

IPR, R&D Capability and Health Care: Key Issues before India

Growing concerns relating to access to health care, stemming from the high costs of medicines, health services and diagnostics have become a major source of concern in India. The enormity of problem arises from the fact that a majority of the country's population cannot afford the high cost of health care and hence they find themselves excluded from the modern health care system that India boasts of. As a result, the disease burden in case of both communicable and non-communicable diseases has remained at unacceptably high levels.

The problems afflicting India's health care system stem from the fact that disease prevention forms a relatively small part of the overall efforts; in other words, there is an overwhelming dependence on the curative element. The lack of preventive health care is particularly galling in case of children, where India lags behind most other major developing countries in providing healthy life to its young population. A stark example in this regard is the inability of the immunisation programme for improving child mortality to make any dent in the occurrence of vaccine preventable diseases like diphtheria, pertussis, tetanus, poliomyelitis, typhoid, and child tuberculosis.

The overwhelming dependence of the India's health care system on curative medicines has brought with it two sets of problems. In the first place, the country's population is grappling with the burden of high prices of medicines, which are threatening to go even further in the wake of India's adoption of the product patent regime. The introduction of the product patent regime in 2005, which was done in fulfilment of India's commitment

under the WTO Agreement on TRIPS, has brought with it the spectre of global drug majors imposing their monopoly control over the Indian market for pharmaceuticals. Consequently, the generic pharmaceutical industry that has been providing cheap medicines since it took roots in India in the 1970s is under considerable pressure to survive in the new patent regime. This desire to change the patent regime is all the more pressing for the developing countries like India which are still grappling with challenges emanating from the health sector.

Orphan Diseases

The second and possibly the more worrisome aspect of the country's health care system is the high degree of prevalence of the so-called neglected or orphan diseases (see table for details). Despite being major killers, effective cures for these diseases have not been found since the population reeling under its burden is amongst the poorest and is, therefore, unable to afford the costs of the medicines. There is no gain saying that this market failure evident in the case of neglected/orphan diseases can be addressed only through meaningful interventions by the government and its various agencies.

There is need to focus on select diseases so that their impact is reduced over a period of time. It may be argued that the above-stated problems should be addressed through a broad-based strategy that government needs to adopt which is aimed at making access to health care affordable to all. Such a strategy should, in particular, take into consideration the emerging reality in the market for pharmaceutical products arising from the

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Table: Profile of Disease Burden in India

S.No	Disease	DAILYs** x 1000 (1998)	Mortality (per 100000 of population)	Disease burden current estimations of cases, 2005/Lakhs
1	HIV/AIDS	5611	-	51
2	Cardio-vascular*	26932	428 (2002)	290
3	Cancer*	8992	109 (2002)	8.07
4	Diarrhea#	22005	20.3 (2000)	760
5	Measles#	-	3.7(2000)	-
6	Malaria #	4200	0.9 (2000)	20.37
7	Pneumonia#	-	18.5 (2000)	-
8	Tuberculosis	7577	-	85
9	Leprosy	208	-	3.67
11	Diabetes	1981	-	310
12	Mental illness	22944	-	650
13	Blindness	3699	-	141.07

Note: **Disability Adjusted Life Years, which is the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability
* Age-standardized mortality rates by cause (per 100 000 population)
Mortality Distribution of causes of death among children aged <5 years (%)
Source: Satyanarayana, K. (2009). 'Dynamics of Innovation in Health Sector in India'. Presentation made at the Workshop on Alternate Patent Regime and Access to Health, organized by RIS and CASTED in Beijing, China on May 25-26, 2009.

introduction of a stronger patent regime wherein the so-called research-based firms, which are in fact the global pharmaceutical majors, have a stranglehold. There are several ways these pharmaceutical majors have been trying to retain their monopoly, for instance, in one case a particular drug from a company got 1300 patents across the EU on a single drug. This patent clustering has become quite common for defending blockbuster drugs. This new reality brings with it the spectre of high prices of medicines that would deprive large sections of the population from benefiting from the modern health care systems.

R&D Capability and IPR

For developing countries like India, a critical component of the strategy is to ensure an affordable health care system is an R&D system that can provide cost effective technological innovations. In fact, most developing countries have been grappling with the problem of finding cost effective solutions for tropical diseases. In case of some diseases like HIV/AIDS, cancer, cardio-vascular diseases while access is a major problem in developing countries, the need for further innovations in medicines, diagnostics and treatment is well accepted. The Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) in its report submitted in 2004, underlined the crucial link

between innovation and realisation of public health objectives. The CIPRH Report led to the constitution of Inter-Governmental Working Group on Public Health, Innovation and Intellectual Property (in short, IGWG) at the World Health Assembly in 2006 that was mandated to work on a global strategy and plan of action on public health, innovation and intellectual property. While setting its agenda, the IGWG emphasised the need for prioritizing research and development needs, promoting research and development, building innovation capacity, and to generate additional and sustainable financing for research and development in order to address the health needs of developing countries.

The focus of the IGWG on the development of an effective innovation system to address developing country problems in health care complemented the broad-based debate that has been taking place which has been dwelling on the implications of the patent regime sanctified by the Agreement on TRIPS. As a result of this debate, several proposals have been made to address the problems caused by the TRIPS-consistent patent regime both on the innovation systems and access to medicines. Among other things, the proposals have tried to identify the contours of an alternative patent regime, which is responsive to the needs of an affordable health care system, and also provides the incentives necessary to stimulate innovation efforts.

Alternative patent regimes seek to overcome the limitations of the patent system through innovative solutions. Some proposals encourage wider dissemination of knowledge embodied in the technologies, while others that propose the use of patent pools and open source drug discovery are aimed to enhance both access and innovation. It must, however, be emphasised that assessment of these proposals, particularly from the point of view of their relevance for developing countries like India, need to be done.

The proposals made to overcome the twin problems of lack of innovation and lack of access, can be categorized as 'push' and 'pull' mechanisms. In push mechanism funding/support is extended to innovators to develop new drugs. This funding will meet the full or a part of the cost of developing a new drug. Examples include research grants, public-private partnerships. The pull mechanisms help in eliminating R&D risk and ensure that research for finding new drugs for Type II, Type III diseases is not starved of financial support. But mere increase in funding may not result in successful development of new drugs.

While funding the science part of the innovation is necessary, translating that knowledge into products cannot be guaranteed as there are issues like regulatory approvals, rejection in the clinical trial phase, etc. In case of drug discovery and development often even most promising drug candidates are found unsuitable at different stages of clinical trial. Push mechanisms are often used to fund the initial stages of discovery and further development including clinical trials are usually done by private firms. Such mechanisms are also necessary as they are often the major funding mechanisms for neglected diseases. Public-private partnerships try to harness the capability of the private sector in developing a drug from the research leads and in meeting the regulatory approvals. Thus while push mechanisms are not the best solutions for problems of lack of innovation and lack of access, they play an important role.

Pull mechanisms in contrast offer incentives to solve a problem. The patent system is a pull mechanism as it offers the incentive of monopoly for a limited period in return for disclosure. Examples of pull mechanisms include prize fund, advance purchase/market commitment, priority review vouchers and incentives modelled on Orphan Drugs Act of USA. Under a pull mechanism, the availability of an incentive is the major feature that will attract the innovator to undertake research and come out with a product. However, a major issue with pull mechanisms is whether the incentive is

strong enough to attract the innovator cannot be determined ex-ante.

The innovator may weigh in all options and may not opt for a pull mechanism, if better and profitable alternatives are available. For example, a prize fund/priority review voucher/advance market commitment may not be attractive enough for a pharmaceutical company, if it finds that commercially it makes better sense to develop a me-too product or a drug for Type I disease than to develop a drug for a neglected/Type III disease. Another issue with pull mechanisms is that they are more or less geared towards the innovators in developed countries. Introducing the concept of priority review vouchers may not be possible in many developing countries which lack bodies like FDA with the requisite experience and expertise. Advance market commitment can be a good incentive in some cases, but not in all cases.

Financing of Health Care

The response of the government to the health care problems that India faces at this juncture has to be at various levels. There needs to be adequate financing of health care, in particular in areas that affect disadvantaged sections of the society. It may be argued that the problem of the neglected/orphan diseases afflicting the most should be taken up. Furthermore, government should finance not only the costs of medicines, but also all other attendant costs of health care, including diagnostics and the related facilities that the disease-burdened citizen would require. In other words, the suggestion is that the government should move away from the professed model of the health-insurance backed health care system to one that is based on direct financing of all health care costs. Such a system can initially be taken up as a pilot project in a few districts most burdened by the neglected/orphan diseases which should focus on full range of health care requirements like diagnostics, drugs and other therapeutic measures.

The other component of the strategy of the government would be to conduct a thorough-going review of the health insurance system to ensure that the negative aspects of current health insurance policies can be obliterated. In this context, there are consistent efforts from the Ministry of Finance for state owned non-life insurers to bring down losses in group health insurance. If in India, we are planning to move ahead with insurance based health support system, then India should opt for universal health coverage. Group Health Insurance accounts for nearly half of the Rs. 60 billion premium of the health

insurance market in India. The current debate on US health reforms may offer important insights on this. Senator Jay Rockefeller has stated that with private insurance companies the cost of health care insurance may go up by 25 per cent. Senator Rockefeller goes on to suggest that various health policies may be assessed using the following criteria: adequacy of coverage, affordability, customer and health provider satisfaction, and transparency of procedures and decision-making.

And, finally, the government needs to play a proactive role in the area of pharmaceutical R&D so as to ensure that the health care needs of the majority are effectively addressed. Like most countries, especially those in the developing world, India suffers from the problem of 10/90, which implies that only 10 per cent of the resources are deployed to address diseases affecting 90 per cent of the population. A step towards obviating this 10/90 problem would be to develop synergies between the government-funded R&D centres and the domestic firms in the pharmaceutical industry in order that meaningful public-private-partnerships (PPP) can be promoted. There is no gain saying that the PPP projects can only be meaningful if they take into consideration the priorities for the health sector as is identified by the Ministry of Health and Family Welfare. It may be emphasised that India has a unique combination of a large and viable pharmaceutical industry that has taken roots in the country and an extensive network of public funded research institutions, and these sets of

organisations can together produce the wherewithal to address the most pressing health care needs of the country.

Way Forward

In light of the above, there is clearly a case of substantial increase in government financing to address the health care needs of the country. Although in the recent past, the government has increased the Budget support granted to the Ministry of Health and Family Welfare, the allocations are not in tune with the enormity of health care problems that the country faces. This would be evident from the fact that in the 2008-09 Union Budget, the allocation for the Health Ministry was nearly Rs. 170 billion, which is now expected to go to Rs. 220 billion, but these amounts would account for barely 1 per cent in our GDP. This is despite of the fact that two major government programmes, viz. the National Rural Health Mission (NRHM) and the National Urban Health Mission (NUHM) are in operation.

It is by now well recognised that an affordable health care system is critically dependent on an innovation system that is sensitised to the needs of the majority of the population. In case of India, such an innovation system can be put in place by building effective synergies between the Scientific Ministries and the Ministry of Health and Family Welfare on the one hand, and the domestic pharmaceutical firms, on the other.

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RIS
Research and Information System
for Developing Countries

Core IV-B, Fourth Floor
India Habitat Centre
Lodhi Road, New Delhi-110 003, India.
Ph. 91-11-24682177-80
Fax: 91-11-24682173-74-75
Email: dgoffice@ris.org.in
Websites: <http://www.ris.org.in>
<http://www.newasiaforum.org>