THE RIGHT TO HEALTH, UNIVERSAL HEALTH COVERAGE, ACCESS TO MEDICINES: PROBLEMS AND PROSPECTS

Opening Speech: By Martin Khor

Chennai 7 August 2014

WHO India-Indian Institute of Technology Chennai-Ministry of Health India Consultation on "Trade, Trust and Technology in times of Universal Health Assurance: Improving Access, Promoting Innovation."

I: BACKGROUND TO THE ISSUES

The WTO's TRIPS Agreement led to systemic changes in IPR law and policy in most developing countries and thus globally. Developing countries have had to establish high patent standards, to provide patents for at least 20 years, and are not allowed to exclude sectors such as food and medicines from patentability, contrary to the previous practice of many countries.

However TRIPS has some flexibilities, though limited, including national discretion for interpreting the criteria for patentability (including what constitutes novelty and inventive step); the granting of compulsory licenses, and government use order; the setting of royalty terms for CL; parallel importation; the discretion to interpret the issue of data exclusivity, and leeway to act when patent holders abuse their monopoly rights vis-à-vis competition principles. Nevertheless, the patent regime has changed fundamentally as the flexibilities are taken (by developed countries especially) to be rarely used exclusions rather than the norm, and the norm is taken to be enforcement of high IP standards.

After TRIPS, the developed countries, under the influence of their corporations, continued "forum shopping", looking for venues to introduce new rules that further upgrade the standards for IP, especially for developing countries. They tried WTO itself, WIPO, even WHO and then FTAs, to reduce

or eliminate the TRIPS flexibilities, lengthen the patent term, and to establish "data exclusivity" in a manner that favours the patent holder and would prevent generic drug companies from obtaining marketing approval even if they are granted CL or if the drugs are not patented. Enforcement of IP laws, whether in developed or developing countries, are also sought to be tightened through the use of the international customs and postal organisations, or through unilateral actions. For example due to a EC regulation, multinational drug companies can ask customs authorities to seize consignments of generic drugs in transit in European ports or airports on the suspicion that they may be counterfeit. Several legitimate Indian generic drugs on the way to Africa and Brazil have been seized in European airports.

It is crucial that TRIPS flexibilities be maintained and developing countries make full use of these in their own national laws and practice. Attempts to further strengthen IP rules in international fora should be resisted. Wrongful tightening of enforcement in TRIPS-plus ways in venues including those involved in international trade, IP, health, customs and postal organisations should not be allowed. Inappropriate regulations and actions in developed countries should also be fought. FTAs should not have TRIPS-plus provisions, and developing countries should not enter into agreements if partners insist on TRIPS plus provisions. Developing countries should be ever on the alert for these attempts at rolling forward even more this TRIPS-plus IP agenda, and to counter these initiatives.

Developing countries should also draw up their own agenda and initiatives. Medicines, especially those that are life-saving and to treat diseases that are prevalent in developing countries, should be recognised as international public goods. The use of TRIPS flexibilities should not only be encouraged but their easy use should be promoted; so that CLs and government use orders are granted as a matter of course, if the applicants fulfil the conditions.

II: IMPORTANT ROLE OF INDIA

India is a most important country in relation to access to medicines. **First,** its huge population means that the laws and practice of this country are themselves of global importance. **Secondly,** the Indian drug industry is the

largest provider of generic medicines for developing countries, earning it the title "the pharmacy of the developing world." Many developing countries depend on imports from India for their access to affordable and life-saving medicines. **Third,** Indian companies have also been leaders of innovation; for example the Indian firm Cipla came up with the three-in-one combination HIV-AIDS drug which was not only affordable (at a price now at $100 a patient a year versus over $10,000 for original products) but also convenient to use, and that has saved millions of lives.

Fourth, India had among the best patent legislation in the pre TRIPS era which facilitated the growth of the drug industry; it also now has among the best patent laws and practice among developing countries in the present TRIPS era. It has made use of TRIPS flexibilities in national law, such as the non-granting of patents for second use, the pre- grant opposition, interpretation of data exclusivity, grant of CL, etc.

Fifth, there is widespread and deep understanding of the issues among policy makers, industry, academics, NGOs, lawyers, media, which has thus institutionalised the issues of access to medicines in the country. **Sixth,** India has also helped to transfer technology and the capacity for local production to other developing countries, including through the setting up of production facilities by Indian companies in these countries.

Thus, what happens In India with regard to its patent laws, the use of TRIPS flexibilities, developments in the drug industry, and access to medicines in India, has tremendous implications for developing countries and the world. India is a major positive practitioner, role model and pioneer. It can of course still do more.

III: UNIVERSAL HEALTH COVERAGE

The WHO pioneered the concept that everyone has the right to health and the access to health care, with the Alma Mata declaration on Health for All by the year 2000 adopted in the 1970s. It was perhaps the first concrete MDG before the MDGs were formulated. Since that clarion call, there were several negative developments that worked against it, including the user-pay principle

in structural adjustment programmes, and the TRIPS-led patent laws that hinder the growth of generics products and industries. However public health also improved in most countries including because of better water and sanitation facilities, income and food.

The human right to health has also been more recognised and many countries have tried to make it more of a reality. Today there is a call for universal health coverage. It is a concept that embodies many principles, including the right to health, access to medicines, that everyone has the right and expectation of treatment even if they cannot afford it, and that healthcare and treatment should not cause significant economic burden to people. A resolution on universal health coverage was adopted at the WHA. The WHO is also promoting the concept to be included among the targets in a health SDG.

It should be up to each country to interpret the implementation of universal health coverage. The method of financing to make it work is also a matter of great debate. However the increasing acceptance of the concept is by and large to be most welcomed. One important effect that can be foreseen is that significantly more patients will be covered for free or more cheaply by public health facilities in terms of extent of coverage of patients within each disease and also in the number of diseases covered. This in turn will put pressure on governments to obtain medicines more cheaply, to avoid an unsustainable explosion of the government's health expenditure. And this in turn will encourage governments to seek more affordable generic medicines. If a generic drug can be obtained at a tenth of the price of the original drug, then ten times more patients can be treated with the same size of budget. And this in turn would encourage governments to make use of TRIPS flexibilities. The emerging era of universal health coverage could also be the era of greater appreciation of generics and TRIPS flexibilities.

IV: ADDRESSING SOME CURRENT CHALLENGES

There are several challenges facing developing countries including India in meeting the goals of access to medicines and universal health coverage, and the need to address them. **First,** the domestic generic drug industry may be able to produce non-patented medicines but would face uncertainty and

unpredictability with regard to future production of new drugs, due to the TRIPS regime. This affects the companies' plans for future investment. The uncertainty would be even greater in countries that have signed FTAs with TRIPS-plus provisions and if international organisations or developed countries take on international or unilateral TRIPS-plus regulations and enforcement.

This needs to be addressed at global and national levels. **At global level,** developing countries should be on the alert to prevent global institutions to which they belong from taking on TRIPS-plus rules. They should object to unilateral measures by developed countries to block legitimate trade in generic drugs. They should take the initiative to have life-saving and essential medicines to be recognised as international public goods which should not be subjected to the strict standards of TRIPS. Or else a global system to facilitate the easy use of TRIPS flexibilities in developing countries should be established for these medicines.

At national level, TRIPS flexibilities should be put in place in national law, and new ways should be found to mainstream their use for life saving and essential medicines. A systematic framework and approach for the implementation of TRIPS flexibilities can be established to improve the quality of patents, and to make it easier for the application and approval of CL and government use. There should be systemic involvement of patients' groups, consumer and health groups, domestic drug industry, experts and scholars, in the formulation of policy. The national actions are even more important if the global reforms are not taking place.

Second, governments should examine options for implementing universal health coverage, aimed at providing for access to medicines and health care for all. There should be the upgrading of the role of affordable good quality generic drugs, vaccines, diagnostic tools, to increase the supply of health care products while keeping the health budget within sustainable limits.

Third, the trend of local drug companies or health facilities like hospitals being taken over by foreign multinational firms should be monitored and addressed. Plans for takeovers or mergers of local firms should be subjected to regulation, with appropriate guidelines on approval. Takeovers of local firms especially if this significantly reduces the share of local firms' products in the domestic

market, can make the country dependent on foreign firms and on imports, and the country also runs the additional risk that a firm that is acquired by foreign a foreign firm may in future stop producing certain products, and thus increase dependence on imports. Medicines should be accorded a special status together with food as products that are essential to the nation's security; thus food security and medicines security should entail a certain degree of local self sufficiency to anticipate situations of inadequate or expensive imports or to prevent excessive dependency. If an important private local firm is open for sale, there should be the preferable option of purchase by other local firms, including from the public sector, to retain the share of local firms' production in the total production in the domestic market.

Fourth, developing countries can consider establishing a good mixture of private and public sector firms in the domestic drug industry. This is to prevent over-dependence on the private sector. Products that the public sector health facilities use in great quantities or that are of crucial health importance could be among the products that are suitable for public enterprise production. Public sector firms can also be designed to run on efficient lines and be competitive with private firms. There are several developing countries which maintain publicly owned (or joint-venture) drug enterprises that supply medicines used in government hospitals and clinics and also in the market, and some of these government-owned enterprises are commercially operated.

Fifth, the role of trade and industrial policy is also important. The state should encourage and incentivise local firms to be more and more competitive and to have good quality standards to match as far as possible the products produced in other countries. Innovation and upgrading of technology should be actively encouraged. There is need to balance the desirability of having a thriving local industry and the ability to import the products more cheaply, and thus the importance of upgrading local firms' technology and management systems. Trade policy can be used to ensure that local firms are not damaged by a surge of imports, especially if the imported products are of critical importance to the industry as a whole (for example, active pharmaceutical ingredients) or if the imports are cheaper because they are subsidised.

V: CONCLUSION

Developing countries are facing multiple challenges in providing affordable medicines to their populations. Acceptance of the principles of the right to health and universal health coverage will be an impetus to addressing these challenges. On one hand the resolve to provide necessary health products and facilities will increase the responsibility of governments as well as increase public sector's health expenditure, and this will pose a fiscal challenge. On the other hand, it will pressurise the government to seek economically and policy-wise rational solutions, including the use of the more affordable generic products. The country may therefore take a greater interest in the use of TRIPS flexibilities in legislation and in practice. It may have more reasons to avoid TRIPS plus initiatives in international fora and in FTAs, while also taking initiatives to expand the scope of TRIPS flexibilities. Governments should also take an active interest in promoting technology upgrading and innovation among local firms, whilst also consider playing a more active direct role in production.

The role and future of the Indian industry is of great importance. It is important for India to continue to play its leading role in the use of TRIPS flexibilities and of being the "pharmacy of the developing world" whilst also helping to transfer technology to other developing countries. Thus, how India addresses the challenges of fulfilling the public's increasing demands for access to medicines and on their right to health is of great interest and importance not only for India but for the world.