

2016 Conference on the Politics of Access to Medicines and Human Rights

(Políticas de Acceso a Medicamentos e DH)

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highest attainable standard of physical and mental health)*

1. Hello everybody. Firstly, let me apologise for not being able to attend your important International Conference on the Politics of Access to Medicines and Human Rights, 2016 due to my prior commitments. I hope you all have a great and fruitful conference. I would like to thank the organizers of this conference for giving me this opportunity to address this distinguished gathering.
2. As you know, access to essential medicines is an integral component of the Right to Health and has been specifically enunciated under a number of international instruments, including the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12 of the ICESCR provides for the right of everyone to the highest attainable standard of physical and mental health. States have an obligation to respect (not interfere with the right itself), protect (prevent interference by others) and fulfill (take all administrative measure) the right to health.
3. This right is elaborated by the Committee on Economic, Social and Cultural Rights in General Comment No. 14 (2000). General Comment 14 provides that all health services, goods and facilities, including medicines, are to be made available,

accessible, acceptable and of good quality. Furthermore, the provision of essential medicines to all persons in a non-discriminatory manner is a core obligation on the State, which would also include ensuring availability and access to quality affordable medicines.

4. Latin American countries being civil law countries have an advantage, as any international human rights treaty that has been signed and ratified becomes the domestic law, unlike in common law countries like India which need to domesticate the law in compliance of the international treaty.
5. The role of the law in saving lives is evident from the time HIV was wreaking havoc all over the world. The mid-nineties saw the advent of triple-combination Anti-Retroviral Therapy (ART) which became available in the West immediately, while millions of PLHIVs in the developing world could not access ART even in 2000. During this time, the drugs were priced about USD 10,000 per patient annually, directly denying access to life saving ART to PLHIVs in poorer developing countries. It was only when developing countries like Brazil took initiative to provide better health care, did the movement to make ART more accessible in developing countries, begin.
6. When Indian generics announced that they would provide ART at USD 350 per patient, accessibility of ART became more possible. The resulting increasing level of competition in the generic market thereon led to a 99% drop in the prices of ARV drugs from 2000-2010, providing access to medicines to millions of people across the world.
7. Indian generic companies were able to sell ARVs at these prices because the Indian patent law at the time did not recognize patents on pharmaceutical products. Before 1972, the original Patents Act, 1911 in India, allowed a patent protection for both,

products and processes, allowing the patent holder to exercise absolute monopoly rights and control on both, the availability and the price of a drug. The consequences of the 1911 Act were drug prices which were amongst the highest in the world. Realising the need to prioritise the public health agenda, the patent law was amended in 1970. Protection for only process patents was allowed and no protection for product patents was granted. This simple measure allowed competition to flourish, and by the 1990s, Indian generic industry became the pharmacy of the developing world, offering lowest medicine prices. Thus, by the late 1990s, 90% of the ARVs in the developing world were provided by the Indian generics.

8. While all Latin American countries do not follow an identical system of providing affordable medicines, in spirit they are trying to enforce a system that follows the principle of access, affordability, availability and quality of medicines. While in Brazil, the development of public health policy is intertwined with intellectual property legislation, Chile has been battling HIV/AIDS by focusing on health care reforms and promoting competition within its pharmaceutical sector to decrease medicines prices. The access to medicine, however, is gravely affected in situations of emergency as is the case of Venezuela, where the government decreed a “State of Exception and Economic Emergency”. The attempt to make medicines available through a legislation allowing medical help through foreign channels did not see the light of the day when Venezuela’s Supreme Court ruled that such a law violated the constitution.
9. In the early days of the fight for access to medicines, Brazil had major role to play. The 1996 policy of the Brazilian government to provide free ART to PLHIV was instrumental in improving health and providing access to medicines to thousands of Brazilians. This was possible, partly because of the expertise of the Brazil’s domestic

pharmaceutical industry, which allowed the country to produce generic versions of antiretroviral drugs. Thus, Brazil provided a shining example to the rest of the developing world. I regret to say that unlike Brazil, though India had many generic companies, the free ARV support for the PLHIV, like in Brazil was introduced in India only in 2004, almost 10 years after its introduction in Brazil.

10. At the global platform, the Brazilian policy of free access to ART was regularly used as an example to demonstrate that goal of access to medicine is achievable. The “3 by 5” initiative from the WHO, implemented in 2003 is one such instance. In fact, the Doha Declaration which emphasized on TRIPs flexibility for better access to medicine is often seen as an acknowledgement of Brazil’s policy of free ART. Because of Brazil, rest of the developing world started free ART, thanks to the likes of the Global Fund on HIV, TB and Malaria, PEPFAR and UNAIDS.

11. While protection of product patent could be excluded earlier, the TRIPs agreement changed that. Under it, protection had to be provided to both, product and process patents. India and the developing countries agreed to the TRIPs agreement because of the flexibilities that could be used in their domestic IP Laws. The flexibilities enshrined in the TRIPs Agreement were fought for on the basis of public health interests. These flexibilities aid the objective of making medicines available at affordable prices. These include allowing members to define their own patentability criteria, provide compulsory licensing safeguards and opportunities to challenge patent applications, among others.

12. Exercising this flexibility provided under TRIPs, in 2005, India amended its patent laws and added higher standard of patentability in its patent law to address the evergreening of patents and inserted Section 3(d) in the Patents Act. Section 3(d) does not

allow patents on new form of known substance unless there is significantly more efficacy. Section 3(d) was crafted based on the experience in US and EU where over 76% of pharmaceutical patents were new forms without any additional therapeutic effect. This provision was challenged by Novartis when its patent application on cancer drug “Gleevec” was rejected. Novartis claimed that Section 3(d) violated the TRIPs agreement and the constitutional equality provision. Section 3(d) was upheld by the Supreme Court of India, among other grounds as a fulfillment of the right to health obligations of the Government. Section 3(d) is crucial to promoting generic competition and reducing the prices of costly drugs which have exceeded their patent period.

13. However, developed countries and powerful MNC blocs such as “Big Pharma” are increasingly focusing on furthering the narrow industry agenda of super profits, forcing developing countries to do away with their laws which ensure access to affordable medicines. India, for example, is facing immense pressure from the US to dilute section 3(d) of the Patents Act. The pressure is also to not allow countries to introduce provisions like Section 3(d). Philippines and Argentina have introduced provisions similar to Section 3(d) in their patent laws. I am of the view that more and more countries should adopt provisions similar to Section 3(d).

14. The pressure is also not to allow local manufacturing. Access to medicines has been determined by the local manufacturing capacity of states. Sadly, there are a limited number of developing countries capable of drug manufacturing. Local production must be encouraged as a long-term investment in the security of access to medicines. This involves States considering statutory and policy measures which create an enabling environment for local producers to promote the growth of the pharmaceutical industry.

15. Today, access to affordable medicines is under threat from a variety of fronts. The primary danger, as always, is the pressure that the US and the EU are exerting on developing countries to dilute their IPR regime through threats of trade sanctions such as US 301, and Free Trade Agreements like NAFTA that had a devastating effect on Mexico. Negotiations in large multilateral trade deals like the Trans-Pacific Partnership Agreement and Transatlantic Trade and Investment Partnership indicate the aggressive stance of US of pushing for TRIPS-Plus standards of patent protection. This will destroy any tools for making medicines affordable.
16. The latest tool of the big pharma companies is the use of voluntary licenses granted to the generic players in developing countries, thereby influencing accessibility and affordability of medicines. Because of this, the generic companies are not filing patent oppositions or demanding compulsory license. For example, in the case of Sofosbuvir, a hepatitis C drug, in India, the generic companies withdrew their patent oppositions and did not even demand a compulsory license because of the voluntary license offered to them. Though the countries like Latin America and MENA are most in need of drugs like Sofosbuvir, they have not been included in the list of countries to which Indian generic companies can export the drug. In my view, the voluntary licenses have passed on the initiative from the state to the private sector and have put the MNCs in the driver's seat to control the accessibility and affordability of medicines. Though this challenge has to be met internationally, unfortunately civil society organisations which were united at the turn of the century are now divided over voluntary licenses.
17. I would like to conclude by saying that, the framework on right to health makes it clear that medicines must be available, accessible, acceptable and of good quality, and reach ailing populations without discrimination throughout the world. Affordable

access to medicines cannot be achieved sustainably without sufficient market competition. The need of the hour is for developing countries to utilize and preserve the flexibilities embodied in the TRIPS agreement in their national laws, and prioritise the right to health above all.

18. For this, the civil society again needs to be united across continents, from Latin America to Europe, Africa and Asia, to challenge the agenda of MNCs of FTAs and bilateral agreements, as well as the voluntary license regime through consultative processes and timely interventions. This is required so that state can be back in the driver's seat to make medicine accessible and affordable to for its own people. I hope this conference works towards this objective.

19. Finally, I thank you all for your attention, and I hope that the recommendations derived from this conference will benefit the people living with ailments across the globe.