent of total global deaths due to infections occur in developing countries; (iii) there is insufficient R&D on the ‘neglected diseases’ and ‘poverty related diseases’ especially by the pharma industry; the pharma industry should address this public health needs by enhancing R&D to bring out new products, enhance the therapeutic efficacy of existing ones and not only look for potential market gains to make them available universally and (iv) need to urgently address the new public health problems with international impact as the severe acute respiratory syndrome (SARS); there is a need to establish conditions that are conducive to R&D to spur innovation for new medicines for the developing countries, the World Health Assembly (WHA) in 2003\(^4\) decided to establish “a time-limited body to collect data and proposals from different actors involved and produce an analysis of IPRs, innovation and public health, including the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries”. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) set up in 2004 made an in-depth analysis of the issues and in April 2006 came out with its report “Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health” with 60 recommendations\(^5\).

After considering the CIPIH report, the WHA established an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)\(^6\) in 2006 “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”. Such a Strategy and Plan of Action would aim at, inter alia, (i) securing an enhanced and sustainable basis for needs-driven, essential health R&D relevant to diseases that disproportionately affect developing countries; (ii) proposing clear objectives and priorities for R&D; and (iii) estimating funding needs in this area. The IGWG was charged with agreeing on a global strategy and plan of action to submit to the 2008 WHA, “giving particular attention to needs-driven research and other potential areas for early implementation”\(^6\).

The IGWG discussions were intensive extending to twice the planned duration and as the opinions were diverse on a clear North-South divide, the meeting ground was often thin. Bringing consensus was very tough but all sides had to make concessions in order to reach a balanced compromise in what was called the ‘Geneva spirit’. Yet, coming as it did after the historic Doha meet\(^7\), in many ways the discussions of the IGWG are considered, the second important

* Type I diseases are prevalent in both rich and poor countries, with large numbers of vulnerable population in each; Type II diseases are prevalent in both rich and poor countries, but with a substantial proportion of the cases in poor countries; Type III diseases are those overwhelmingly or exclusively prevalent in developing countries\(^4\).
milestone in the long and exhausting process of global negotiations on the very vexing issue of providing access to medicines to those who need most. The IGWG went several steps beyond the 2001 Doha Declaration, by addressing the need for a serious rethink on both the way R&D for health products for the poor is to be financed and to delink R&D cost from the price of the product to promote access. The negotiations thus covered significant new ground to address at once both innovation and access that has eluded years of debate that finally (hopefully) should spur (developed country) governments and other stakeholders (pharma industry and civil society) to move toward this new paradigm.

The outcome of the negotiations of possibly the longest working group in the WHO’s negotiating history has some tangible gains; some contentious issues (at least) were discussed but set aside, and a few made little headway as there was just no agreement. The realization and tacit admission that despite tremendous advances in medical research, about 1.7 billion people continue to be deprived of life-saving medicines was a positive gain. So was the perceptible shift in the mind-set of some developed countries, especially from the European Union, that these issues should be addressed seriously and with some urgency. The need for encouraging needs-driven rather than market-driven R&D for Types II and III diseases was also recognized although the means of execution remained hazy and uncertain. Up until now the current patent-driven system of R&D has treated innovation and access as contradictory objectives that constantly needed to be counterbalanced with each other. The negotiating countries have for the first time acknowledged that innovation and access need to be (may be could be) complementary public health objectives as the developing world needs “innovation plus access”.

The IGWG negotiations recognized the strategic and central role of the WHO as the lead UN agency in international public health with the expectation for the WHO to play its legitimate role towards balancing IP, innovation and public health to promote access to products for diseases of the poor. But with a significant rider: the WHO Director General (is) to take actions “in implementing the global strategy and agreed parts of the [Plan of Action] without prejudice to the existing mandates.” (italics ours)

Other positive steps considered for product development for Types II and III diseases by the IGWG included (i) strong reiteration on the use of compulsory licensing and other flexibilities in protecting public health; (ii) drug registration requirements to be in conformity with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects for clinical trials carried out in developing countries; (iii) discussion on a biomedical R&D treaty, a global mechanism of sharing cost of R&D; and (iv) a system of collective management of IP, patent pools, the use of similar mechanisms, like prizes, to institutionalize incentives and rewards in lieu of patent protection to delink R&D cost from product prices. These positive steps need to put on a fast track by the WHO.

Not surprisingly, one of the most contentious issues through out the negotiations has been the consistent emphasis accorded to IP protection by statements as: “intellectual property rights an important incentive for the development of new health products” and efforts towards including TRIPS-plus measures in the text. These argument are perhaps untenable as, for possibly Type II and surely for Type III diseases, there is little R&D (see 9) and even when where there is generation of new IP, it is almost never exploited due to lack of market: “….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 the market”. The CIPHI Report in fact goes on to add that increasing levels of IP protection will not reverse the neglect of R&D: “there is no evidence that the implementation of the TRIPS agreement in developing countries will significantly boost R&D in pharmaceutical on Type II, and particularly Type III diseases. Insufficient market incentives are the decisive factor”. The core issue of new R&D needs to be addressed as the current system of industry-driven drug development has failed to provide health products due to lack of market access. What is more, even publicly-funded R&D done in academic settings in the developed world is unavailable for exploitation by others due to (excessive) IP protection necessitating the Philadelphia Consensus Statement. The Statement, among others, calls for The Equitable Access License to promote unfettered access to university intellectual property to make available health products to both public and private sector markets in low- and middle-income countries besides granting research exemption for any patents held or licenses executed by the Universities .

Surely, there is a need for a serious rethink on this issue through options as alternative or complementary
incentives to IP protection regimes. Hopefully, the discussions at the WHO i) on the estimation of funding needs for priority R&D, or create a framework for sustainable sources of funding; and ii) find new mechanisms that de-link R&D incentives from product prices, will start soon. As a starter, all existing and new complementary incentive schemes that could lead to sustainable financing for R&D on Types II and III should be strengthened as the funding gap for R&D is colossal. The R&D needs for TB, for example, is an estimated at US$ 950 million per year, a fraction of the 2007 global drug sales of US $ 712 billion. To that end, the WHO should carry out an objective assessment of the (hugely contested) costs of R&D for drug development and complementary incentive schemes.

There are issues outside the IP that also form barriers. Like anti-competition policies, another area of serious concern on which there is relentless pressure on governments in developing countries. The CIPIH has recommended that developing countries “adopt or effectively implement competition policies and apply the pro-competitive measures allowed under the TRIPS Agreement in order to prevent or remedy anti-competitive practices related to the use of medicinal patents”. Yet, the document falls short of really addressing the role of competition and cost of medicines through stimulating generic competition and how TRIPS flexibilities such as compulsory licensing could be used to increase access while patents are still in force.

While these global efforts are on, the agenda for the developing countries especially countries like India, Brazil, South Africa which have demonstrable capability for taking up innovative R&D, is quite clear. These countries should start implementing proposals argued for global implementation at the IGWG meetings. The existing R&D initiatives in India for Types II and III diseases are neither strong nor focused. A national plan of action is needed, especially since a significant mortality due to Types II and III occur in India and simply not enough is being done despite our demonstrable capability. What is probably required is a national commitment at the highest level. As a starter, a national priority setting exercise to identify the needs, researchable areas, systems of national co-ordination with a lead agency for each area is required. Also, multi-disciplinary partnerships and networks with R&D institutions, the academia and industry with clear mandate and goals, milestones for achievement with appropriate allocation of resources are required with a mission-mode approach. Such focused technology-generation programmes have been very successful in India, especially in the Space sector. The ongoing initiatives from agencies like the DST, CSIR and DBT, some with collaborators from abroad, could form part of this new national initiative. Currently, almost all R&D on Types II and III diseases in India is Government-sponsored carried out in isolated pockets in public-funded, and other laboratories. New economic models for research to product development should be considered based on some successful Public-Private Partnerships like development of hepatitis B vaccine, a new molecule suderb for TB, and the SBIRI programme of the DBT. These initiatives have shown that it is possible to successfully engage the emerging small and medium industries in pharma and biotechnology to take up such challenges. Wherever operationally feasible, South-South partnerships could be established. The India-Brazil-South Africa initiative could form the fulcrum for a new global initiative.

It is now clear that the current global efforts, significant though, are simply not adequate to seriously address the twin-objectives – augment new R&D for the development of new products and technologies and promote access to existing health products for the poor. The IGWG is the first major global initiative to agreeing on a way forward to reform a global system of medical research and development that has largely failed to meet the needs of people in developing countries. Co-operative efforts within the southern countries therefore are likely to more successful as there is little hope of the current system of market-driven R&D finding quick solutions to essentially our health problems. It is for countries like India to take the call and lead the global war to achieve equitable access to health care for all.

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