

Highlights



Bangladesh needs to pursue two options: (a) take advantage of the waiver offered under the WTO-TRIPS decision on Public Health; (b) to adequately prepare for smooth transition towards a TRIPS-compliant regime



Bangladesh is best positioned, among all the LDCs, to take full advantage of the TRIPS flexibilities and the transition period. This is underwritten by her competitive pharmaceutical sector which caters to the increasing demand in the domestic market and is able to access the global market through higher export



With the forthcoming LDC graduation, Bangladesh should, with the urgency that this matter demands, focus on developing health-related infrastructure and supply-side capacities to be able to ensure healthy lives and expand access to medicines for all her citizens. Bangladesh will need to start thinking about innovative programmes such as universal health scheme



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WTO decision on the TRIPS and Public Health *What does it imply for Bangladesh?*

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The Context

The World Trade Organization (WTO) decision on Trade-related Aspects of Intellectual Property Rights (TRIPS) and Public Health and the derogations provided to the least developed countries (LDCs) did provide a unique business opportunity for Bangladesh. On the other hand, Bangladesh's graduation from the group of LDCs, by 2024, demands that the country takes adequate measures to prepare for the post-Doha TRIPS regime. This policy brief articulates both the benefits for Bangladesh originating from the WTO decision on TRIPS favouring the LDCs, and the initiatives Bangladesh should undertake to maintain and further consolidate the standing and strength of her pharmaceutical industry.

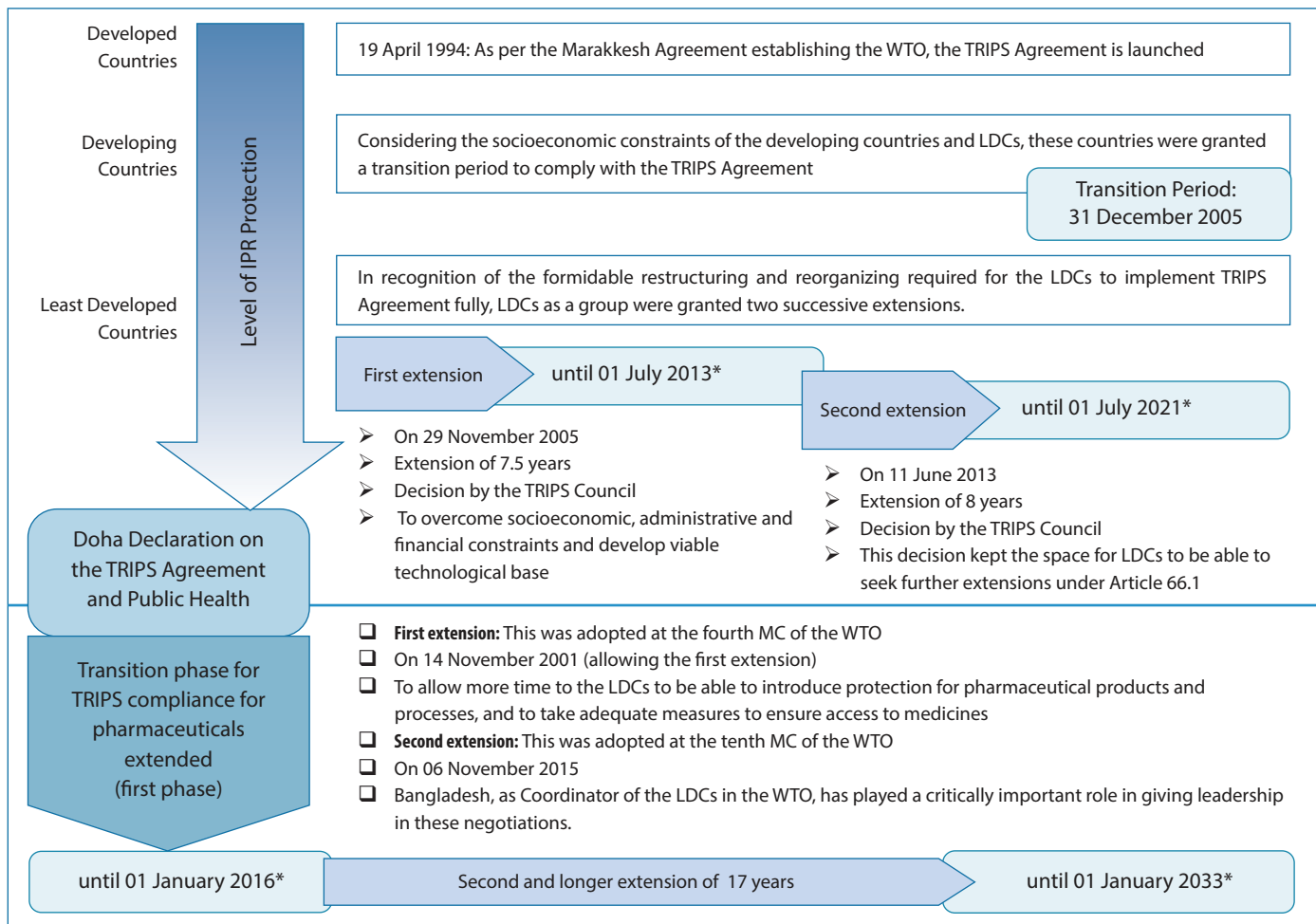
WTO-TRIPS Agreement: Salient Features and LDC Waiver

As is known, the TRIPS Agreement sets global minimum standards for the protection of Intellectual Property Rights (IPRs). All the member states of the WTO are obliged to comply with the TRIPS Agreement by inducing necessary institutional and infrastructural reforms in their respective national regime. An understanding that the implementation of the TRIPS provisions will have starkly different implications on the developed economies, the developing and the LDCs has led to the WTO decisions allowing derogations from the TRIPS Agreement, waivers and transition periods for the latter (Figure 1). The developing economies received a transition period until 31 December 2005, and the LDCs received two successive extensions to the transition periods for patentability of innovation (in all aspects) and for pharmaceutical products, respectively till 01 July 2021 and 01 January 2033.

The TRIPS obligations are applicable for all inventions in any branch of technology (Article 27.1 of the TRIPS Agreement). Pharmaceutical inventions were particularly put under the spotlight because of its direct impact on public interests. As the producers and suppliers of medicine, the pharmaceutical sector plays a critical role in attaining the objective of *health for all* by ensuring availability, accessibility and affordability of necessary medicines. Equitable healthcare has come to be recognised at present as a fundamental human right. That health-related issues are key to attaining accelerated economic growth is also being increasingly given credence in both development policy and praxis. In view of this, the Doha Ministerial Decision on TRIPS and Public Health was an important milestone in advancing the cause of better and affordable access to health for the LDCs. The decision granted the LDCs flexibilities in areas of patent rights and in the application of the various TRIPS Agreement provisions – these offer a unique opportunity to the pharmaceutical sectors in the LDCs to play an essential role in providing medicine at relatively lower prices, without undermining their commercial interests.

Among all the LDCs Bangladesh has the strongest performing pharmaceutical sector, catering to both the increasing demand in the domestic market and also the global market through export of pharmaceutical products. The pharmaceutical industry of Bangladesh is at present one of the fastest growing manufacturing sectors in the country, experiencing a double-digit

Figure1 Development of WTO discussions and decisions as regards TRIPS



Source: Author’s compilation using information from Azam (2016), Chowdhury (2014), and WTO (n.d.)

Note: * in the figure signifies two things: (a) additional part of the WTO decision, which is, LDC Members will not be obliged to enforce rights provided by the TRIPS Agreement until mentioned date (*), or until such a date on which they cease to be an LDC, whichever date is earlier; (b) The decisions made to grant extension to the LDCs is made without prejudice to the right of the LDCs to seek further extensions under Article 66.1 of the TRIPS Agreement.

growth over the past decade. The pharmaceutical industry currently meets ninety-seven per cent of the local demand and exports has doubled over the past decade. Bangladesh is thus uniquely positioned to take advantage of the TRIPS flexibilities and develop health-related infrastructure and supply-side capacities to be able to ensure healthy lives and expand access to medicines for all citizens. . Once Bangladesh graduates out of the LDC status by 2024, she will no longer be able to enjoy the preferential treatment accorded under the TRIPS flexibilities. For Bangladesh, the window of opportunity to make use of the TRIPS flexibilities is, accordingly, only about six years.

Relevance and Importance of the TRIPS Agreement for Bangladesh

The exceptions to the TRIPS obligations allow the LDCs like Bangladesh time to prepare for implementing the TRIPS obligations in terms of economic, legal, regulatory, institutional and infrastructural capabilities. Bangladesh has benefitted quite significantly from the TRIPS waiver granted to the LDCs at the fourth WTO Ministerial Conference in Doha (MC4) in 2001. These benefits could be captured under four broad areas.

(a) The most direct implication of the extended waiver granted in connection with the TRIPS obligations is that Bangladesh with her strong manufacturing capacity can produce generic

medicines to meet national demand; additionally, they can also export to other LDCs or countries where the patent of the drugs being exported has expired or is absent. As is known, cost of production incurred by generic manufacturers is way lower than that of innovator manufacturers. The waiver, thus, enables the pharmaceutical industry of Bangladesh to offer generic medicines at lower and competitive price.

(b) During the extended waiver period till 31 December 2032, LDCs are permitted to produce drugs which are still on patent – this is a prominent benefit since generic versions of drugs whose patents have expired can be produced even without the waiver. Thanks to the TRIPS waiver, the generic manufacturers of *on-patent* drugs do not have to pay royalty or operate in a level-playing field along with innovators. This provides Bangladesh with an opportunity to gain expertise in the production of patented drugs which need advanced technological knowledge via reverse engineering and follow-on innovation. This know-how if acquired competitively and effectively in time, will position the pharmaceutical industry of Bangladesh to gain immensely from the upcoming *patent cliffs*.

(c) Bangladesh can continue to implement the provisions of the National Drug Policy and Drug Control Ordinance 1982, several

of which contravenes the TRIPS Agreement provisions and the WTO-mandated practices. This allows the pharmaceutical industry significant extent of protection from import penetration. Furthermore, the local pharmaceutical companies enjoy some policy space under the existing ordinance, since these place several restrictions on the MNCs operating in the local market.

- (d) TRIPS waiver allow pharmaceutical manufacturers in LDCs to export patented drugs to other LDCs or countries where the patent of the drugs being exported has expired or is absent; drugs that have gone off patent can be exported even in the absence of the TRIPS waivers. Majority of LDCs are partially or entirely dependent on imported medicines. The TRIPS flexibilities and the supply-side capacity of the export-oriented pharmaceutical industry of Bangladesh make her well positioned to meet a significant part of the growing LDC markets.

Implications of Implementing the TRIPS Agreement for Bangladesh's Pharmaceutical Sector

Once the TRIPS Agreement comes into force in Bangladesh, import restrictions will have to be lifted, as a result, local manufacturers of pharmaceutical products which have cheaper import substitutes will face increasingly tough competition. Large-scale generic manufacturers of India and China are likely to emerge as major competitors since they enjoy a comparative advantage as regards price. This heightened competition is likely to result in some transformation as far as Bangladesh's pharmaceutical industry is concerned, small-scale companies with relatively lower competitive strength are likely to experience competitive pressure and could be priced out in the process. There is also a possibility that some of the smaller companies would be acquired by larger foreign companies which are planning to set up local production facilities.

Bangladesh's current patent law and drug ordinance would need major changes to ensure complete compliance with WTO principle of non-discrimination. Providing patent for pharmaceutical products and processes, increasing the duration of patent protection from the current 16 years to 20 years, granting more than four years of validity to foreign-registered patents are, inter alia, some significant changes needed for the full implementation of TRIPS Agreement. These changes, if brought about gradually, will help the evolution of Bangladesh's legislative and regulatory structure concerning pharmaceutical patents and innovations in a TRIPS-compliant manner. As regards the stipulation that IPRs incentivise innovation by preventing free-riding and increasing the rewards from investment, it can be argued that a strong TRIPS-compliant patent regime is likely to stimulate innovation, attract foreign direct investment and foster technology transfer in the pharmaceutical sector. The introduction of patent may incentivise innovation if Bangladesh develops the necessary advancement in research and development (R&D) of new medicines (new drug molecules and raw materials i.e. Active Pharmaceutical Ingredients (APIs)). Contrarily, it can also be argued that restricting reverse engineering and learning by imitation will likely hinder technological advancement. The final implication of all this on the pharmaceutical industry remains rather uncertain.

Import-induced competition may actually help in reducing the prices of drugs, in contrast introduction of pharmaceutical patents

(consequent obligatory royalty fee payment to the patent owner) will put upward pressure on the price since it will increase cost of production. Analysis of the production structure reveals that Bangladesh produces mostly *branded generics* (almost 85 per cent of the local production), and the majority of the essential drugs consumed in Bangladesh are *off-patent* – thus, it can be concluded that, the introduction of patents under the TRIPS-regime will not have a significant effect on locally produced generic versions of *off-patent* drugs. However, concerns remain high for the price, availability and affordability of locally produced patented drugs (about one-fifth of the local production). The overall impact on the price of drugs in the domestic market of Bangladesh will hinge on the net effect of all the aforementioned forces. The impacts are likely to vary across the different genres of drugs. The price impact may be more prominent for lifestyle drugs and relatively lower for essential drugs.

Policy Recommendations for Way Forward

Bangladesh will need to pursue a proactive and strategic stance, in terms of both policy measures and implementation, if it is to build on its past success under the anticipated changed scenario.

Some of the suggested steps in this connection are:

Developing strong research and development (R&D) base

Bangladesh's pharmaceutical companies should focus on the expansion of R&D to strengthen capacities in reverse engineering and in the production of new molecules, APIs, and modern and standard packaging systems. Strategic partnership with R&D based transnational companies to gain necessary skills and benefit from the transfer of technology, incentives by the government regarding R&D related investments are measures which would help ensure post-TRIPS sustainability of the sector.

Addressing shortage of skilled human resources in the pharmaceutical industry

Competitively-waged white collar jobs can provide local companies an edge over competing supplier countries. However, shortage of skilled human resources remains an acute challenge in this connection. The white collar workforce to be engaged in the sector needs to have advanced technological knowledge and will need to possess the capacity to innovate. To encourage this, academic institutions can collaborate with pharmaceutical companies to update curriculum, provide opportunities to work in state-of-the-art laboratories via scholarships, thesis or internship programs and training opportunities.

The API Park should be in operation at the earliest

The pharmaceutical industry of Bangladesh continues to depend on imported API for drug manufacturing, and thus is highly susceptible to external shocks. As it is, the cost of drug production is significantly dependent on the import cost of APIs. The imported APIs are not always of the standard quality; these are also often not available in the required amount. Since a number of the major source countries (such as India, South Korea, China) are also producers and exporters of generic drugs (final formulations), at times supply of APIs are controlled by these supplying countries as part of strategy to curb competition. To address these challenges, the government of Bangladesh should expedite the completion of the API Park.

Scope for joint venture should be explored to attract more FDI

Bangladesh should make the best use of the TRIPS transition period to attract more foreign direct investment to the pharmaceutical sector. Market intelligence evince that a number of large foreign pharmaceutical companies from highly regulated markets are actively looking for joint venture projects in developing countries and LDCs to reap the potential benefits. Bangladesh should pursue those companies to invest in the country. Indeed, one of the proposed special economic zones (SEZs) may be dedicated to setting up specialised pharmaceutical enterprises.

Encourage contract manufacturing

Bangladesh has a solid manufacturing base in pharmaceutical products and manufacturing costs are lower than in many other countries. The country is well-positioned to take advantage of the TRIPS flexibilities and develop the market for contract manufacturing. The government can decide to provide financial and tax incentives to promote contract manufacturing.

Strong branding by the local companies to prevent loss of market share to MNCs and imported medicines

Local manufacturers in Bangladesh should analyse the purchasing dynamics and consumer choice patterns in the local market and should brand their products in a manner that establishes brand loyalty. This will enable Bangladesh to take corrective measures in view of the likelihood of losing market share to imported medicines and manufactures from the MNCs. Even in the market segment of the less-expensive generics items, apprehensions about counterfeit, low-potency, and adulterated medicines impact on consumer

choice. Consumers are willing to pay a premium for high-quality products from trusted manufacturers and brands. Hence the need for building reputation and brand loyalty.

Bangladesh can ask for further extension of the TRIPS transition period as part of the graduating LDCs group

Although only five countries have graduated from LDCs since its inception in 1971, the current decade is considered to be the era of LDC graduation - 15 countries including Bangladesh are expected to be graduated out of LDCs by 2024. So as part of the graduating LDCs group, Bangladesh can ask the WTO for extending the eligibility period to continue enjoying the TRIPS waivers at least till 1 January 2033, as applicable for all the LDCs. It should be noted that the current decision does not preclude the possibility of further extension for the LDCs in future. However, the request for an extension by the graduating LDCs may not receive support from the negotiators of the developing and developed countries. Given the uncertainty of the decision to be in Bangladesh's favour and the imminent LDC graduation by 2024, it is best that Bangladesh takes the preparatory steps and initiatives to ensure TRIPS-compliance at the earliest.

The way forward – taking advantage of the TRIPS Agreement

Some of the TRIPS provision are specifically designed to service the needs of national public health interests: (i) parallel imports; (ii) compulsory licensing; and (iii) Bolar provision - early submission of an application for registration of patented drugs by generic manufacturers. The government should put in place appropriate regulatory and institutional forces to make the most effective and strategic use of the relevant TRIPS provisions.

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