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Research Report 2
WTO Decision on TRIPS and Public Health
A Window of Opportunity for Bangladesh's Pharmaceutical Industry

Mustafizur Rahman
Distinguished Fellow, CPD

Sherajum Monira Farin
Research Associate, CPD

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Centre for Policy Dialogue (CPD), Dhaka

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I. Introduction

The Doha Ministerial Decision of the WTO on TRIPS and Public Health was an important milestone in advancing the cause of better and affordable access to health in low-income countries. Indeed, the Doha decision, taken much earlier, was very much in line with what was later on enshrined in Sustainable Development Goal 3 (SDG-3). Goal 3 of the SDGs aims to ensure healthy lives, promote wellbeing for all ages, and achieve universal health coverage; including access to safe, effective, quality and affordable essential medicines and vaccines for all. 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. There is no denying the fact that, availability, accessibility and affordability of necessary medicines are essential prerequisites to attaining the objective of health for all. These are also closely associated with the implementation of the SDGs. In this backdrop, the pharmaceuticals sector plays a critically important role as producers and suppliers of medicines. The aforesaid Doha Declaration on TRIPS and Public Health has granted the least developed countries (LDCs) some flexibilities in areas of patent rights and the application of the various TRIPS Agreement which have significant implications for the pharmaceutical industries in the LDCs. As may be recalled, the preferential treatment was to be in place for fifteen years (2001 to 2015). By taking advantage of those, the pharmaceutical industries in the LDCs could potentially play a defining role in achieving the global ambitions in the area of health, in light the Millennium Development Goals (MDGs). It is also not surprising that the extension of the Doha decision at the tenth Ministerial Conference (MC10) of the WTO in Nairobi, Kenya in December 2015, coincided with the adoption of the SDGs at the UN Summit in September 2015. One cannot but observe that the MC10 decision's timeframe (extension till December 2032), to a large extent, overlaps the SDG implementation period of 2030.

The Doha decision and its extensions 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 to the global market through export. The pharmaceutical industry of Bangladesh is now one of the fastest growing manufacturing sectors in the country and has experienced double-digit 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. The industry has contributed to achieving key MDG targets and achieving health-related SDG targets will also critically hinge on how the pharmaceutical sector of the country evolves and develops in future.

Whilst the need for a well-regulated pharmaceuticals production and marketing regime, compliant with TRIPS regime, cannot be denied, it is also equally true that this could create a heavy burden for the low-income countries. TRIPS-compliant production could lead to high production cost in these countries, undermining the cause of making drugs available at affordable prices. The purpose of Doha declaration on TRIPS was an attempt, in this backdrop, to help the LDCs to address these challenges, by providing a time-bound derogation from the TRIPS obligations. This paper offers an analysis of the implications of TRIPS implementation in Bangladesh and in this context examines the extent to which Bangladesh has been able to take

advantage of the benefits of the flexibilities, waivers and derogation provided during the transition period. Keeping the deadlines of 2033 (the extension for TRIPS flexibility) and the 2030 agenda (the SDGs) in mind, it is crucial for LDCs such as Bangladesh to take concrete steps to improve health-related infrastructure and supply-side capacities to be able to ensure healthy lives and expand access to medicines for all citizens. In the particular case of Bangladesh, 2033 is indeed somewhat notional – as is known, Bangladesh has reached eligibility for LDC graduation in 2018, and following two triennial reviews by the Committee for Development Policy (CDP), the country is set to graduate out of the LDC group in 2024. Once Bangladesh graduates out of the LDC status, 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, thus, only nine years. In this backdrop, Bangladesh should design, with the urgency that the matter deserves, an appropriate strategy to take the fullest advantage of the WTO-TRIPS decision both from the perspective of reaping benefits of the waiver and preparing for the life beyond the eligibility period.

Research Objectives

The principal objective of the paper is to raise awareness and motivate debate and discussion so that Bangladesh can take advantage of the waiver and also face the implications of phasing out of the patent waiver with adequate preparedness. With this in mind, the paper seeks to answer the following questions:

- What is the relevance of WTO-TRIPS decision on Public Health for Bangladesh and other LDCs?
- What are the challenges that Bangladesh and other LDCs face in realising the potential benefits of the decision?
- What policies should LDCs like Bangladesh pursue towards maximising potential benefits of TRIPS decision of the WTO on pharmaceuticals?
- How best to prepare for life beyond the eligibility period?

Research methodology

The paper is based on an extensive review of the existent secondary literature, use of quantitative exercises, key informant interviews (KIIs) and Focus Group discussions (FGDs). An extensive review was undertaken to glean the needed information from secondary literature including published papers and relevant documents, agreements, government policies, regulations and relevant meeting minutes. The analytical exercises were undertaken by using most updated secondary data available in World Development Indicators (WDI) and Trade Map. KIIs and FGDs included in-depth discussions with representatives of key stakeholders groups as interviewees and participants. Stakeholder groups consulted for this study included marketing professionals and practitioners from various pharmaceuticals companies, academicians and experts dealing with pharmaceutical technology and health economics, government officials from the Drug administration and policy analysts. An FGD was conducted with members of the Bangladesh Association of Pharmaceutical Industries (BAPI) to understand the views of the manufacturers as regards the benefits of TRIPS flexibilities

II. TRIPS Agreement of the WTO and the Pharmaceuticals

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)[1], announced in the Uruguay Round in 1994 as part of the Marrakesh Agreement, was put in place with the aim of protecting the Intellectual Property Rights (IPRs) at the global level. The motivation was to promote rights of innovators, along with the public interest in mind. The TRIPS Agreement set global minimum standards for IPRs protection - all WTO Member states are required to comply with the Agreement by inducing necessary changes (relevant institutional and infrastructural set-ups) in respective national regulatory frameworks. 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 (access and affordability of medicines).

Concerns of incentives for innovation and the urgency of catering to public interest led to a division among the WTO Member states – the developed countries negotiated most actively for the IPR protection to be put firmly in the WTO agenda; they were opposed quite actively by the developing nations. The arguments, from both sides, reasoning are given in Figure 1. The apprehension that patent protection will restrict the production of low-cost generic medicines and will eventually cause essential medicines to be less affordable and accessible were the leading causes of the developing countries' opposition.

Figure 1 Rationale for and against TRIPS

Developed Countries		Developing Countries
Strong IPR protection is imperative to promote innovation and development of new technology	⟷	Strong IPR protection for pharmaceuticals will increase price of essential drugs and curb access to medicine
Patent rights will encourage investment (both foreign and domestic) in research and development of new technological product and process	⟷	Structure and mechanism of patent rights protection developed by the advanced economies may not be compatible with needs of the developing economies. Thus no real benefit may be gained in terms of innovation.
Developing countries and LDCs will *eventually* benefit from foreign investment and consequent technology transfer	⟷	Negative impact of pharmaceutical patent protection will not only affect the developing countries and LDcs with manufacturing capacity but also those who import from these countries.

Source: Authors' compilation from Azam (2016)

In terms of its objectives and likely consequences, TRIPS has been controversial since its inception, and even more so in the context of patent protection of pharmaceuticals. One cannot help but note the opportunistic motive of the developed countries pushing for patentability of innovations; developed economies did not have IPR protection in place when their economies were taking off; they were supporting protection as the main incentive to stimulate innovation only when they had attained a certain level of maturity in technological advancement.[2] Pharmaceuticals was usually kept out of the patent regime, even if they had patents for

[1] Henceforth, mentioned as the TRIPS Agreement or simply TRIPS.

[2] For example, Switzerland introduced pharmaceutical patent in 1977, France in 1960, Germany in 1968, Japan 1976.

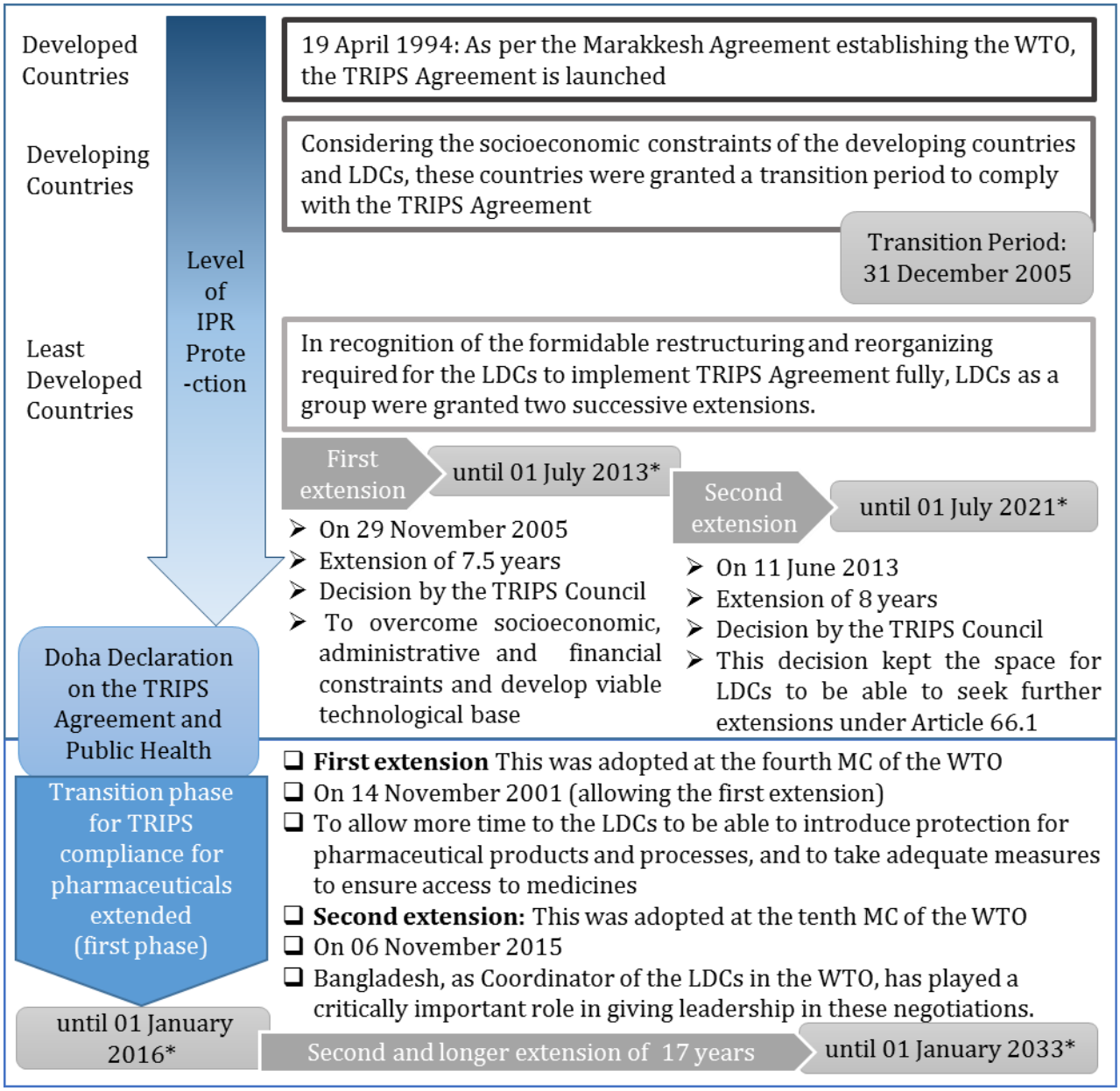
pharmaceuticals; it was for the process part only and not for the products. This allowed entrepreneurs and producers to imitate and produce the same product with different processes. LDCs were offered transitional periods to reap the same benefits, but they did not (in most cases still do not) have the supply-side technological capacity to imitate and produce generic drugs. Contrary to what was held by many of the pro-TRIPS developed countries, foreign direct investment (FDI) and the resultant technology transfer to the LDCs was rather highly unlikely. Moreover, the obligatory stance of the WTO-TRIPS Agreements to be implemented immediately or within a stipulated and limited time curbed the freedom of the LDCs to rely on learning through imitation towards technological advancement (Azam, 2006).

Given the above, each group of countries negotiated the TRIPS Agreement with great fervour and tried to protect their respective interests. The reflection of this can be seen in specific provisions of the TRIPS Agreement which besides setting mandatory standards of international obligations for innovations, also contains some "flexibilities"[3]. The TRIPS Agreement allowed a transitional period for developing countries and LDCs to develop necessary regulatory and institutional capacity to be able to implement the TRIPS obligations. The provisions under TRIPS flexibilities allowed Member states to prioritise their national development goals while complying with international rules and standards. Indeed, several of these flexibilities were applicable only in the face of a national emergency. Following the introduction of the TRIPS flexibilities, inconsistency and ambiguity emerged as to what should qualify as a 'national emergency'. The Doha Declaration on TRIPS and Public Health was an attempt to assuage the concerns of the LDCs in particular, in the backdrop of the challenges these countries were facing in the context of complying with the TRIPS provisions.

Figure 2 below shows the series of decisions which led to the current state of waivers for LDCs regarding the extension of the transition period, and Box 1 presents the TRIPS flexibilities for the LDCs. These include exceptions and waivers from obliging with certain provisions of the TRIPS Agreement. In a number of instances, the TRIPS Agreement offers provisions which empower implementing Member States to prioritise national interests in the face of a public health emergency. For instance, the provisions for "compulsory licensing" and "parallel imports" of the TRIPS Agreement. Besides these, Article 8.2, 40.1 and 40.2 of the TRIPS Agreement relate to provisions to prevent anti-competitive practice that allow the Member government to take necessary actions (for example, policy reforms and change in national legislation) to prevent patent owner or any other IPR holder from abusing the IPRs in a way that could disrupt conduct of trade or international flow of technology.

[3] Hereon, to be referred to as the "TRIPS flexibilities". TRIPS flexibilities can be referred to as waivers to oblige with the TRIPS Agreement, transition provisions, and TRIPS waivers.

Figure 2 Development of WTO discussions and decisions as regards TRIPS



Source: Authors' compilation using information from The WTO website (accessed in February 2018), Azam (2016), and Chowdhury (2014)

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 (X*),* 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.

Box 1 TRIPS Flexibilities and Exceptions for LDCs

Exceptions from granting patents

Member governments are allowed to refuse to grant patent for

- Inventions whose commercial exploitation needs to be prevented to protect human, animal or plant life on earth (Article 27.2)
- Diagnostic, therapeutic and surgical methods for treating humans or animals (Article 27.3a)
- Certain plant and animal inventions (Article 27.3b)

Exceptions for experimental and government use

- ***Research exception***
  This provision can be used to allow researchers to use the patented product to achieve complete understanding of the invention. This allows advancement of science and technology
- ***Regulatory exception or "Bolar" Provision***
  Under this provision, generic manufacturers are allowed to reverse engineer the patented invention (permission granted by the public authorities but not the patent holder) and use it to apply for marketing approval, so that they can market these generic versions as soon as the patent expires.

Exceptions which were introduced or clarified by the Doha Declaration

- ***Compulsory Licensing***
  This provision allows Member governments to permit any other producer to produce a patented invention without the authorization of the patent right holder, mainly for non-commercial use to uphold public interests. This provision comes with a handful of conditions, ensuring the protection of the patent right holder's interest and also the public interests. (Article 31(b, c, h & k) of the TRIPS Agreement)
  The Doha Declaration specifies the term Compulsory Licensing and the grounds under which it is applicable (for instance, national emergencies, extreme urgency and anti-competitive practices). (Article 5(b) and 5(c) of The Doha Declaration)
- ***Importing under Compulsory Licensing***
  This provision, applicable only for pharmaceutical products, offers three waivers:
  - Exporting member countries can export generic pharmaceutical products made under compulsory licensing to meet the needs of the importing countries
  - Importing countries do not have to remunerate the patent holders (original manufacturers), remuneration is only required on the export side.
  - Developing countries and LDCs are exempted from exporting constraints
- ***Parallel imports or grey imports***
  This provision has risen due to the concept of "exhaustion" of rights. These are products marketed by the patent owner (or trademark- or copyright-owner, etc.) or with the patent owner's permission in one country, but imported into another country without the approval of the patent owner. (TRIPS Article 6 and Doha Declaration Article 5(d))

Transition Provision (the Mailbox waiver)

Article 70.8 and 70.9 of the TRIPS, respectively, obliges a Member to make available a mechanism for filing patent applications for pharmaceutical products (mailbox) or to grant exclusive marketing rights to such applications. LDCs have waiver from obliging to these to provisions.

Source: Authors' compilation of information from the WTO website.

2.1 Importance of the TRIPS Agreement

On the face of it, protection of IPRs appears to provide an incentive to invest in research and innovations. The incentives for innovations encourage both domestic and foreign investments to pursue research and development (R&D). The TRIPS Agreement proposed changes at the firm-level to enhance technical expertise and innovation to maintain competitiveness (Ala, 2013). Apropos this logic, there is widespread support in the literature to the effect that many of the pharmaceutical and chemical inventions would not have happened if there were no stipulations for and enforcement of patent protection (Arora et al. 2008; Acemoglu et al. 2011; Phelps 2015; and Mansfield 1995).

On the other hand, protection of IPRs via TRIPS could prove to be very costly to LDCs. The linkage between TRIPS protection and trade agreement directly affects technology flow and development in the LDCs (Tully, 2003). In relevant literature, the TRIPS Agreement has been widely viewed as a source of uncertainty for the developing world (Chowdhury, 2014; Danzon 2007; Yu 2011; Sampath 2012). In general, some potential sources of concern for poor countries include unequal bargaining power, the role of multinational companies (MNCs) in the domestic market, increased price of raw materials and technology, increased imports of medicines, fall in the competitiveness of small firms (Kuanpoth 2006; Wendt 2007; Li 2008; Guzmán 2012; Kapczynski & Hall 2009; Yu 2011). In LDCs, most technologies are imported; however, increased imports and mere access to new technology are unlikely to result in technology transfer into countries with weaker absorptive capacity (Acharya & Keller 2009; Yang & Maskus 2009). There is a significant lacking in the ability of the LDCs to assimilate and adopt technological know-how and, thus, in these countries, the necessary enabling environment required to incentivise technological advancement via IPR protection develops at a languid pace or does not develop at all. In the absence of primary conditions such as significant market size, adequate capital, efficient professionals (e.g. pharmacists, chemists etc.), innovation-oriented entrepreneurs, and a scientific base, a strong IPR protection can lead to widening of the technology gap and can permanently threaten the technological development of the LDCs (Syam, 2014).

IPR protection or patent implementation is so critically important for the pharmaceutical industry is because of the unique nature of the pharmaceutical products. Before a drug is given the final nod for launching, it has to go through time-consuming and rigorous testing and cost-effectiveness analyses[4]. The complexity of the process suggests why only a small fraction of new-drug applications are for new molecular entities (the basic component to form a drug), whereas a majority of the applications are either reformulations or incremental modifications of existing drugs or new "on-label" drugs uses. Out of the small fraction of new molecular entities entering the approval process, only a few get to be finally approved by the competent authorities[5]. Investing in this is risky because this new molecular entity can fail at any stage of the process, and, also, it requires a lot of time. This explains why TRIPS is so vital for the developed economies who are making strides in technological advancement and want to make investing in research and development of new drugs profitable for the investors.

[4] For example in the US market it takes an average of 12 years for a new drug to reach the market after initial stage of invention (WebMD article accessed on 25 March 2018)

[5] For every 25,000 compounds that start in the laboratory, 25 are tested in humans, 5 make it to market and just one recoups what was invested. (Torjesen, 2015)

The high risk and investment factor somewhat justify the patent protection. However, there have been many instances of the protection provided having been abused by the inventors of new drugs. Pharmaceutical companies may sometimes engage in *evergreening* their original patent via either late filing the follow-on patents, developing follow-on drugs with minor modifications, or even engaging in collusive agreements with generic manufacturers[6]. According to Arndt (2017), Bannerjee and Siebert (2015), Gotzche (2018), and Thomas (2017), the price hikes of drugs are not always in line with the R&D expenditure and do not necessarily contribute to innovations and technological knowledge space. However, what it does for sure is add to the sufferings of the patients. Patent protection gives a monopoly to the innovator manufacturer and that paired with the unique nature of drugs having inelastic demand leads to the high prices of *branded drugs*[7].

Another unique feature of pharmaceutical products is that most of the products can be easily replicated and manufactured by *reverse engineering.* Research to find alternative ways of manufacturing a drug is relatively less time-consuming and cheaper, unlike other technological sectors where replicating a product requires time, money, and effort that are almost similar to the original process. This unique feature of pharmaceuticals allows for the production of cheaper generic substitute for branded drugs. For a generic drug to have equal physiological effectiveness as the innovator drug, it has to be *bioequivalent*[8] to the innovator drug. Then only it can be produced, registered and sold in markets where the patent of the innovator is not applicable. This is where the potential benefits of the TRIPS Agreement for the LDCs become evident. The WTO-TRIPS Agreement requires all Member states to provide patent protection to innovator drugs, LDCs have now been given an exception to this requirement till 1 January 2033. Therefore an innovator drug is off-patent subject to two conditionalities – if the patent protection period has expired, or if the market where it is being sold has a waiver on patent obligation, i.e. the LDC countries or non-WTO members.

2.2 LDC perspectives on TRIPS flexibilities

The exceptions to the TRIPS obligations allow the LDCs time to prepare for implementing the TRIPS obligations in terms of economic, legal, regulatory, institutional and infrastructural capabilities. But no less important the exemptions allow LDCs a window of opportunity to reap

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[6] Patent *evergreening* in the pharmaceutical industry is the practice of filing for a secondary patent by developing small modifications to existing product/process which is already patented. The most prevalent practice is the development of a modified version of the prime raw material, an (patented) active pharmaceutical ingredient (API). This new API *may be* better than the existing version in terms of solubility, ease of formulation, stability and enhancing the effectiveness of the drug (final product) (Grobler, 2017). This practice effectively increases the 20 years of patent protection period and helps the manufacturer (originator or patent owner) enjoy monopoly over production and marketing of the drug for a longer time.
http://www.vonseidels.com/patent-evergreening-in-the-pharmaceutical-industry/

[7] The *branded drugs* are innovator (original) medicines which are patented and the exclusive right- of their production and marketing belongs to the patent owner. Henceforth, branded drugs, innovator drugs and patented drugs are used synonymously in this paper.

[8] As per the widely cited article by Birkett (2003), *bioequivalence* in two pharmaceutical products means that they are pharmaceutically equivalent and their bio availabilities (rate and extent of availability) after administration in the same molar dose are similar to such a degree that their effects, with respect to both efficacy and safety, can be expected to be essentially the same. Pharmaceutical equivalence implies the same amount of the same active substance(s), in the same dosage form, for the same route of administration and meeting the same or comparable standards.

significant benefits. According to the decision on extensions, LDCs such as Bangladesh can avoid applying and enforcing IPRs on all innovations (processes and products) till 01 July 2021, and specifically on pharmaceutical innovations till 01 January 2033. Two more flexibilities accompanied the second extension of the transitional period (up to 01 January 2033): an extension of the waiver concerning the obligation to provide exclusive marketing right of five years (Article 70.9) [9], and a new waiver from obligation as regards Article 70.8. As per Article 70.8, Member states (non-LDCs) are obliged to keep regulatory arrangements which allow the filing of patents, so that when protection commences upon implementation of the TRIPS, the filed applications can get patent protection immediately, to be valid for the remainder of the time (20 years) (Box 1).

The most direct implication of the extended waiver granted in connection with the TRIPS obligations is that LDCs with 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 apparent, cost of production incurred by generic manufacturers is way lower than that of innovator manufacturers. The waiver, thus, enables the LDCs to offer generic medicines at lower and competitive price. The absence of the royalty fee component in the cost components allows firms in LDCs to sell medicine at a relatively cheaper rate, be competitive and make a decent profit. Thus the waiver serves the cause of attaining a critical SDG – access to essential drugs at affordable price. This will no longer be the case if the generic manufacturers of on-patent drugs have to pay a royalty or have to operate in a level-playing field along with innovators. Thus, pharmaceutical patent protection will not only affect LDCs with manufacturing capacity but also those who import from the manufacturing countries.[10] Box 2 below shows possible implications of the implementation of patent protection provisions of the TRIPS Agreement.

[9] This waiver was initially put in place in 2002 and is now extended up to 2032.

[10] For example, after the introduction of IPR protection in India, availability of cheaper drugs in Bhutan, an LDC, was significantly curbed (Dorji, 2008).

Box 2 Implications of the implementation of the TRIPS Agreement, with focus on pharmaceuticals

Obligations under the TRIPS Agreement applicable for all technological innovations	❑ New, non-obvious and useful inventions will get patent protection irrespective of the field of technology or place of invention ❑ National regulation of the Member states should provide this patent protection; otherwise a Member country (say A) violating TRIPS obligations may have to incur commercial sanctions imposed by the WTO Dispute Settlement Body if allegations placed against country A, by pursuant Member state (say country B), are proven to be right. ❑ The TRIPS Agreement protect not only the product but the process of the new invention. So there is no scope for manufacturing and selling the patented product with a new process – this means *reverse engineering* of a patented drug is forbidden in countries where TRIPS is fully implemented*.
Implications, specifically for pharmaceuticals (TRIPS provisions: Article 27.1, Article 33)	❑ Monopoly power of the originator drug producer (owner of the patent) will increase in terms of power to set the price, and charge it for a longer duration of time (20 years). ❑ Manufacturers of generic drugs will have to wait for longer period for the drug to go off-patent, to produce and market their version. ❑ Consumers have to wait for longer period to get the drug at a lower, much affordable price. ❑ As soon as the TRIPS provisions come into force, copies of the patented drugs, produced locally or imported, has to be banned from the national market. ❑ Upon implementation of the TRIPS Agreement, unauthorized copies of patented drugs can only be produced and commercialized with the authorization of the patent holders.

Source: Authors' analysis of the TRIPS Agreement.

Note: * To prevent this, in the initial years of development, many countries excluded the patentability of pharmaceuticals or patented only the processes (not the products). The countries were, namely, India, China, Brazil, Malaysia, Thailand, Mexico, Argentina, Egypt and Canada. This gave them the opportunity to manufacture and sell the drug after developing it through a different (new) process, thus making cheaper versions of the patented product (drug) available locally.

Among all the LDCs, Bangladesh has the most active and well-established technological base to develop a pharmaceutical industry that is most capable of reaping the benefits of the TRIPS waiver. According to Trade Map data analyses, at present, exports of pharmaceuticals by Bangladesh accounts for about 47.4 per cent of the total exports of the item by the LDCs in 2016. Uganda, Senegal, and Nepal with respective shares of 17.4 per cent, 14 per cent and 4.9 per cent falls far behind Bangladesh. Accordingly, Bangladesh offers an appropriate case study to understand the implications of the implementation of TRIPS on LDCs, with the attendant opportunities and challenges. For this analysis, we need to have a good understanding of the Bangladesh pharmaceutical industry. The next section deals with some of the pertinent facts and issues in this connection.

III. Pharmaceutical Industry in Bangladesh

A brief overview of Bangladesh's pharmaceutical industry is given below in Box 3. The impressive growth of Bangladesh's pharmaceutical sector owes, in no small extent, to a large consumer base, fiscal incentives and supportive regulatory framework. Pharmaceuticals industry of Bangladesh has grown significantly over the past years. For example, between 2012 and 2017, the five years CAGR (Compound Annual Growth Rate) was 13.5 per cent. According to industry experts, domestic market size of pharmaceuticals may reach about USD 4.1 billion by 2020, almost double the market size in 2017 (USD 2.44 billion)[11]. Pharmaceuticals production in Bangladesh is set to grow at a compound annual rate of 15 per cent over the next five years, riding on the expanded domestic market as well as new export frontiers, according to a 2017 research (LR global industry insights 2017).

3.1 *Growing importance of the pharmaceutical sector in the economy*

The manufacture of the pharmaceutical industry has contributed to 1.2 per cent of the GDP in FY 2018 (was 0.93 per cent of GDP in FY 1996)[12]. According to industrial weight, the manufacture of pharmaceuticals and medicinal chemicals occupies the fourth highest place (8.2 per cent)[13]. The prominence of the sector is also revealed by the fact that, the pharmaceutical sector is the second largest contributor to the national exchequer (after tobacco). The sector provides the largest white-collar-intensive employment opportunity in Bangladesh.

3.2 *Major trends suggest the dominance of local companies and production of branded generic drugs*

Bangladesh's pharmaceutical market is dominated by branded generics[14] - about 85 to 90 per cent of the total market production is generic drugs (Saad, 2012 and Azam, 2016). Production of generics takes place on a "me too" style, meaning, primary drivers of a product's success in the Bangladesh market are price competitiveness and distribution efforts. The domestic pharmaceutical market in Bangladesh is cost-sensitive and highly concentrated in terms of production and market share (Box 3). Local companies (the top 10) capture the major share of the market. One observes a natural propensity to expand and enhance competitive strength. Some of the large manufacturers have started to venture into new terrain – for example, production of anti-cancer drugs, anti-retroviral drugs for the treatment of HIV/AIDS and anti-bird flu drugs. These are mostly patented drugs which require state-of-the-art production plants. Only about one-fifth of the production is generic versions of patented drugs

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[11] The estimate is made for allopathic medicines only. (Source: Annual Report 2016-2017, ACME Laboratories Ltd., p. 54). BDT 330,000 thousand million is equivalent to USD 4.1 billion at 2017 annual average conversion rate as per Bangladesh Bank (1 USD = BDT 80.5).

[12] Contribution of pharmaceutical industry was estimated according to the following formula: (QIIP weight* total values added by large and medium enterprises)/ GDP in current prices. For FY2017, the share of contribution was 1.16 per cent. Note: For FY18 the figures used for this calculation were provisional.

[13] Manufacture of wearing apparel (34.9 per cent), manufacture of textile (14.1 per cent) and manufacture of food products (10.9 per cent).

[14] *Branded generics* most often refer to original medicines no longer on patent, offer treatment at a lower cost but are equal in terms of quality, efficacy and safety – with a reliable supply. It should be noted that *branded generics* are different from *branded drugs* or innovator drugs. IMS defines branded generics as either novel dosage forms of drugs that have lost patent protection and were not developed by the company marketing the branded generic, or simply as a generic drug that's given a trade name (Dearment, 2011).

Box 3 Bangladesh's Pharmaceutical Sector at a Glance

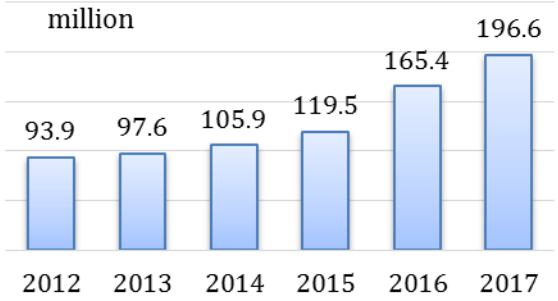
Pharmaceutical industry at a glance: *Major trends*

Production trends

Allopathic Drugs

- Market size in 2017: USD 2.4 billion
- Contribution to the GDP: 1.9 per cent in FY2017
- Approximately 257 manufactures are operating in Bangladesh, out of which 150 in actual production
- As of 2016, top-10 companies accounts for 68.5 per cent of the market (share of top 20 is 86.3 per cent)
- Multinational companies account for only 9.4 per cent of the market

- Domestic market size has more than doubled since 2012
- In 1982, market size was only BDT 1.7 million



Pharmaceutical Market size in BDT billions

Systems	No. of Manufacturers	No. of Registered Drugs	No. of Retail Pharmacies
Allopathic	269	28,957	1,07,830
Unani	272	5787	647
Ayurvedic	202	3939	371
Homoeopathic & Biochemic	32	2313	2164
Herbal	451	463	10
Source: Directorate General of Drug Administration (DGDA), GoB (as of February 2018)			

Consumption perspective

- Bangladesh's pharmaceutical industry meets 97 per cent of the total domestic demand
- 3 per cent of the national demand relate to specialized items such as vaccine, anti-cancer products and hormone drugs – these are met by imports
- Top five therapeutic classes sold in the Bangladesh market constitute 82.1 per cent of the total market
  - Alimentary T. and Metabolism (Gastro-intestinal) – 36.4 per cent
  - Systemic anti-infective (Antibiotics) – 16.4 per cent
  - Nervous system (Antipyretics) – 10.8 per cent
  - Cardiovascular system – 9.7 per cent
  - Respiratory system – 8.9 per cent

Source: Authors' compilation of information from IMS Healthcare report (2017), LR global industry insights 2017, EBLSL Securities Limited report (2018), BAPI, DGDA, BBS, and EPB.

3.3 *Supportive regulatory framework helped the emergence of a thriving pharmaceutical industry*[15]

It needs to be appreciated that, the first National Drug Policy, formulated in 1982, had set a solid foundation for the emergence of a thriving pharmaceutical industry in Bangladesh. It was supplemented by the Drug Control Ordinance 1982 which stipulated a rigorous enforcement framework to regulate the manufacturing, importing, distributing and selling of pharmaceutical products. The National Drug Policy 1982 was followed by two more drug policies in 2005 and 2016 (Box 4).

The 1982 National Drug Policy played a crucial role in increasing local production of essential drugs – the dominance of multinational companies in local production and sales was significantly curbed (market share of MNCs fell from 70 per cent in 1981 to 10 per cent in 2017). It made a significant contribution towards the increased local production of essential drugs, drug price stability, improvement in the quality of drugs, and less dependence on imported drugs. The policy also played a pivotal role in the areas of affordability and availability of drugs which benefitted the consumers in Bangladesh significantly. Price control over imported raw materials helped reduce the cost of production which in turn reduced the Maximum Retail Price (MRP) of final drugs. The range of restrictions on the MNCs provided the local producers space to develop a technological, commercial and economic base and enhance competitiveness. Similarly, regulations were put in place to address the problems of unregistered products and counterfeit medicines, with penalties of imprisonment. The two national drug policies of 2005 and 2016 mention about encouraging investment, public-private partnership, joint research and modernisation in the pharmaceutical sector. However, discussion with relevant stakeholders gives the impression that these policies were not as successful in attaining the objectives set out in the policies.[16] Whilst some of the policies were revised, not much progress could be made to build on the achievements of the 1982 National Drug Policy.[17]

[15] In Bangladesh, key legislation relating to pharmaceutical sector are: (1) the *Drugs Act, 1940* and its amendments (the *Drug Rules, 1945* and the *Drug Rules, 1946*); and (2) the *Drugs (Control) Ordinance, 1982* (DCO 1982) and its amendments [*Drug (Control) (Amendment) Ordinance, 1984* and *Drugs (Control) (Amendment) Act, 2006*]. Key patent laws are *Patent and Designs Act 1911* and *Patent and Designs Rules 1933.* To keep the current course of discussion relevant, only the major drug policies and ordinances and their prominent features have been discussed.

[16] As was pointed in National Drug Policy 2016, the second drug policy of 2005 was not able to achieve the expected targets.

[17] The National Drug Policy 2005 noted that the National Drug Policy 1982 helped attain the followings: (i) production of substandard drugs fell from 36 per cent in 1970 to only about 2 per cent in 2002; (ii) a total savings of USD 600 million per year thanks to lower import dependency; (iii) reduction in drug prices in real terms; (iv) local production rising from BDT 1.73 billion to BDT 40 billion in 2002; (iv) Bangladesh was able to transform itself from a majorly drug importing country to a drug-exporting one.

Box 4 Salient features of the National Drug Polices of Bangladesh

National Drug Policy 1982

- NDP 1982 identified a list of 150 essential drugs to be supplemented with a list of 100 specialized drugs
- NDP 1982 promoted use of generic drugs by
  - □ Mandating the manufacture and sale of 45 most essential drugs among the 150 drugs under their generic name only
  - □ Introducing the National Formulary with formulations of all the listed essential and specialised drugs
- Product patents for pharmaceutical substances were disallowed
- To ensure the quality of drugs NDP 1982 mandated
  - □ Manufacturing companies to employ qualified pharmacists and obliged them to pursue adequate quality control practice
  - □ Establishment of a properly staffed and equipped National Drug Control Laboratory

Drug Control Ordinance 1982

- The directives mandated that the government to control the price of finished drugs and also raw materials, packaging materials and intermediaries (DDA was to be responsible for this)
- MNCs were disallowed to produce a range of products: Production of vitamins, enzymes and cough syrups were restricted only to local companies
- Restriction on importation of any pharmaceutical products which are locally produced by at least three companies or has three close substitutes

National Drug Policy 2005

- NDP 2005 was focused on attaining self-sufficiency, raising export competitiveness, providing better R&D facilities, setting up better-equipped DDA, reduction of import dependency, and encouraging production by following GMP
- Ban on manufacturing under contract or license by Bangladeshi companies was lifted
- NDP 2005 flagged the idea of setting up a dedicated industrial park for the production of APIs so that cost of drug production is reduced

National Drug Policy 2016

- NDP 2016 took cognisance of the necessity to be adequately prepared to ensure compliance with the TRIPS Agreement
- One noticeable addition in NDP 2016 was the aim to establish an effective surveillance system for medicines
- Bangladesh National Formulary and prices of essential drugs are to be regularly updated and published online
- cGMP (current GMP) should be followed in drug production

Source: Authors' compilation from various government documents: National Drug Policy of 1982, 2005 and 2016, and Drug Control Ordinance 1982 (Note: NDP is National Drug Policy, and DCO is Drug Control Ordinance, DDA is Directorate of Drug Administration).

3.4 *Pharmaceutical industry of Bangladesh remains highly dependent on imported raw materials*

Local pharmaceutical companies import raw materials that include active pharmaceutical ingredients (APIs), excipients, and packaging materials. Azam (2016) estimated that almost 85 per cent of the required raw materials is imported.

Drug production in Bangladesh is primarily concentrated in final formulation stage, which is preceded by an equally complicated process of API manufacture. These two stages[18] require different sets of skills and capacity. Bangladesh till now has been able to develop those that are needed for final formulation stage only. Development of technology and the manufacturing of pharmaceutical raw materials, especially the APIs, requires high levels of engineering skills and knowledge in chemistry. These are mostly absent in the LDCs such as Bangladesh. As a consequence, pharmaceutical firms mostly depend on imported raw materials (Sampath 2007). Only a handful of the APIs is locally produced, by big market players. The API production involves chemical operations[19], and the final formulation or drug production belongs to the manufacturing sector. For the API production, economies of scale are a major concern, unlike for the final drug formulation stage where a single plant with adaptable equipment can produce bulk amount of drugs. The pharmaceutical industry of Bangladesh thus continues to depend on imported API for drug manufacturing[20], and thus is highly susceptible to external shocks – the cost of drug production is significantly dependent on the import cost of APIs. Bangladesh imports most of the API from China, India and South Korea[21]. Interviews with industry professionals suggest that the imported APIs are not always of the standard quality; these are also not available in the required amount. Since a number of the major source countries such as India and China are also producers and exporters of generic drugs (final formulations), at times supply of APIs are controlled by the supplying countries to curb competition. To address these challenges, the government of Bangladesh decided in 2008 to establish an API park. Details about the initiative are given in Box 5 (Annex).

The recently announced FY2019 budget has proposed exemptions and reduced rate of duties on a number of pharmaceutical raw materials including that of cancer medicines and raw materials for the APIs. Of the common raw materials of the pharmaceuticals industry, CDs for 12 items were reduced from the existing 10% to 5%, and from 25% to 15% for eight items. CDs on ninety-seven API materials is proposed to be exempted in this budget. Import duties on two raw materials (Lenvatinib, Mesylate and Palbociclib) for cancer-related medicines have been proposed for exemption. VAT on a number of pharmaceuticals ingredients reduced to zero from 15%. It is estimated (CPD, 2018) that the reduced rates will bring down the tax incidence by about 14%. The proposed revised rates are likely to reduce the cost of imported raw materials of the pharmaceutical industry and encourage enhanced production of the APIs. These proposals are also expected to have a positive impact on the balance sheet of local producers. VAT is proposed to be exempted on the import of Erythropoietin, a medication for cancer and kidney diseases.

[18] Drug production or conversely pharmaceutical manufacturing generally involve two steps. Manufacturing of active pharmaceutical ingredients (APIs), the first step, which is a highly sophisticated process. The second step is the drug's final formulation. During this process, firms mix APIs and excipients (other non-active ingredients); press the mixture into pills, tablets, or solutions; and then package the product for the consumer market (World Bank 2008).

[19] Commodity API manufacturing business tends to be a high-volume, low-margin business based extensively on scale economies and large dedicated manufacturing lines.

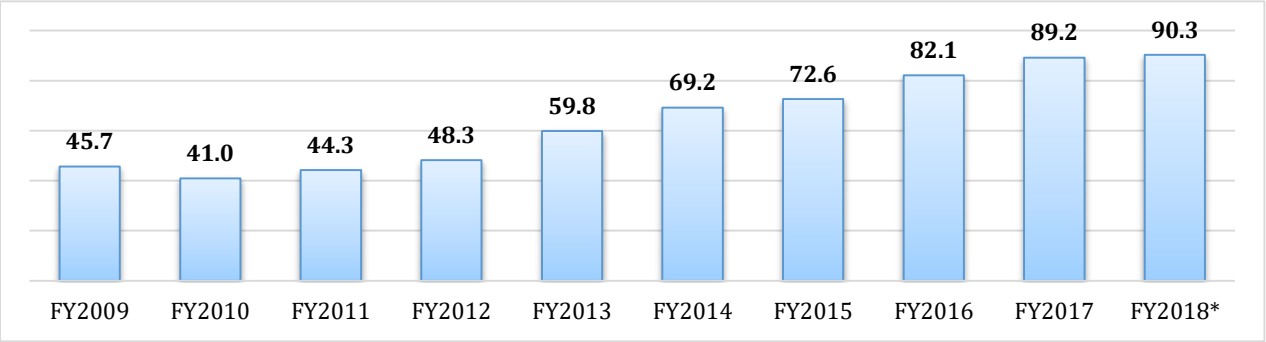
[20] More than 90 percent of the BDT 47 billion worth of raw materials are imported every year (LR global industry insights 2017).

[21] KIIs suggest that the imported APIs are not always of the standard quality and required amount.

3.5 *Export of Pharmaceuticals on the rise*

Exports of pharmaceutical products registered a CAGR of 14.6 per cent in FY2011-2016. Bangladesh exported pharmaceuticals to 107 countries in FY2017, with exports earnings of USD 89.2 million. Figure 3 provides the trend of pharmaceutical export over the past decade. The top seven export destinations of Bangladesh in FY2017 were Myanmar, Sri Lanka, Philippines, Vietnam, Afghanistan, Kenya and Slovenia; these countries have a combined share of 60.3 per cent of the total pharmaceuticals export.

Figure 3 Pharmaceutical exports (in USD million)



Source: EPB, GoB
Note: FY2018* is for the period July-May FY2018

However, as the KIIs suggest, Bangladesh does have the potential to branch out into other markets, particularly the developed country markets. Targetted initiatives to register eligible products could open up the USA and other developed markets for exports of Bangladesh-made drugs. Along with exporting off-patented generics in the USA and European market, Bangladesh could also focus on less regulated emerging markets by taking advantage of its assembling and marketing capabilities. One observes that all the leading pharmaceutical companies in Bangladesh have kept export opportunities on their radar screen. Bangladesh pharmaceutical exports account for only about 8 per cent of the total production of the local pharmaceutical companies that are involved in the export business. It is to be noted that, in recent times, persistent efforts have resulted in Bangladeshi companies getting approval in the highly regulated markets of the US, EU and Australia[22]. Approximately 1200 pharmaceutical products have received approval for exports in the 2016-2017 period. source?

Analysis of export data indicates that Bangladesh has the potential to capture a larger share of the global market particularly in items where it already has a strong export footing.

[22] USFDA, Therapeutic Goods Administration (TGA), Australia, ANVISA, Brazil EMA, UK MHRA, Health Canada, TFDA, and Taiwan has given approval to the pharmaceutical products of Bangladesh.

Table 1. Export potential of Bangladesh top pharmaceutical products

	Global import of HS3004 = USD 353.3 billion			Global import of HS3003 = USD 136.5 billion		
	Bangladesh's export in 2016 (in million USD)	Share in global imports	Country ranking in terms of export value	Bangladesh's export in 2016 (in 000 USD)	Share in global imports	Country ranking in terms of export value
Bangladesh	63.3	0.018	74	1997	1.46E-06	55
China	2,772.0	0.785	19	613682	0.00045	6
India	11,612.0	3.287	10	352350	0.000258	10
Vietnam	84.0	0.024	67	941	6.89E-07	65
HS 3003: Medicaments that contain two or more constituents mixed for therapeutic or prophylactic uses						
HS 3004: Medicaments that contain mixed or unmixed products for therapeutic or prophylactic uses						

Source: Authors' calculation from the data available at Trade Map
Note: HS3003 and HS3004 are the highest exported pharmaceutical products of Bangladesh (in 2016).

The government of Bangladesh has acknowledged pharmaceutical industry as a *thrust sector*[23] and has declared pharmaceutical products to be the 'Product of the year' in 2018. Despite the potentials, the pharmaceutical sector of Bangladesh is constrained by a number of bottlenecks that undermine its prospects both in the domestic market as also in export markets.

Table 2 Challenges facing pharmaceutical sector of Bangladesh

Within Bangladesh	In exporting countries sector of Bangladesh
• The absence of bio-equivalence testing facilities • Delay in issuance of 'Free Sale Certificates' by the National Regulatory Authority • Restrictions on transferring funds for overseas sales and market promotion • Bureaucratic complicacies and resultant delays related to customs procedures at the time of shipment of samples • Lack of supportive policies for export promotion[24]	• Information asymmetry as regards registration procedures and regulatory formalities in export destinations • Difficulty in finding reliable distributors and agents overseas • Complexity in export registration procedures for drugs in highly regulated importing markets (e.g. Europe, USA)

Source: Authors' compilations from FGDs, KIIs

[23] Thrust sectors declared by the Government of Bangladesh are the ones with high export potentials which are then supported by the Government with various incentives.
[24] Lack of adequate export incentives; lack of support and cooperation by Bangladesh's foreign missions and offices.

IV. Relevance of the WTO decision on TRIPS for Bangladesh

Relevance and importance of the WTO decision on TRIPS in the context of Bangladesh can be viewed from three angles. Firstly, benefits offered by the TRIPS flexibilities and their implications for the pharmaceutical industry of Bangladesh. Secondly, necessary institutional and regulatory changes that need to be brought under a TRIPS-compliant regime. Thirdly, impacts of implementation of the TRIPS Agreement in Bangladesh (without the flexibilities, after the transition period is over).

4.1 Benefits offered by the TRIPS flexibilities and their implications for the pharmaceutical industry of Bangladesh

Thanks to the TRIPS waiver and transition period, pharmaceutical companies of Bangladesh enjoy the following benefits: (i) companies can make any drug, irrespective of whether these are off-patent or on patent; (ii) companies can learn from and explore making of new drugs through imitation and follow-on innovation; (iii) Bangladesh can continue to implement the provisions of the National Drug Policy and Drug Control Ordinance 1982, which have several provisions contradicting the WTO-promoted practices; (iv) pharmaceutical industry enjoys protection from import penetration under the existing provisions of the Drug Control Ordinance 1982; (iv) Drug Control Ordinance 1982 allows policy space to local pharmaceutical companies by putting several restrictions on the MNCs in the local market (Box 4).

4.1.1 Bangladesh is allowed to produce generics of drugs which are patented

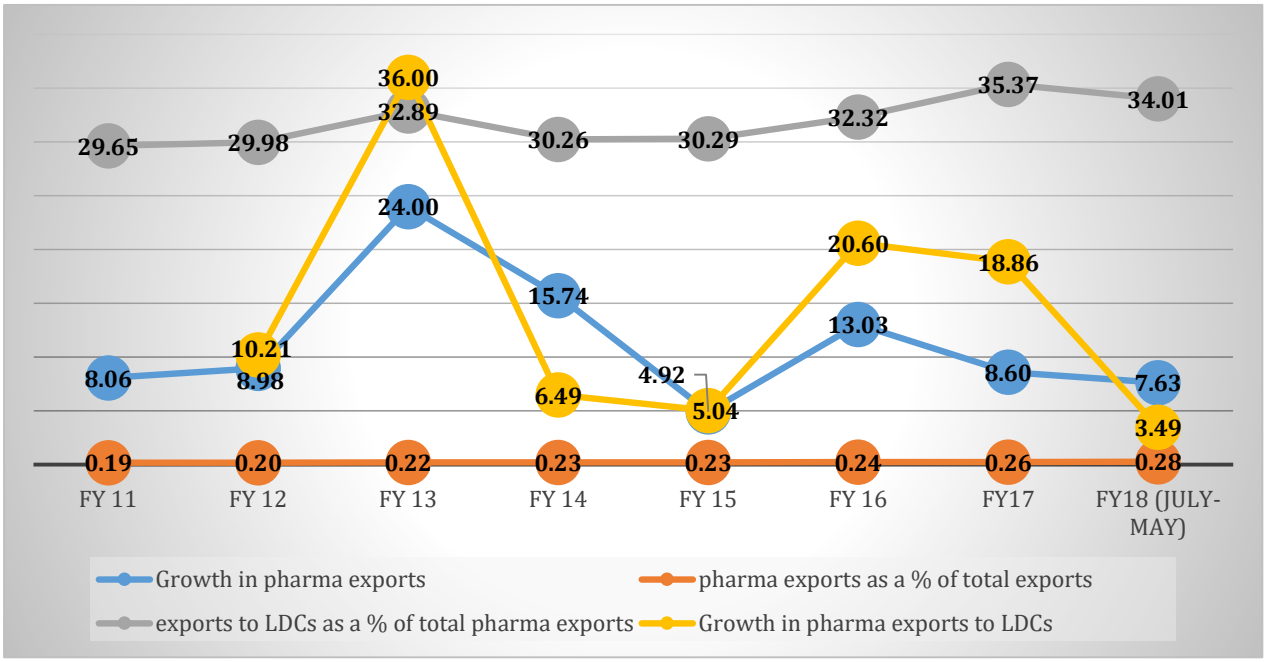
During the waiver period, Bangladesh as an LDC is exempted from obliging with the TRIPS Agreement and is permitted to produce drugs which are still on-patent. Analysis of the production structure reveals that Bangladesh produces mostly branded generics (almost 85 per cent of the local production). Most of the locally produced drugs (which are on patent) are in the category of new or second-generation drugs that address diabetes, cardiovascular disease, allergies and psychological disorders, sexual problems, cancer, HIV/AIDS and anti-malarial diseases (Saad, 2012). This provides Bangladesh with an opportunity to gain expertise in the production of these drugs which need advanced technological knowledge via reverse engineering and follow-on innovation.

4.1.2 Export of patented drugs to the LDCs

TRIPS flexibilities allow pharmaceutical manufacturers in LDCs to export patented drugs to other LDCs; drugs that have gone off patent can be exported even in the absence of the TRIPS flexibilities. Majority of LDCs are partially or entirely dependent on imported medicines. Of all the LDCs, Bangladesh is the most export-oriented in terms of global share and least import-dependent in terms of national consumption (only 3 per cent the domestic demand is met with imported drugs). The TRIPS flexibility and the supply-side capacity of the export-oriented pharmaceutical industry of Bangladesh makes it well positioned to meet a significant part of the growing LDC markets. Bangladesh can make generic versions of patented (not to speak of non-patented) drugs and significantly enhance its exports to the LDCs and other low-income countries which have low or no manufacturing capacity. This, Bangladesh is capable of doing at a relatively lower price.

As may be seen from Figure 3 below, the share of pharmaceuticals exports to the LDCs in global pharmaceutical exports of Bangladesh ranges from 29.7 to 35.4 per cent. The share has not seen any significant rise during the period FY2009 to FY2017.

Figure 4 Growth of pharmaceutical exports of Bangladesh to the LDCs relative to that to the World



Source: EPB, GoB

According to export data for FY2017, the top five major LDC destinations of Bangladesh's pharmaceutical exports are Myanmar, Afghanistan, Cambodia, Nepal and Yemen[25]. Several LDCs have put in place stringent regulatory reforms concerning exports to their market. Exports to these African LDCs countries requires bio-equivalence reports and other technical credibility tests which are not available in Bangladesh. Some of these tests need to be outsourced to facilities outside the country, mostly in Malaysia and India. This entails significant cost and in the end, undermines Bangladesh's export competitiveness.

The high costs involved could have been accommodated had the destination markets been large in scale. However, the relatively smaller market size of the LDCs (compared to that of the developed markets) makes it less attractive to the exporter-manufacturers. Additionally, a significant rise in license fees in some of the potential markets has increased the cost burden to be borne by Bangladeshi exporters. These cost-escalating reforms act as non-tariff barriers (NTBs) as far as Bangladeshi exporters were concerned.

Indeed, African LDCs could have been a major export destination for Bangladesh, since they do not have the required capacity to produce essential drugs. On the other hand, Bangladesh produces affordable generic drugs. In some of the African countries diseases such as HIV-AIDS, Tuberculosis (TB), and Malaria are the most prevalent. Consequently, appropriate drugs and medicines are in high demand. Import meets a large part of this demand under donor-funded programmes like the Global Fund, the Clinton Health Access Initiative (CHAI) and the US President's Emergency Plan for AIDS Relief (PEPFAR) (Syam, 2014). A significant part of the

[25] Following five countries in the top ten LDC destinations, namely, Somalia, Ethiopia, Rwanda, Uganda, and Burundi. (EPB, GoB).

essential medicines for the diseases mentioned above are either on-patent or involve technological know-how which is not yet there in Bangladesh. For example, multi-drug resistant TB (MDR TB) can be treated with second-line drugs which are usually not produced by Bangladesh.[26]

***4.2** Bangladesh's patent law and policies relating to the pharmaceutical need to be updated in accordance with the TRIPS Agreement*

Bangladesh's current patent law and drug ordinance contravenes several provisions of the TRIPS Agreement and would need major changes to ensure compliance with WTO principle of non-discrimination. The existing legislative and regulatory framework need to be amended to take full advantage of the exceptions and limitations available under the TRIPS flexibilities, and also to ensure a smooth transition from a regime under TRIPS flexibilities to one without the flexibilities. Some of the suggested changes are provided below:

i. At present pharmaceutical patents are disallowed in Bangladesh. Under the TRIPS Agreement patents should be provided for both pharmaceutical products and processes.[27]
ii. Duration of patent protection has to be increased from the current 16 years to 20 years as obligated by the TRIPS Agreement
iii. Combination drugs are not allowed in Bangladesh; only single-ingredient products are allowed for production and distribution in the local market. This will need to be changed.
iv. MNCs are not allowed to produce or import certain drugs which have close substitutes or are locally produced by at least three manufacturers. This will need to be allowed.
v. MNCs are allowed to sell their products in Bangladesh market only if they have a local production facility. In addition, they are not granted marketing approval if the drug is not locally produced. The provisions will have to be revised.
vi. A foreign (original) manufacturer of any particular drug is permitted to produce in Bangladesh only under an agreement with a local manufacturer. This requirement will need to be amended to allow investment under single ownership.
vii. Advertising of any drug or any claim concerning therapies or treatment, without the approval of DGDA, is prohibited. Such permissions will have to be given to ensure TRIPS compliance.
viii. Under the current mechanism, there is no protection for test data. This will change since this is a discriminatory practice as per the WTO provisions. The government will no longer be able to obligate the revelation of the formulaic composition of drugs. This should be changed in accordance of the disclosure provision of the TRIPS Agreement, where the details about the invention (and if applicable also the best method to carry it out) must be required by the Member country governments with patent application (Article 29.1 of the TRIPS), but it does not ask explicitly for the formulaic composition.

[26] The bacteria that causes tuberculosis (TB) can develop resistance to the antimicrobial drugs used to cure the disease. Multidrug-resistant TB (MDR-TB) is TB that does not respond to at least isoniazid and rifampicin, the two most powerful anti-TB drugs (WHO). Isoniazid and rifampicin are two first-line drugs to treat TB which are produced in Bangladesh; however, the second-line drugs used to treat MDR-TB are not produced locally.

[27] Product patent was disallowed by National Drug Policy 1982 and later, in 2002 process patents were also prohibited through notification of an Official Gazette by the GoB. (Azam, 2016).

ix. At present foreign-registered patents can be cancelled after four years. As per TRIPS, these cannot be cancelled.

Some of the above measures are discriminatory and hence a violation of WTO and TRIPS principles, and some are against international practices as these could interfere with marketing strategies of the manufacturers. 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 intellectual property rights 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. On the other hand, restricting reverse engineering and learning by imitation could also hinder technological advancement. The final implication of all this remains rather uncertain. It varies from sector to sector, and country experiences also tend to vary. However, Bangladesh will not be able to avoid addressing the attendant challenges, and it is better that it takes the preparatory steps an initiatives to ensure TRIPS-compliance. The regulatory and legislative framework in place in Bangladesh will need to be adjusted to the requirements of the TRIPS Agreement. As Gay (2017) has emphasised, Bangladesh's main challenge will be to keep the technological learning curve in an upward sloping mode if it is to tap the emerging opportunities in a TRIPS-compliant way.

4.3 *What will happen in the absence of the TRIPS flexibilities – Implications of Implementing the TRIPS Agreement*

4.3.1 Import restrictions have to be lifted: As a result, local producers will face tough competition

As discussed earlier, the current policies in place in Bangladesh allows for significant restrictions on imports of pharmaceuticals and pharmaceutical raw materials that are locally produced. If an item is not on the DGDA's essential medicines list, or if the item is produced by more than three local companies, then the particular item is not permitted to be imported - this has protected the local manufacturers. However, the protection will need to be withdrawn if the TRIPS Agreement is implemented in Bangladesh. The pharmaceutical industry will be affected the most by this. Once the TRIPS Agreement comes into force, local pharmaceutical companies will face competition from imports which in many cases are cheaper. If an importer can offer a lower price for a particular product of the same quality, the local producers will likely lose their market share. Large-scale generic manufacturers of India and China could prove to be major competitors, and threats since they enjoy a comparative advantage regarding price. The pharmaceutical companies in these countries have well-established backward linkage industries in producing the raw materials and most importantly in the form of APIs. This again reinforces the need to establish a functioning API park at the earliest and work towards developing competitive strength before the TRIPS transition time is over.

4.3.2 Implications of introducing pharmaceutical patents

Bangladesh mostly produces branded generics, which are already off-patent. Bangladesh thus will be able to continue producing these even after the TRIPS flexibilities are withdrawn or when Bangladesh graduates from the LDC status. As was noted earlier, 85 to 90 per cent of the pharmaceuticals produced in Bangladesh are off-patent. Thus, the introduction of patents will not have a significant effect on the local production of generic versions of off-patent drugs. In this context, as should be noted, *patent cliffs* are very important for drug manufacturers in

Bangladesh[28]. During global patent cliffs, a huge number of drugs go off-patent. The current business model of the top players of Bangladesh pharmaceutical industry involves targeting a drug that will soon go off patent. The market prospects and feasibility of production are tested, and then a drug is selected to be produced. Bangladesh should focus on gaining competitiveness and comparative advantage in producing these "potential" generic drugs. This may be achieved through reverse engineering of as many products as possible, while Bangladesh is still enjoying the TRIPS waiver. This will also help Bangladesh to reap the advantages of future patent cliffs by strengthening its readiness. Bangladesh's pharmaceutical industry should pursue this forward-looking strategy in all earnest by expanding their R&D capabilities. In this connection, the government of Bangladesh should lend the necessary policy and regulatory support to the pharmaceutical industry of the country.[29]

4.3.3 Impact on the price of drugs in Bangladesh

The overall impact on the price of drugs in the domestic market of Bangladesh will hinge on the net effect of all the forces. Since import restrictions on pharmaceuticals and pharmaceutical raw materials will have to be lifted if TRIPS compliance is to be ensured, the resultant competition faced by locally produced drugs, from the imported drugs, will likely have a downward pressure on the prices of locally produced drugs. From consumers' point of view, the lower prices of drugs should be welcome. However, since the demand for drugs is inelastic because of the nature of the product and consumers have little role in deciding on which drugs to consume (drugs are prescribed by physicians), the overall impact on locally produced drugs facing competitions from imported ones remains uncertain. 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.

Since the majority of the essential drugs consumed in Bangladesh are off-patent, the introduction of patents will not have a significant effect on locally produced generic versions of off-patent drugs. Analysis shows that the top 10 drugs in Bangladesh in terms of sales are off patent and are produced by local companies. Moreover, the top-selling drugs which are produced and marketed by the MNCs are off patent. Azam (2016) has analysed that most of the drugs required to treat the most prevalent diseases in Bangladesh are off patent. Thus the patent implementation is unlikely to have any significant effect in Bangladesh.

However, concerns remain high for the price, availability and affordability of locally produced patented drugs (about one-fifth of the local production). As was pointed out, this concerns HIV-AIDS, cancer, cardiovascular diseases, and cases of multi-drug resistance. Introduction of payment of royalty fee to the originator drug manufacturer will raise the cost of production of locally produced drugs which are on patent. This will put upward pressure on the price of drugs in general in the domestic market of Bangladesh. Under the TRIPS-compliant regime, these patented drugs can no longer be produced without the permission of the innovator drug manufacturer or by evading the royalty fee payment to these innovators. All this will likely have an adverse effect on availability and affordability of these drugs.

[28] A *patent cliff* is when the originator firm's revenues could "fall off a cliff" when one or more established products go off-patent, since these products can now be replicated and sold at much cheaper prices by competitors.

[29] Top players in the Bangladesh pharmaceutical scenario are aware of this, and taking due preparation. However, this should be an industry-wide concern rather than concern of only the large companies.

4.3.4 Relatively small-scale firms will face shift competition with the resultant restructuring of the market

The heightened competition consequent to market liberalisation (e.g. lifting of import restrictions) is likely to put the pharmaceutical industry through some degree of structural transformation[30]. Bangladeshi pharmaceutical companies have been used to operating in a closed market and been enjoying a significant measure of protection. Greater competitiveness in the market could put pressure on small-scale companies with relatively lower competitive strength. It is conceivable that the share of imported drugs will rise, at least for some types of drugs and there will be a rise in market consolidation by the relatively larger firms which will gain larger market share. There is also a possibility of smaller companies being acquired by larger foreign companies that will be planning to set up local production facilities.

V. Policy Recommendations

It may be recalled that Bangladesh has made significant strides in attaining health-related targets. Since the mid-1980s, the maternal mortality rate has fallen by one-third, and in the last decade, child mortality rate has reduced by half. Improved life expectancy, immunisation coverage, and tuberculosis and diarrhoea control are also part of this remarkable success story. Bangladesh is ahead of India, Pakistan, Nepal and Afghanistan in terms of providing access to quality healthcare to citizens, according to a study of British medical journal The Lancet[31, 32]. Without a doubt, Bangladesh's thriving pharmaceutical industry has made a significant contribution to this success story.

In view of the above discussion and the emerging challenges, the pharmaceutical sector of Bangladesh currently stands at crossroads. The broader issue that needs to be given due consideration in this connection relates to striking a balance between the competing interests of a variety of stakeholders, namely, the generic-medicine producers of Bangladesh, the R&D community, multinational pharmaceutical companies, global institutions that oversee and enforce health-related agreements and the citizens of Bangladesh. There is a need to consider coverage and quality of health care, out of pocket expenses and affordability, and the type of industrialisation strategy that Bangladesh is planning to pursue in the coming days. There is a need for wide ranging debate and discussion to move towards the right balance in this context. Key stakeholders including the pharmaceutical industry, citizens of Bangladesh and policymakers should be party to this discussion. The future of the health system in Bangladesh and the role of the pharmaceutical industry of the country should play in this will hinge on its outcome.

In light of the above, three sets of policies are recommended in this section – the first set addresses explicitly the steps necessary to avail of the benefits of the TRIPS flexibilities. The second set of recommendations relates to getting prepared for the time beyond the TRIPS

[30] There is widespread agreement that firms in economies with liberal trade policies and greater openness show stronger economic growth and overall development performance in the long run. However, in the process SME firms may face enhanced difficulties and some may be priced out of the market.

[31] Bangladesh ranked 133rd among 195 countries in providing access to quality healthcare, according to the study

[32] http://www.newagebd.net/article/41997/bangladesh-ahead-of-india-pakistan-in-healthcare-access

waiver period. The third set of recommendations concerns reaping benefits accruing from the existing provisions of the TRIPS Agreement.

5.1 Recommendations to reap the benefits of the TRIPS flexibilities

5.1.1 Developing strong research and development (R&D) base

Bangladesh's pharmaceutical companies should focus on the expansion of research and development to strengthen capacities in the production of new molecules and reverse engineering. Pharmaceutical companies may form a strategic partnership with R&D based transnational companies to gain necessary skills and benefit from the transfer of technology.

In Bangladesh, R&D activities are, in general, carried out by product development teams of large companies which are involved in reverse engineering of existing drugs to check the viability of the producing the particular drug. Common R&D activities involve design and selection of profit-maximising efficiency, environmental impact assessment, testing accelerated and longer stability of the selected drug, product quality optimisation and channelling new scientific insights into identifying suitable products for the local market. However, fundamental research to produce the basic ingredients of new drugs and new molecules is not very common in Bangladesh. Pharmaceutical companies will now need to address this lacuna in view of the maintaining sustainable growth in a TRIPS-compliant context.

Research should also be geared to developing raw materials, and modern and standard packaging systems. These activities are at present mostly limited to export-oriented large local companies. It is also to be noted that the majority of the MNCs have their R&D facilities located in the developed countries; development of research and innovation capacity of the local manufacturing unit is not given priority.

Research in Bangladesh (e.g. to develop new molecules) is also constrained by the fact that patents are not available for pharmaceutical processes and products. Several manufacturers argued that the national drug policy, in spite of its significant contribution to the rise of the pharmaceutical industry in Bangladesh, has failed to come up with the needed incentives to encourage and stimulate technological advancement and innovation. The tendency has been to utilise the TRIPS flexibilities to reverse engineer existing products and focus on earning quick money rather than going for long-term investment keeping future strategic interests in the focus. However, the scenario has been changing now, although only the large manufacturers are aware of the challenges and taking the necessary measures in view of this. In this backdrop, the government should put in place appropriate incentives to promote the cause of investment in R&D related activities. Such measures will help ensure post-TRIPS sustainability of the sector.

5.1.2 Addressing shortage of skilled human resources in the pharmaceutical industry

Experts from leading manufacturers agreed that availability of relatively low-cost skilled professionals was one of the key comparative advantages that the sector have gained from, both in the local and international market. Competitively-waged white collar jobs relative to competing supplier countries provided local companies with an edge. This competitive edge will need to be maintained by persistent efforts to raise the quality of the human resources that service the sector.

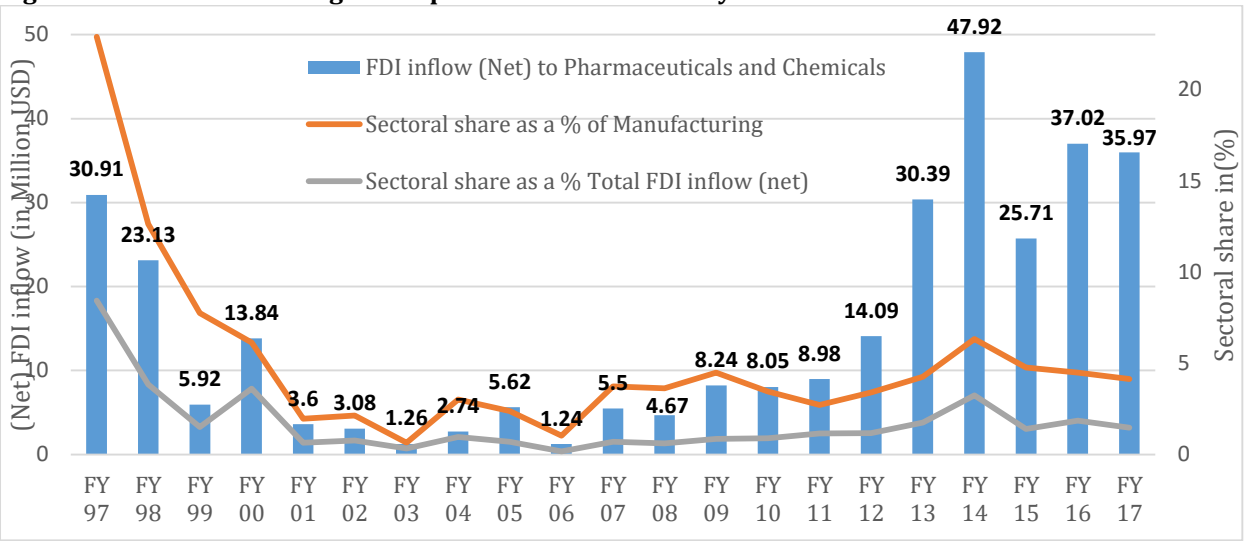
However, shortage of skilled human resources remains an acute challenge that constrains the capacity and ability of Bangladesh's pharmaceutical industry in penetrating the global market. In future, this will also define the sector's ability to compete in the domestic market (against cheaper imports). It is observed from analysis and interviews with concerned professionals that, more often than not, the pharmaceutical graduates are not familiar with the technologies and skills required by the state-of-the-art companies. This is mainly due to lack of harmonisation of the existing curriculum with the advanced technology requirements of the industry. Lack of laboratory facilities in most academic institutions is also a reason. This skill-deficit and mismatch between demand and supply will need to be addressed as quickly as possible.

Lack of correspondence between education and functional demands invariably leads to the obligatory longer-than-usual training period to familiarise fresh graduates and recruits with up-to-date technologies and processes. This protracted lead time can be reduced if there is close collaboration between the industry and the academic institutions. This will ensure correspondence between the design of the courses taught and the needs of the industry. Representation of pharmaceutical professionals in curriculum setting entities could be helpful. Pharmaceutical industry trade bodies and associations can play an vital role in this regard. Dependence on foreign professionals at mid and higher rungs of employment can also be reduced through this. The nature of the white collar jobs in the pharmaceutical sector requires innovation and advanced technological knowledge. To encourage this, top pharmaceutical companies could think of introducing scholarship and training programmes in collaboration with top academic institutions. This will help potential recruits develop the necessary knowledge in areas of lab practices and use of technology. Internships (some companies do have such programmes), sponsored thesis program, in-depth research etc. will need to be encouraged proactively to develop the needed human resource of the future.

5.1.3 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. Indications are there that 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. It is understood that a number of companies have signed contracts to deepen collaboration – Indian and Chinese pharmaceutical companies are keen to go for this. As was noted, Bangladesh can manufacture APIs for foreign companies for export. However, for this to happen, the establishment of the API Park will need to be fast-tracked. The net FDI inflow to the pharmaceutical sector, although rising in recent years, remains at the dismally low-levels of USD 36 million in 2017. This number will need to be increased manifold.

Figure 5 FDI inflows in Bangladesh pharmaceutical industry



Source: Bangladesh Bank

5.1.4 Encourage Contract manufacturing[33]

Contract manufacturing has excellent potential in the Bangladesh context. It saves the client company from undertaking significant capital investment since the local contract manufacturer already has the plant and equipment necessary to make the product. Since Bangladesh has a solid manufacturing base in pharmaceutical products and manufacturing costs that are lower than in other countries, the country is well-positioned to take advantage of the TRIPS flexibilities and develop the market for contract manufacturing. The government can think of providing financial and tax incentives to promote contract manufacturing. It is to be noted that, the global contract manufacturing market for pharmaceuticals is expected to reach U$79.2 billion in 2019, increasing at an average annual rate of 7.5%[34]. Bangladeshi pharmaceutical firms should explore the possibilities of tapping into this highly potential opportunity.

These abovementioned initiatives should be taken during the TRIPS transition period with a view to ensuring a smooth transition of Bangladesh to a TRIPS-compliant future regime.

5.2 Steps to ensure a smooth transition for the time beyond the TRIPS transition period

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

Interestingly, it is observed that brand loyalty arises not from the originator company but reputable, recognisable local firms. The local manufacturers should analyse the purchasing dynamics and consumer choice patterns in the local market and should brand their products in a manner that could create brand loyalty. This will prevent losing market share to imported medicines and manufactures from the MNCs. In Bangladesh, there is a perception that MNCs tend to charge higher than justified price, arising from the pre-1982 experience. Under the new

[33] Toll manufacturing is a contract to manufacture a finished or semifinished product for a client company. It is also referred to as toll processing, tolling, toll conversion, contract manufacturing or custom manufacturing, and can be defined as performing a service for a fee (toll). (Source: http://fhsons.tripod.com/toll.htm).

[34] *Strong Growth Ahead for Contract Manufacturing*
http://www.pharmamanufacturing.com/articles/2016/strong-growth-ahead-forcontract-manufacturing

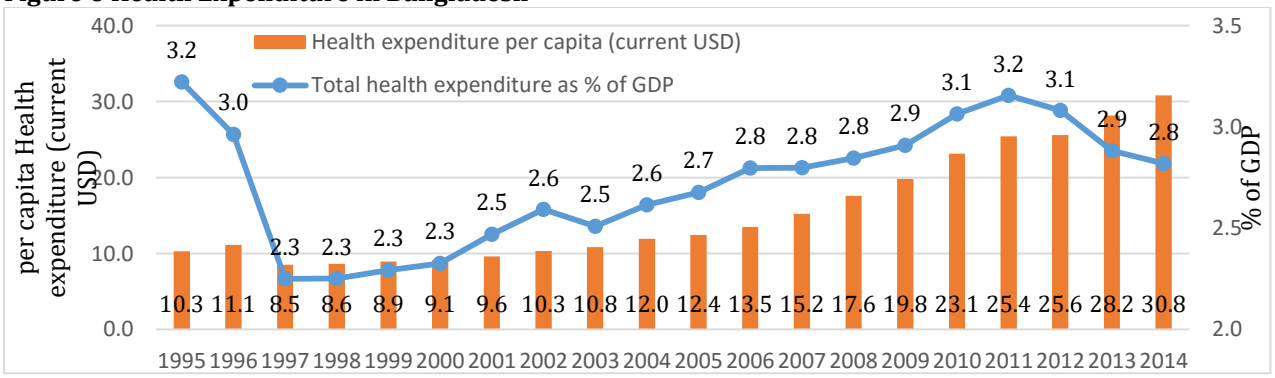
circumstances, the local companies will be able to sustain if they are able to come up with business models that are capable of offering lower-than-MNC prices. Even in the market segment of the less-expensive generics items, apprehensions about counterfeit, low-potency, and adulterated medicines impact 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. The advantage of this is already seen in the domestic arena where a few local companies have been able to build up a good track record and significant consumer allegiance.

Whilst the need for increasing the budget for health sector cannot be overemphasised, availability and affordability of essential drugs will depend on the prices offered by domestic pharmaceutical companies, to a large extent. Indeed, the success of the proposed health insurance scheme will hinge on the number of financial resources needed to underwrite the scheme and whether the government can afford this expenditure. The pharmaceutical companies from which the bulk of the medicines will need to be procured by the government will play a critically important role if the scheme is to be successful. Thus, the introduction of health insurance scheme ought to be seen as a public-private partnership where pharmaceutical companies have to be factored into the equation. Hence support for the pharmaceutical industry of the country should be seen from a broader perspective.

5.2.2 Well functioning insurance system should be established to address the price increase resulting from implementation of TRIPS Agreement

In Bangladesh, the budget allocation to the health sector is as low as 1 per cent whereas total health expenditure is 2.8 per cent of GDP. Indeed, out-of-pocket health expenditure is 67 per cent of total health expenditure, as per WDI data of 2014. This share has been on the rise in the recent past. The government is contemplating the introduction of a universal health scheme. Universal Health Coverage (UHC) is also enshrined in SDG3. However, this will be a most challenging undertaking.

Figure 6 Health Expenditure in Bangladesh



Source: World development indicators (WDI database), World Bank.

5.3 The way forward – taking advantage of the TRIPS Agreement

Bangladesh should be able to make strategic use of TRIPS flexibilities to make these work to her advantage. Some of the TRIPS provisions are important in this connection: A. parallel imports; B. compulsory licensing; and C. Bolar provision - early submission of an application for registration of patented drugs by generic manufacturers (Box 1). These provisions are in place

to ensure that member states can safeguard their public health interests even after full implementation of the TRIPS Agreement.

5.3.1 Parallel imports

The TRIPS Agreement allows for parallel importation of products patented in countries other than the country of origin or the country to which the drug is imported. This mechanism may be used if the price of the product is cheaper in other countries than in the local market. The TRIPS Agreement leaves the Member States free to decide whether or not to apply parallel imports. In this context, the infrastructure and regulatory framework need to support the application of this provision, if and when needed. Bangladesh will need to have the necessary arrangements in place to deploy the provision as necessary.

5.3.2 Compulsory licensing

Bangladesh should take advantage of a compulsory licensing provision of the TRIPS Agreement by bringing in required changes in the patent laws and drug policies. The provision allows the granting of a license without permission from the patent holder. In practical terms, this would mean that the GoB may allow the competent national authority to grant a third party the permission to manufacture or commercialise a drug which is still under patent. This provision may be made use of now if the manufacturing of this type is needed by any other countries. This can be resorted to also in the future under the TRIPS-compliant regime in case of emergence of a national emergency.

5.3.3 Implementation of the Bolar provision

A Bolar provision allows interested (generic) manufacturers to start producing test-batches of a product before the expiry of the patent, to collect necessary data for submission to regulatory authorities. This provision can be made use of Bangladesh's pharmaceutical companies even after the TRIPS flexibilities expire. This is a relevant provision that will be useful for the manufacturers of branded generics. There is a need for greater awareness about such provisions so that pharmaceutical companies are able to take advantage of the derogations.

VI. Conclusion

The pharmaceutical sector of Bangladesh currently stands at crossroads, with significant opportunities and formidable challenges. The sector is set to play a key role in realising the SDGs, particularly SDG-3 in Bangladesh that aspires to have universal health coverage for the citizens and sets the ambition of making essential drugs accessible to all at affordable prices. As the analyses presented in the preceding sections testify, Bangladesh is uniquely positioned to take advantage of the waiver from TRIPS obligations granted to the LDCs and at the same time, by being adequately prepared, to reap benefits accruing from putting in place a TRIPS-compliant regime.

Since Bangladesh will be finally graduating out of the LDCs by 2024, it has about six more years to make use of the preferential regime although TRIPS waiver for LDCs will remain in force for another fourteen years. Bangladesh should try its best to make the best use of the window. Bangladesh should also actively pursue the proposal that graduating LDCs be allowed to enjoy the benefit of TRIPS waiver till the end period of the waiver (till January 2033). Whatever be the case, the interim period must see an intense effort to prepare the pharmaceutical industry for the next lap over the coming decades.

The GoB's interest in promoting the interests of the sector is reflected in the Prime Minister's announcement of pharmaceuticals products being 'product of the year' for 2018. Indeed, public policies have played a crucial role in taking the pharmaceutical sector where it is today. The entrepreneurs have made good use of the supportive policies put in place through successive drug policies. Thanks to the commendable performance of the private sector, backed by strategic public policy support, the pharmaceutical sector of Bangladesh has not only been able to attain commanding heights in the domestic market but also have been able to make impressive inroads into the global market. Now that the sector is poised to reach newer heights, the necessary homework will now need to be strategically implemented. This paper has identified a number of areas which will call for particular attention in view of this: how best to make use of the current derogation; how best to prepare for a TRIPS-compliant regime; the emerging global market opportunities and policies that need to be pursued in areas of human resource development, technology upgrade and policy reforms. The global market size for pharmaceutical products matches the global market size for textile and apparels.

There is a high possibility that despite the significant changes in the policy regime (underwritten by TRIPS-compliance), changing global scenario (with increasing competition both in domestic and overseas market) and heightened demands (in areas of process and product upgradation and technology), Bangladesh has the potential and the capacity to take the pharmaceutical sector to newer heights. It is hoped that the recommendations put forward in this paper will contribute to realising this potential.

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Annex

Box 5 Developments as regards the API Park

Objective: To facilitating a steady supply of raw materials of drugs to reduce import dependency.

Project Developer: Bangladesh Small and Cottage Industries Corporation (BSCIC)

Location: Gazaria, Munshiganj (beside the Dhaka-Chittagong Highway)

Duration: Originally five years (the construction of the complex was delayed for land acquisition and the addition of new components to the project), revised date of completion is June 2020

Recent developments

- 41 plots have been allotted to 27 companies
- The companies are scheduled to take possession of the plots. The companies will lease the plots for 99 years. It is hoped that some companies will start operation in the API park by 2019
- This API park project was initiated in 2008 with project cost BDT 2.13 billion
- The **project cost** has been revised multiple times and stands at BDT 3.64 billion as of June 2017; this may go up further. As suggested by BXCIC, the final cost of the project is expected to rise when it is close to completion, according to the BSCIC.
    - Of the cost, BDT 80 crore will be needed for the Effluent Treatment Plant (ETP) to be set up by BAPI
    - The government is offering each acre of land for BDT 2.9 crore, and entrepreneurs will have to pay the total in instalments over a ten-year period at 10 per cent interest
- As of now, land acquisition and development, construction of other roads and power substation have been completed. Gas connection is yet to be established.
- The drug makers who have got plots will get 180 days to submit their factory layout plans, which the BSCIC will have to approve in one month.

Proposed policy reforms

The Ministry of Commerce has recently formulated a draft policy[35] to incentivise API production. The benefits proposed under this draft are:

- Unconditional tax holiday to all API and laboratory reagent producers (both local and joint ventures for five years from FY2017 to 2022 (But it is already the end of FY2018)
- If a producer can manufacture at least five molecules every year, it would get 100 per cent tax holiday from fiscal 2021-22 through to December 31, 2032.
- VAT and VAT deduction at source will be waived on purchase and sales of locally made API, laboratory reagents, all raw materials, immovable assets and services up to 2032.
- Firms that will produce at least three molecules will be entitled to a 75 per cent tax holiday.
- Waiver on advance income tax and tax deduction at source will also be offered.
- The policy has proposed a 20 per cent cash incentive if producers add at least 20 per cent value. However, the government will review the value addition issue after 2026.
- Raw material manufacturers will be allowed to retain 40 per cent of their export earnings, according to the draft policy.
- The policy also promises to extend foreign currency support to API producers.

[35] The policy will aim to cut raw material import reliance from 97 percent in 2016 to 80 percent in 2032. It also plans to raise API export income to $9 lakh in 2032 from $1.5 lakh in 2016 and create 5 lakh jobs by 2032. It also plans to ensure the entry of new firms in the raw material producing sector and attract $1 billion in foreign direct investment.

- For example, it says, the duration for late payment for import of raw materials will be extended to 360 days from 180 days at present. In case of machinery import, the payment could be made within 360 days and it would be extended up to 3 years in case of irregular payments. The tenure of term loans for factories and equipment could be 12 years instead of the six years at present.
- The single borrower cap will also not be applicable for API and reagents producers. They will also receive back-to-back letters of credit facility.
- API and reagents producers will get priority in getting land at the under-construction industrial parks and economic zones.