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Potential and Future Prospects

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- WTO: TRIPS and Bangladesh
- Compulsory Licensing
- Future of Bangladesh's Medical Sector
- Possible Solutions

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## ACKNOWLEDGEMENTS

This report titled "Bangladesh and Compulsory Licensing: Potential and Future Prospects," explores Bangladesh's rapid economic growth, particularly in the pharmaceutical sector, and the challenges it faces as it transitions from a Least Developed Country. Emphasizing the impact of the WTO: TRIPS agreement, the document highlights the significance of compulsory licensing for Bangladesh's pharmaceutical industry. It underscores the need for a delicate balance between domestic interests and international regulations. The report anticipates future challenges, including economic evolution, regional competition, and potential domestic monopolization. Possible solutions include focusing on specific sectors or diversifying production. Overall, the report suggests that Bangladesh's handling of these challenges will influence its global standing and serve as a model for other developing nations.

We extend our sincere gratitude to SAAPE Secretariat team for their research, invaluable input, layout design and unwavering support throughout the preparation of this report. The technical and financial support provided by the PVA Secretariat and Action Aid International has played a crucial role in ensuring the success of this report.

We sincerely hope this report will contribute to Bangladesh's efficient implementation of compulsory licensing as it transitions to a developing nation, balancing growth and regulatory checks. The report also stresses the importance of preventing domestic monopolization and underscores the need for global pandemic preparedness in Bangladesh's medical sector.

SAAPE Secretariat,  
Kathmandu Nepal

# INTRODUCTION

As the world recovers from the Covid era slowdowns, the rise of several developing states in a slow yet steady pace shows the tenacity and capacity of these nations. The likes of Indonesia, India, Brazil, Nigeria, Thailand, South Africa and Turkey have all displayed commendable and surprising progress in the past decade, pushing to break into a higher stratum and nearing better infrastructure environments. However, there is a Least Developed Country, one from the lowest tier in the UN lists, that is making even larger strides than the aforementioned states. The South Asian giant Bangladesh has emerged as one of the fastest growing economies in the world with a voracious consumer market, heavy export capacity and large labor sector. Bangladesh has made rapid strides in the last three decades, and retained a healthy GDP growth rate of 7.2 % after the global pandemic in the fiscal year 2021-22.<sup>1</sup> According to the Economics Department at the London School of Economics, the global economy's center of gravity i.e. the area where economic activities are concentrated globally, by 2050, will shift eastwards between India and China, exactly where Bangladesh is located. This shift is caused precisely due the rise of countries like Bangladesh. Bangladesh was adjudicated as one of the new eleven (N-11) states by Jim O'Neill in the early 2000s, a group of states that were projected to become the world's largest economies in the 21st century.<sup>2</sup> Bangladesh is well on course to match this projection thanks to its booming business sector. An economy propped up by small and medium size enterprises, Bangladesh's private

industry forms the backbone of the country's finances.

Bangladesh has undergone tumultuous times since its independence, emerging from great strife to make rapid strides and reach a position where it has become the fastest growing economy in South Asia and one of the quickest in the world.<sup>3</sup> A combination of internal financial directives aimed at creating investments and innovations, the massive numbers in workforce, access to easy trade routes and the benefits of LDC status in international trade have aided Bangladesh in its rapid ascent. The fourth factor has played a pivotal role as it has allowed Bangladesh to have some advantages over its peers in production, provision and pricing. However, as the nation nears its graduation from LDC status in 2026, questions have arisen regarding its ability to sustain its financial progress. A key player in the Bangladeshi economy is its lucrative pharmaceutical industry which is especially relevant in the post Covid era.<sup>4</sup> This article shall explore the links between Bangladesh, its pharmaceutical sector and its LDC graduation: a major part of the nation's future, and capable of global repercussions.

## WTO: TRIPS AND BANGLADESH

To understand how Bangladesh has emerged as a key player on the global scale and reached its speed of economic expansion, it is imperative to understand the WTO: TRIPS deal (World Trade Organization: Trade-Related Aspects of Intellectual Property Rights). Described as, "the most comprehensive multilateral agreement on

1 <https://country.eiu.com/bangladesh>

2 <https://www.bloomberg.com/news/articles/2012-08-07/goldman-sachs-s-mist-topping-brics-as-smaller-markets-outperform#xj4y7vzkg>

3 <https://www.brookings.edu/articles/why-is-bangladesh-booming/>

4 <https://www.bu.edu/gdp/2021/09/13/why-bangladeshs-burgeoning-pharmaceutical-sector-is-on-a-collision-course-with-global-trade-and-investment-rules/>

intellectual property (IP). It plays a central role in facilitating trade in knowledge and creativity, in resolving trade disputes over IP, and in assuring WTO members the latitude to achieve their domestic policy objectives. It frames the IP system in terms of innovation, technology transfer and public welfare. The Agreement is a legal recognition of the significance of links between IP and trade and the need for a balanced IP system.<sup>5</sup> The agreement was signed by WTO member states in 1994 in Morocco, and further amended in 2001 in Doha. The 'Doha Declaration' was particularly created to give developing nations a better platform for access to medicines. The basic purpose of TRIPS is to safeguard intellectual property from blatant imitation and exploitation, and thus secure investments and protect innovators. TRIPS has been a major part of the spread of capitalism and corporatization of the past decades as it was the first legal agreement of its kind, providing the WTO with a legitimate and lawful framework. The TRIPS framework allows the WTO to settle disputes, set clear guidelines and limits, and provides transparency. By design, TRIPS is intended to create overall global development. However, critics argue that it favors developed countries.<sup>6</sup> The push for dissolving IPR (Intellectual Property Rights) came from developing countries in the 1960s and 1970s as they sought to breach technological gaps with the developed world.<sup>7</sup> In turn, corporations in the developed countries used this opportunity to push for stricter regulation because they were losing out on trade due to counterfeiting.<sup>8</sup> Therefore, TRIPS's validity as a neutral instrument remains a highly debated topic.

5 [https://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/trips_e.htm) (WTO, n.d., Para. 1)

6 <https://www.cadtm.org/WTO-favours-developed-countries>

7 <https://www.e-ir.info/2013/12/23/the-arguments-for-and-against-the-trips-agreement/>

8 <https://www.e-ir.info/2013/12/23/the-arguments-for-and-against-the-trips-agreement/>

There are issues with the deal's makeup that resulted in the Doha Declaration and continue to be felt by less developed nations. For example, a recurring point of contention is TRIPS' strictness on IP protection which can inhibit local industry evolution in developing countries, leading to a lack of jobs and innovation. Developing states do not possess counter measures to such rules as they lack infrastructural capacity for alternatives. LDCs like Bangladesh are exempt from such practices because they get a TRIPS waiver. Nevertheless, experts believe that such an exemption does little to promote internal development in LDCs. Two critical issues have arisen: First, international planning and commitment have been inadequate for structural changes and for meeting aid, trade and WTO targets.<sup>9</sup> Second, the weak institutional and governance mechanisms in LDCs are unable to take advantage of international support provisions.<sup>10</sup> Despite its potential for more growth and economic development, Bangladesh has often been constrained by internal weaknesses and TRIPS handicaps. Therefore, the nation epitomizes these issues.

## COMPULSORY LICENSING

In 2015, the WTO extended the period for exemptions in patents in the pharmaceutical industry to 2033 for LDCs on the verge of graduation such as Bangladesh and provided time to become completely in line with WTO laws.<sup>11</sup> Bangladesh's medical sector has grown exponentially in the 21st century. The industry output grew a thousand times since 1982 to 2017.<sup>12</sup> When the

9 <https://books.openedition.org/obp/3141?lang=en>

10 <https://books.openedition.org/obp/3141?lang=en>

11 [https://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/agrm7\\_e.htm#:~:text=In November 2015, the TRIPS, member, whichever date is earlier.](https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm#:~:text=In November 2015, the TRIPS, member, whichever date is earlier.)

12 <https://www.un.org/ldcportal/content/what-ldc-graduation-will-mean-bangladesh's-drugs-industry>

time of graduation from LDC arrives and LDC privileges are lost, a rise will be seen in the costs of production and subsequently, in the prices of drugs and medicines that Bangladesh produces. The key concept of Compulsory Licensing will come into play once the South Asian nation graduates. Compulsory Licensing is a part of TRIPS that focuses on the legitimization processes of patent imitation and copying. It is described as, "Compulsory licensing is when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself."<sup>13</sup> Bangladesh is currently free to produce such licenses without contacting patent holders and use them for creating commodities. They face no repercussions from the original creators as their LDC status protects them. Bangladesh with its rapidly expanding economy and large workforce was thus able to become a rising force in pharmaceuticals in a short period of time. During the pandemic, Bangladesh's ability to produce vaccines was displayed as the Bangladeshi vaccine 'Bangavax' was developed by Globe Biotech Limited.<sup>14</sup> The vaccine was cleared for human trials in 2022 and is currently undergoing further development. If Bangladesh had greater access to vaccine technology, it is plausible that it would have experienced a much faster development. However, such access is restricted by developed states and reinforces the need for an equitable global vaccine production scenario.

Bangladesh is the only LDC that is largely self-sufficient with its internal medical industry. The nation meets nearly 98% of its domestic demand with a sizable market of \$3 billion.<sup>15</sup> Bangladesh

supplies medicines to over 150 nations, and revenues were \$169 million in the fiscal year 2021-22.<sup>16</sup> Such numbers place Bangladesh in a strong position for the next decade, especially when it comes to existing infrastructure for pharmaceuticals. The issue lies in international patenting laws and the withdrawal of TRIPS privileges, as Bangladesh will now have to notify, track down and gain permission from patent holders. Consequently in 2022, Bangladesh updated its patent laws for the first time since 1911. The old 1911 act had a combined approach to patents and laws which were separated in the new act.<sup>17</sup> The details of the old act are shown below<sup>18</sup>

"The law of patent in Bangladesh is guided by the Patents and Designs Act, 1911 and the Patent and Design Rules, 1933. In order to be patentable, an invention should relate to a manner of manufacture which is novel after coming through some inventive steps and it should have a practical existence as a manner of manufacture. Besides, it must not be contrary to law or morality. Then a patentee or an entity fills in the application, containing a description of how to make and use the invention, information about the usefulness of the invention and technical problems solved by the invention. Sometimes, it's necessary to attach the drawings demonstrating the invention. After that, a patentee has to wait for the "patent pending" period for inspection and only after a patent will be enforced."

Similarly, the details of the current terms are displayed below<sup>19</sup> -

13 [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm#:~:text=What is compulsory licensing?,the patent-protected invention itself.](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=What%20is%20compulsory%20licensing?,the%20patent-protected%20invention%20itself.) (WTO, n.d, Para. 1)

14 <https://www.observerbd.com/news.php?id=375112>

15 <https://www.trade.gov/country-commercial-guides/bangladesh-healthcare-and-pharmaceuticals>

16 <https://www.trade.gov/country-commercial-guides/bangladesh-healthcare-and-pharmaceuticals>

17 [https://www.researchgate.net/publication/373927935\\_Compulsory\\_Licensing\\_under\\_the\\_Bangladesh\\_Patents\\_Act\\_2022\\_A\\_reflective\\_overview](https://www.researchgate.net/publication/373927935_Compulsory_Licensing_under_the_Bangladesh_Patents_Act_2022_A_reflective_overview)

18 <https://www.fmassociatesbd.com/insights/intellectual-property-law-in-bangladesh> (Rahman, n.d., Para. 7)

19 [https://www.researchgate.net/publication/373927935\\_Compulsory\\_Licensing\\_under\\_the\\_Bangladesh\\_Patents\\_Act\\_2022\\_A\\_reflective\\_overview](https://www.researchgate.net/publication/373927935_Compulsory_Licensing_under_the_Bangladesh_Patents_Act_2022_A_reflective_overview) (Sheikh, 2023, Para. 4-5)

“The Act describes a ‘Compulsory license’ as a permission given by the right authority to someone or a government-controlled organization, not the patent owner, to use a patented invention in Bangladesh. Provisions of compulsory licenses are primarily outlined in section 21 of the law. Under section 21, compulsory licenses can be granted under certain circumstances, such as when there’s a need for public interest, national security, health, or economic development. They may also come into play if a court determines that a patent holder’s or licensee’s method of utilizing the invention is anti-competitive, in which case, the government can decide that the invention should be utilized through a CL. Further, if a patentee uses their exclusive rights without authorization or fails to prevent unauthorized use by the licensee, a compulsory license may be issued. Additionally, if a patented invention isn’t available in Bangladesh in the required quantity, quality, or at a fair price, a CL can be considered. Moreover, if a new patent application claims a valuable invention that is related to a prior patent and which cannot be used without infringing the previous patent, in that case, the government might grant a CL for the use of such patent.”

While comprehensive to some degree, the new licensing laws neither accommodate all needs nor rectify all issues. The challenge for Bangladesh will be to balance its existing capacity with the checks and balances that will be imposed on Bangladeshi companies. Furthermore, as a growing economy, there will be considerable pressure on the government and private sector to sustain the current trajectory of economic progress. Bangladesh has so far relied on manufacturing generic drugs by undertaking only the final synthesis processes by using mostly importing or domestically producing Active Pharmaceutical Ingredients (APIs) instead of the complete

chemical synthesis processes.<sup>20</sup> Around 85% of the drugs sold in Bangladesh are generic and the rest are patented.<sup>21</sup> Due to current successes, the next plan in the Bangladeshi pharmaceutical sector is to go upscale. Companies in the country will focus on producing APIs and reagents to boost manufacturing capacity over the next decade.<sup>22</sup> Bangladesh is now in a territory many LDCs have experienced when they graduated. Furthermore, the prospects of another pandemic are very real and this would add another dimension to the Bangladeshi medical sector. Globally, this could be a key reference point for other LDCs as the fate of Bangladesh will greatly influence everything from how LDCs will cultivate their medical sector to the upcoming pandemic accord which is being heavily contested by poorer states because of its kowtowing contents to affluent powers.

## FUTURE OF BANGLADESH’S MEDICAL SECTOR

For Bangladesh, the structure of Compulsory Licensing is in place and WTO deadlines are set too. The state has until January 1, 2033 for complete pharmaceutical patenting overhaul as this was the deadline agreed by the WTO in 2015.<sup>23</sup> The main challenges for Bangladesh’s medical industry are as follows:

Economic evolution - As Bangladesh becomes a developing country, there will be a period of stagnation in its financial sector and its booming growth rate. However, such a stasis seems implausible in the current decade. With a need to

20 <https://bangladesh.uz/pharmaceutical-industry>

21 <https://bangladesh.uz/pharmaceutical-industry>

22 <https://www.bu.edu/gdp/2021/09/13/why-bangladeshs-burgeoning-pharmaceutical-sector-is-on-a-collision-course-with-global-trade-and-investment-rules/>

23 <https://www.bu.edu/gdp/2021/09/13/why-bangladeshs-burgeoning-pharmaceutical-sector-is-on-a-collision-course-with-global-trade-and-investment-rules/>



recover from Covid and slowing economies around them, it is likely that the Bangladeshi government will look to solidify its position. This means that Bangladeshi companies will be under pressure to perform and produce results in high numbers. This will apply especially to the pharmaceutical industry in the country, as it has become a key strength of the Bangladeshi economy. Furthermore, pharmaceutical industry is very lucrative and thus its contribution to the national income is much significant compared to clothing, textiles or agricultural exports. The existing framework will allow for a substantial upscaling in product quality and production capacity. The various pharmaceutical companies in Bangladesh will have much incentive to grow further, and this will only be possible by maintaining the delicate balance between compulsory licensing and patent protection.

Regional economic competition - Bangladesh's rise coincides with the increasing economic power of the two financial juggernauts of the region, China and India. The two Asian powers have grand ambitions of their own when it comes to the pharmaceutical industry, as displayed by their vaccine production and distribution during Covid. China, India and Bangladesh are the only non-developed states who export medicines, and the Sino-Indian markets dwarf that of Bangladesh at \$220 billion for China and \$40 billion for India.<sup>24</sup> Both powers are keen to dominate Asian and global medical supplies with their own domestic products<sup>25</sup> <sup>26</sup> and this makes Bangladesh's potential upcoming a worrisome prospect for them. Bangladesh has a slight leverage in the

case of distribution of products as unlike China and India, Bangladesh's smaller geographical area makes it easier for manufactured goods to reach its ports. In times of urgent demand, this advantage may place Bangladesh as the first-choice option for many countries ahead of China and India. Hence, the two nations are going to be embroiled in a tough contest with Bangladesh to gain a stranglehold in the regional and international markets. Additionally, the Bangladeshi government may have to differentially adhere to or join regional trade cooperation initiatives, some of which may hinder Bangladesh's expansion plans<sup>27</sup>. Moreover, Bangladesh's medical industry has greatly benefited from the work of powerful pharmaceutical companies in affluent states. These companies will lobby and seek protection from their governments by restricting Bangladeshi organizations as they have the potential to emerge as genuine alternatives. Western companies have continually sought to dictate global health agreements, as displayed in the debates regarding the proposed pandemic accord. Therefore, Bangladesh's pharmaceutical endeavors maybe disrupted not only by regional powers but other western states too.

Domestic monopolization - In contemporary times, there are 100 pharmaceutical companies in Bangladesh. However, it is an unstable & concentrated industry as the top 20 companies produce 85% of the revenue.<sup>28</sup> As the Bangladeshi industry evolves there is a real possibility of market monopolization if the government fails to control and manage the companies. It is absolutely necessary for the government to carefully manage its compulsory licensing laws,

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24 <https://www.thedailystar.net/business/economy/news/huge-export-market-awaits-pharma-industry-3270616>

25 <https://www.cnbc.com/2022/05/27/india-needs-to-fill-china-gaps-to-become-the-pharmacy-of-the-world.html>

26 <https://www.bloomberg.com/news/features/2022-04-11/india-hopes-pharma-city-will-break-china-s-grip-on-drug-industry#xj4y7vzkg>

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27 <https://www.bu.edu/gdp/2021/09/13/why-bangladeshs-burgeoning-pharmaceutical-sector-is-on-a-collision-course-with-global-trade-and-investment-rules/>

28 [https://bangladesh.uz/pharmaceutical-industry#:~:text=The top ten manufacturers by,Drug International \(3.7 percent\).](https://bangladesh.uz/pharmaceutical-industry#:~:text=The top ten manufacturers by,Drug International (3.7 percent).)

and act strictly when a company looks to create an unchallenged market scenario. The current licensing laws are not specific enough for some experts, who fear that these laws cannot prevent a monopoly.<sup>29</sup> The coming years will see a broad expansion in this industry, and companies will be forced to accelerate their growth. The bigger producers will be keen to avoid competition and if licensing laws are not rigid enough they could succeed in building a monopoly which would impact the functioning of both the Bangladeshi market and the global consumers.

## POSSIBLE SOLUTIONS

Bangladesh can evolve by following a Turkish model of focusing on a specific sector. The Turkish medical industry has benefited from healthcare tourism by focusing on hair transplants and surgery. The nation is the world's most popular destination for hair related operations with more than 100,000 surgeries per year.<sup>30</sup> Bangladesh has the capacity to specialize its production thanks to existing infrastructure. Targeting specific markets and aligning production towards specific consumers could be the way forward for Bangladesh.

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29 [https://www.researchgate.net/publication/373927935\\_Compulsory\\_Licensing\\_under\\_the\\_Bangladesh\\_Patents\\_Act\\_2022\\_A\\_reflective\\_overview](https://www.researchgate.net/publication/373927935_Compulsory_Licensing_under_the_Bangladesh_Patents_Act_2022_A_reflective_overview)

30 <https://www.usatoday.com/story/special/contributor-content/2023/07/14/istanbul-is-the-worlds-largest-destination-for-hair-transplantation/70414668007/#:~:text=Many people from all over,100,000 operations performed each year.>

Diversification of production to avoid competition with neighbors. China and India will be in direct competition with Bangladesh if the latter's production focuses on the same medicines. However, if Bangladesh can prioritize production on alternative medicines that the two giants are not heavily invested in, the Bangladeshi industry may flourish. Bangladesh has a strong foundation for medicine manufacturing which means it can adapt to varied demands. Therefore, exploring the possibility of production of remedies that provide Bangladesh with comparative advantage may become an effective strategy.

Regardless of what approach the Bangladeshi economy takes, it is inevitable that compulsory licensing will be a determining factor between success and failure. Efficient and well managed utilization could help the state become a *crème de la crème* pharmaceutical producer in the world. Conversely, the mismanagement could pave the way to sector collapse and financial ruin. Furthermore, the fate of Bangladesh will be a model for all developing and least developed states who harbor ambitions of closing the financial gap between them and the developed states. If Bangladesh can successfully navigate the next few decades and maintain its prowess in the pharmaceutical industry then a path for other states to follow suit opens up. Compulsory licensing will therefore play a key role in geopolitics for the foreseeable future and its usefulness and effectiveness will be tested in environments where stakes are high.

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- 12 <https://www.un.org/ldcportal/content/what-ldc-graduation-will-mean-bangladesh's-drugs-industry>
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## LDC Watch

LDC Watch is a global network of national, regional and international civil society organisations (CSOs), alliances and movements based in the Least Developed Countries (LDCs), defined by the United Nations (UN). It acts as a coordinating body for LDC civil society to advocate, campaign and network for the implementation of the Doha Programme of Action (DPoA) for LDCs for the Decade 2022-2031 and other Internationally Agreed Development Goals (IADGs). LDC Watch has Special Consultative Status with the Economic and Social Council (ECOSOC) and is accredited to the UN Framework Convention on Climate Change (UNFCCC).

## South Asia Alliance for Poverty Eradication (SAAPE)

South Asia Alliance for Poverty Eradication (SAAPE) is a regional platform of civil society organisations, social movements and people's networks fighting unitedly against the structural causes of poverty and social injustices in the region and beyond. SAAPE's mission is to facilitate the process for establishing mechanisms to ensure people's genuine participation in the decision-making processes at all levels to contribute towards poverty eradication and sustainable development. SAAPE facilitates linkages among and between groups in the region, throughout the global South and with like-minded groups in the North.

## South Asia Alliance for Poverty Eradication (SAAPE)

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