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The need to extend the WTO TRIPS pharmaceuticals transition period for LDCs in the COVID-19 era: Evidence from Bangladesh

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Abstract

Bangladesh is one of the most successful least developed countries (LDCs). The country has made such strides that in 2021 the United Nations Committee for Development Policy will consider whether it should graduate out of the LDC category altogether. Like few others, Bangladesh took advantage of WTO flexibilities to build a vibrant pharmaceuticals industry that not only provides needed industrialization and employment but also gives access to essential medicines to millions of Bangladeshis as well as people in other developing countries and LDCs. LDC graduation would bring a loss of WTO exceptions, particularly in the intellectual property arena. This policy brief synthesizes recent research, showing that Bangladesh's vital pharmaceutical industry would be threatened if the country had to adhere fully to WTO rules upon graduation from LDC status. Given that COVID-19 has dealt such a severe blow to Bangladesh's development and health prospects, these papers point to the need for Bangladesh to be able to maintain its WTO flexibilities in order for the sector to remain a source of economic growth and health provision in the years to come.

1. Introduction

Bangladesh's pharmaceuticals industry is a remarkable success story whose growth is now in jeopardy. Nominal output has risen over a thousand times since 1982, reaching US$2.8 billion in 2018, or 1.2% of gross domestic product. As the biggest white-collar employer, the industry supplies 97% of the domestic market and 131 other countries.[1] Yearly average growth of 8.3 per cent from 2014 to 2018 was faster than that of gross domestic product.[2] Exports also expanded more rapidly than the national average in recent years, with annual growth reaching a record in 2019. Bangladesh is the only one of the 47 least developed countries (LDCs) -- and among few developing nations -- where pharmaceuticals production has reached scale, sophistication, and export-orientation. Not only has the country built a vibrant industry that helped diversify the domestic and export economy while expanding employment, Bangladesh's policies have helped expand access to essential medicines to Bangladesh and other LDCs.

The existence of a vibrant and low-cost pharmaceutical industry has contributed to Bangladesh's impressive healthcare achievements over recent decades. Access to medicines, infant survival, immunization, access to sanitation and other health outcomes have all improved markedly. Life expectancy grew from 46.6 at independence in 1971 to 72.3 in 2018 according to the World Bank, higher than the South Asian average. The infant mortality rate fell from 148.4 to 25.1 over the same period, again outperforming South Asia.

Although poverty remains widespread, and Bangladesh is suffering a devastating impact from Covid-19, the country has come to be lauded for its human development progress, overcoming war and famine to eventually achieve relatively broad-based poverty reduction, economic growth and stability on top of its feats in health and education (Gay 2018).

Progress in the pharmaceuticals industry has been undergirded by an active, homegrown industrial policy, latterly facilitated by a special World Trade Organisation (WTO) transition period for LDCs dating back to 2001, which allows Bangladesh not to enforce patents. Under the transition period LDCs can deviate from WTO Trade Related aspects of Intellectual Property Rights (TRIPS) rules in pharmaceuticals until 2033.

A series of new studies finds that this measure has helped support the industry, lowering medicine prices at home and abroad and improving health outcomes. Upon expected graduation from LDC status in 2024, and without an extension, Bangladesh would lose access to this transition period and be compelled to comply fully with TRIPS in pharmaceuticals by 2024 instead of 2033. Recent progress may be jeopardised, as well as the country's ability to cope with ongoing and new health challenges.

Covid-19 is the most obvious such risk. Tackling the economic devastation and human cost of the pandemic will require full international support. In 2020 the Asian Development Bank, International Monetary Fund and World Bank delivered a $1.43 billion package of assistance and loans. Longer-term international support is also needed, including an extension of the TRIPS transition period.

Bangladesh is perhaps uniquely equipped to address the impact of Covid-19 given its pharmaceuticals capabilities.[3] Bangladeshis also already face emerging problems of morbidity and mortality. Infectious illnesses

[1] UN Comtrade.

[2] Bangladesh Bureau of Statistics.

such as tuberculosis remain among the main causes of death. Non-communicable diseases such as cancer, diabetes and cardiovascular disease are increasing. Ensuring the availability and affordability of medicines will prove more critical than ever.

The five new studies, by researchers at Bangladeshi think tanks, intergovernmental organisations, Boston University and the UN, all find that LDC graduation will pose serious risks to Bangladesh's pharmaceutical industry. Bangladesh can ill afford such challenges, especially in the face of COVID and the associated economic crisis. The authors converge around the notion that the loss of access to the TRIPS extension could potentially jeopardise not only the domestic economy and health, but also undermine parts of the industry and raise prices or restrict supply for other countries which import inexpensive generics from Bangladesh.

The body of research recommends that Bangladesh and importing countries take maximum advantage of the concession until 2024 but also seek an extension at the WTO, as permitted under article 66.1 of TRIPS -- ideally until 2033.[4] Covid-19 makes this task imperative, given the need for mass production of low-cost treatments and any possible vaccine. This policy brief synthesizes the main findings and policy conclusions that stem from the new studies on the impacts of losing WTO flexibilities if Bangladesh were to graduate from LDC status (box 1).

Box 1. Recent studies on TRIPS and pharmaceuticals in Bangladesh

Gay, D. (2018) 'Pharmaceutical dreams: TRIPS and drugs policy in Bangladesh,' working paper, New York, UN Department of Economic and Social Affairs

Islam, D. W.A. Kaplan, V.J. Wirtz and K. Gallagher (2020) 'The Social Costs of Graduating from LDC status: Analyzing the impact of increased protection on insulin prices in Bangladesh,' Boston, Boston University Global Development Policy Center

Rahman, M. and S.M. Farin, (2018) 'WTO Decision on TRIPS and Public Health: A Window of Opportunity for Bangladesh's Pharmaceutical Industry,' Dhaka, Centre for Policy Dialogue (CPD)

Razzaque, M.A., R.I. Rabi and H. Akib (2020) 'Bangladesh's Pharmaceutical Exports: Trends, Market Prospects, and Policies,' ch. 11, Navigating New Waters: Unleashing Bangladesh's Export Potential for Smooth LDC Graduation, Dhaka, Bangladesh Enterprise Institute, pp.363-408

South Centre (2020) 'The End of the LDC Transition Period for Pharmaceutical Products Under the Trips Agreement Upon LDC Graduation: Implications for Bangladesh,' Geneva, South Centre

[3] Two Bangladeshi companies are already exporting to India a generic version of Remdesivir, an experimental antiviral patented by Gilead Sciences in the US and found to be effective in the treatment of coronavirus, at a tenth of the conventional cost for a five-day course.

[4] Article 66.1 states that "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period." The general TRIPS transition period ends in July 2021. The pharmaceuticals transition period continues until 2033 but ceases to apply to any LDC graduating before then.

2. Four more years?

There are two forms of TRIPS special and differential (S&D) treatment; one general transition period ending in 2021, and one for pharmaceuticals until 2033. Starting in 1996 LDCs were exempt from the general TRIPS agreement for 10 years, other than Article 3 (national treatment), Article 4 (MFN treatment) and Article 5 (precedence of World Intellectual Property Organisation procedures). This was extended until 2013, then again until 1 July 2021, or earlier if an LDC graduates from the category.

In addition to this general TRIPS provision, the specific pharmaceuticals transition period, dating to 2001 but extended for 17 years at the end of 2015, exempts LDCs from obligations under the TRIPS agreement related to patents or other intellectual property rights on pharmaceutical products and clinical data until 2033. As noted, this provision would be lost if Bangladesh graduates from the LDC category in 2024.

It is this exception that has recently helped support the industry, particularly after the government in 2008 took full advantage by suspending the examination and granting of patents. Although most of the approximately 150 pharmaceutical companies operating in Bangladesh make generics, or non-originator medicines, the patents of which have often expired, around a fifth of medicines produced in the country are patented outside Bangladesh, and those patents cannot be enforced in Bangladesh.

The transition period allows Bangladesh's 1911 Patent Law to run contrary to what would otherwise be required by TRIPS in a number of ways. The law provides patent protection for only 16 years, not the stipulated 20. No patent protection exists for plant and animal varieties; compulsory licences can be introduced by entities other than government; and foreign patents can be cancelled after four years if the product is not also manufactured domestically.

The Drugs Control Ordinance of 1982 allowed the authorities to fix prices and restrict the imports of any medicine if it or a substitute is produced in the country. The 1940 Drugs Act permits government to regulate how imported medicines are labelled, requiring complete formulaic information to be visible. Bangladesh as an LDC can export generic versions of patented medicines to any country where those drugs are not covered by patents or where compulsory licences are issued, often with the aim of treating diseases like cancer or HIV/AIDS.

Production and export come at a fraction of the cost in many other countries. The possibilities for Covid-19 treatment and prevention, as well as other diseases, are significant. As noted above, Remdesivir can be produced at a tenth of the originator cost. Sofosbuvir, used in the treatment of hepatitis C, is supplied by 13 local generic companies at about $4 to $40 per tablet. A study by the University of Sao Paolo found that the price of Sofosbuvir increased to $231 per pill after the granting of patent protection. The Bangladesh Pharmaceutical Industry reports that the generic Harvoni costs $12 in Bangladesh as against $1,130 in the United States. A 10mg dose of the anti-cholesterol drug Crestor (rosuvastatin) costs 25 cents to manufacture in Bangladesh versus $7.25 in the US. A 50mg dose of the anti-diabetic drug Januvia (sitagliptin) also costs 25 cents to make in Bangladesh but sells for $11.25 in the US.

Although pharmaceutical patent filings in Bangladesh are unsurprisingly low, the number of speculative applications in anticipation of the expiry of the transition period or of graduation suggests that filings might rise rapidly thereafter, raising prices. South Centre (2020) points out that the Bangladesh patent law does not currently require sufficient novelty or inventiveness. Without revision of the Bangladesh patent law, including robust patentability requirements, patents could be granted on products which already exist or are unoriginal.

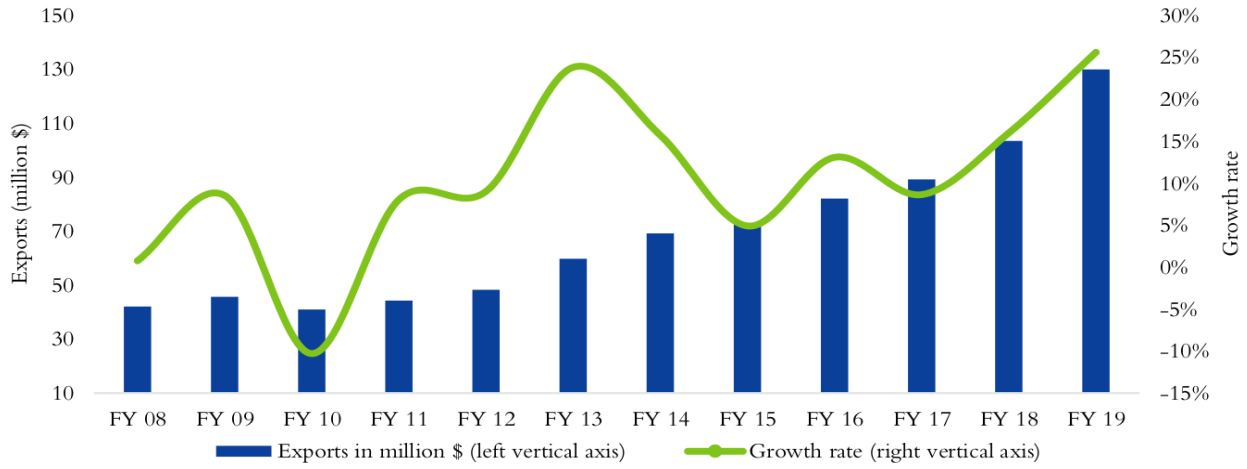
The resulting price increases could restrict access to affordable medicines, particularly in priority areas. They would also constrain the development of active pharmaceutical ingredient (API) capabilities.[5]

Deen et al (2020) develop a model to examine how TRIPS may impact the prices of insulin in Bangladesh and the subsequent impacts on welfare and poverty. They find that without policy adjustments, full implementation of TRIPS would trigger a significant jump in insulin prices, reducing the welfare of Bangladeshi households with one or more members living with diabetes by up to half. Poverty in such households of those needing insulin could rise up 40 percentage points.

3. A global good

Bangladeshi pharmaceuticals exports have boomed, almost quadrupling in the decade after 2006, an average annual compound growth rate of 16%.[6] A record yearly expansion of 25.6 per cent in 2019 resulted in exports worth $130 million that year (Razzaque et al 2020), almost 65 times higher than in 2000. Growth has been almost identical to that of India, widely considered to be one of the most dynamic pharmaceutical producers, even if production remains much smaller in absolute terms. Initial reports suggest that Covid-19 has hit the industry hard, but less than the garment industry and not enough to reverse recent progress.

Figure 1: Pharmaceuticals growth and exports ($ million)



Source: Razzaque et al (2020)

Table 1. Market size and projections

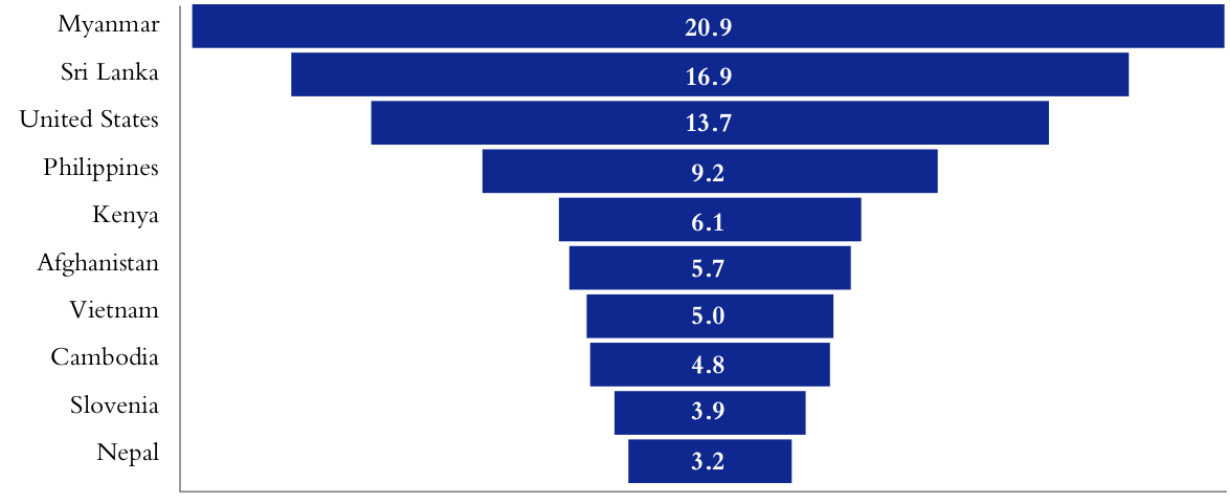
Year	GDP per capita (current $), PPP	Health expenditure per capita (current $), PPP	Pharmaceutical market size
2017	$3,696	$90.6	$2.5–3.0 billion
2025	$6,300	$215	$6.5–7.5 billion
2030	$8,550	$375	$12–13 billion

Source: Razzaque et al (2020)

[5] APIs are excipients and solvents that are used as raw material in producing final drug formulations.
[6] Gay (2018) using UN Comtrade data.

Bangladesh's medicines industry is in effect a global good, serving developing nations in Asia, Africa and the Americas at low cost, as well as the United States and Europe. According to Export Promotion Bureau data, exports go to more than 120 countries including 31 LDCs. The top destinations in the 2019 financial year were Myanmar, Sri Lanka, the United States, the Philippines, and Kenya, which together accounted for 51 per cent of the total.

Figure 2: Top 10 export destinations, $ million



Source: Razzaque et al (2020)

Several of these economies are growing quickly and need low-price medications. Myanmar's market is expected to reach $1 billion by 2023. Around $251 billion of patented medicines are expected to go off-patent globally by 2024 (Indian Pharmaceutical Agency 2019). As the largest global generic hubs like China and India lose cost advantage, Bangladeshi manufacturers have an opportunity to take advantage of this trend, using what they have learned by manufacturing otherwise patented medicines.

Razzaque et al (2020) project that at the last five years' average annual export growth rate of 23%, exports would reach $1.3 billion by 2030. At 10 per cent, the average of the past ten years, exports would top $400 million by 2030. A conservative 5 per cent per annum would take receipts to $222 million by 2030. Pharmaceuticals are thus not only a growing source of production, foreign exchange and employment but an increasingly vital supply of affordable drugs for other LDCs and developing countries.

4. "For once, the little guy won"

Bangladesh's pharmaceuticals growth can be traced to forward-looking government strategy, a unique history, low labour costs, the size and dynamism of the domestic market and recent growth in domestic and international healthcare expenditure. An innovative and homegrown health-orientated industrial policy also underpinned progress -- and the TRIPS transition period in place since 2001 has helped maintain this policy space.

To a certain extent, the reverse engineering and learning-by-doing made possible by the absence of patent enforcement has also helped build the pharmaceuticals cluster and enhance product sophistication, with spillover effects for the wider industry. The reverse engineering of complex formulations and manufacturing of APIs is still at a nascent stage. More time is required to consolidate and sustain these developments.

After independence most medicines were imported, with eight multinationals manufacturing almost 75 per cent of domestically produced medicines by value. Around 160 small and medium-sized firms accounted for the remainder of production (Reich 1994). Industrial policy began with the 1982 National Drug Policy, which supported domestic producers of critical medicines, limited and controlled import prices and placed curbs on multinational production. One of the motivations was to stop multinationals manufacturing "Unnecessary and useless medicines such as vitamin mixtures, tonics, alkalizers, cough mixtures, digestive enzymes, palliatives, gripe water and hundreds of other similar products" (Expert Committee 1982). The policy aimed to make quality essential medicines available at an affordable price (Ahmed et al. 2015).

Under the first industrial policy, most of which remains in place, firms were required to reinvest a proportion of their income. Government restricted the imports of products or close substitutes if these were produced in the country by two or more national firms. A dedicated committee continues to determine imported and domestic prices. "This is a remarkable tale of a battle between Big Pharma and a military dictator-backed group of medical professionals and activists in which, for once, the little guy won. The policy continues to be credited with having brought good-quality medicines in reach of the masses" (Hossein 2017). The number of firms is around the same as in 1982 but, unusually for a developing country, local firms account for approximately 90% of market share, with around 20 dominating production. Four multinational corporations – Sanofi, Novo Nordisk, Novartis, and GlaxoSmithKline – also rank among the top 20 (South Centre 2020).

The original policy was updated in 2005, with the removal of a ban on manufacturing under contract or license by Bangladeshi manufacturers. An API park was proposed, aimed at substituting local ingredients for the approximately 70% of APIs that are currently imported. The policy emphasised self-sufficiency, export competitiveness and good practice -- although not all of these broad goals were achieved (Rahman and Farin 2018). This phase of industrial policy, which attempts to substitute nationally produced ingredients for imported ingredients, is only relatively recent and needs continued policy space in order to develop.

A further update in 2016 emphasised preparedness for TRIPS compliance; suggested the establishment of an effective surveillance system for medicines; proposed regular updating of the list of available medicines; and recommended updating and publishing of the prices of essential medicines online (Razzaque et al 2020). In 2018 the government designated pharmaceuticals the product of the year, underlining its importance as a strategic industry.

The most recent policy grants generic medicines exporters a 10 per cent cash subsidy. For API exports, the figure is 20 per cent. In 2018 the government announced that API producers would receive a 100 per cent tax holiday until 2021–22. Companies manufacturing at least two molecules per year will continue to pay no tax until 2032. APIs and reagent imports are duty-free until December 2025. Producers are exempted from advance income taxes and tax deductions at source until 2032 and will receive 20 per cent tax incentives for API exports. Other incentives include longer-term loans and back-to-back letters of credit. Pharmaceutical producers also receive priority in obtaining land in industrial parks and zones (Razzaque et al 2020).

5. Standing on the shoulders of the Maldives

Any extension of the transition period would depend on precedent. Only six countries will have graduated by the end of 2020 (Botswana, Cabo Verde, Samoa, Maldives, Equatorial Guinea and Vanuatu), so it is difficult to establish case history. No other graduating LDC has a substantial medicines industry and Botswana graduated in 1994, before the WTO existed.

In 2005, however, the TRIPS Council granted the Maldives a two-year general extension of the general TRIPS transition period,[7] following UN endorsement of its LDC graduation in 2004. Prompted in part by the need to reduce the impact of the Maldives's graduation, the UN General Assembly passed resolution 59/209 in 2004 on smooth transition, urging development and trade partners, as well as WTO members, not to withdraw various forms of support suddenly upon LDC graduation.[8] Following a delay due to the impact of a cyclone, the Maldives eventually left the LDC category in 2011, after the end of the extension period. The General Assembly passed a second resolution on smooth transition, 67/221, in 2012. [9]

Article 66.1 of the TRIPS Agreement makes it clear that any LDC may submit a request for an extension to the TRIPS Council at any time before its graduation. The request must be "duly motivated", although no authoritative interpretation of this requirement exists, presumably meaning that the LDC should only demonstrate ample reason (South Centre 2020).

Notably the 2002 TRIPS Council decision extending the transition period did not require a formal request from an LDC, instead using paragraph 7 of the Doha Declaration on TRIPS and Public Health. The only rationale was to recognise the gravity of public health problems afflicting both developing countries and LDCs and the need for TRIPS to address these problems. Going by precedent, public health should be sufficient grounds. The WTO Secretariat has clarified this in an informal note, referencing the Maldives.

The Maldives only received a two-year extension, which ended before graduation, suggesting that securing a longer period may prove difficult. Its request, however, was for a general TRIPS extension, which is more ambitious than only pharmaceuticals. It should also be noted that article 66.1 **does not *require* early expiry of the transition period upon graduation**. In addition, the criteria for LDC graduation are unrelated to the vulnerabilities, special needs, and requirements of LDCs mentioned in article 66.1, and which may remain. Any LDC graduating before 2033 may use these grounds to argue that it is entitled to the full transition period.

Article 66.1 itself does not state that the transition period will expire if a country graduates. A requirement was added later in the TRIPS Council decision granting an extension. The language in article 65.2 also differs, stating categorically that a developing country member is entitled to a four-year transition period in addition to a general one-year period available to all members. Article 66.1 only refers to the "...special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base".

Opportunities to use the Maldives precedent therefore exist and may be considered all the more pressing due to the urgency surrounding Covid-19. Rather than Bangladesh only applying for an extension itself, and given the industry's global importance, the LDC group may wish to seek a general extension -- an option which would bring strength in numbers. An opportunity may arise before the expiry of the general TRIPS transition period on

[7] Decision IP/C/35, 17 June 2005.

[8] "The General Assembly... Invites all members of the World Trade Organization to consider extending to a graduated country, as appropriate, the existing special and differential treatment and exemptions available to least developed countries for a period appropriate to the development situation." Not all members or international entities comply. Notably the TRIPS and pharmaceuticals extension ends abruptly upon graduation.

[9] "The General Assembly… Reiterates its invitation to all members of the World Trade Organization to consider extending to graduated countries the existing special and differential treatment measures and exemptions available to least developed countries for a period appropriate to the development situation of the country."

1 July 2021. Bangladesh should ensure that the request is dealt with at the TRIPS Council and not deferred to the WTO Ministerial Conference or linked to other negotiating agendas.

6. Conclusions and recommendations

Bangladesh's impressive achievements in pharmaceuticals can be traced to its unique national story, large, low-cost labour force, and increasing global and national health spending. While missteps were made, and policy was at times over-complicated, a series of innovative and experimental industrial strategies -- with health-related objectives -- has also underpinned progress. The policy space provided under the TRIPS and pharmaceuticals extension remains vital. The industry is of growing importance not only to the domestic economy and health outcomes; it supplies other LDCs and developing countries at low cost.

Covid-19 has dealt a severe blow, one from which recovery will take many years. Yet Bangladesh is unusually well-positioned to respond. Two companies already export an experimental treatment to India. Further treatments may emerge. Cheap, mass production of any vaccine may even be possible. As noted, communicable and non-communicable diseases are growing in impact. It would be highly undesirable to withdraw an important form of international support at such a crucial juncture -- especially so close to the 2030 deadline for Sustainable Development Goal 3.8, "access to safe, effective, quality and affordable essential medicines and vaccines for all". The UN smooth transition resolutions underscore the commitment of the international community.

Whilst movement at the WTO is currently slow, and any request for an extension is likely to be met with objections from developed countries and developing country competitors, the Bangladesh government should as a matter of priority request the WTO TRIPS Council for a national extension of the transition period under article 66.1.

Bangladesh should also seek the support of other LDCs in submitting a joint, duly motivated request for an extension of the period, at the same time submitting a request for an extension of the general TRIPS transition period for LDCs in 2021, ensuring that the period does not end upon graduation. Such initiatives could prove vital at a critical time not just for Bangladeshis, but for the developing world.

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