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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 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.

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 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.

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

Source: Razzaque et al (2020)

APIs are excipients and solvents that are used as raw material in producing final drug formulations.

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-

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

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.

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