Original Research Article

Prospectof Pharmaceuticals Sector of Bangladesh and Graduation Challenges

ABSTRACT

Aims: The paper aims at identifying prospect and challenges of pharmaceutical sector of Bangladesh after graduation and explores potential area of market and product diversification. Addressing the upcoming challenges of graduation, the paper centers the focus on pharmaceutical sector-based trade-related challenges and potentials and dig out a way forward.

Study design: The study is conducted through using secondary data from different publication and sources. A qualitative survey tool is used for assessing the view of the stakeholders and graduation impact on the pharmaceutical sector.

Methodology: The study uses qualitative tools to evaluate the area of market and product diversification of pharmaceutical industry and finally used ARIMA model to forecast what will be the export figure after 2032 and what interventions are needed to be taken to reach the expected level of growth amid graduation challenges.

Results: The pharmaceutical industry will confront significant hurdles in terms of value addition, paying for patents, and license fees for the production of pharmaceuticals after graduation. Moreover, the industry faces difficulties due to excessive reliance on API imports, limited product baskets, lack of R&D and lab testing facilities, lack of infrastructure in the API park, complexity in industrial plots payment, dearth of bioequivalence test facilities, and patentable molecules in the post-graduation era.

Conclusion: Bangladesh needs to accentuate self-reliance in API production, R&D, reverse engineering and technical know-how as well as make functional API Park, develop curriculum to have experts in Synthesis Chemistry and establish accredited bioequivalence study center to secure patentable molecules and API.

Keywords: Pharmaceuticals& API, Product Diversification, Export Diversification, LDC Graduation, Challenges& Potential, Autoregressive Integrated Moving Average (ARIMA)

1. INTRODUCTION

Bangladesh is on the pathway to LDC Graduation in 2026 and meets all three criteria in the 1st and 2nd UN CDP triennial review in February 2021. Even after the Pandemic spreads out, Bangladesh retains its positive economic growth starkly. Graduation from LDC will pose a multifaceted pressure for market access, preference erosion, value addition conditions, additional tariff, and likely reduction of overall export and employment. It is estimated that export proceeds may fall 5.5 % to 7.5% in the graduation period and exporters will face an additional 6.7% tariff which could result in an estimated export loss of $2.7 billion as estimated by UNCTAD [1]. The study will alsofocus on pharmaceutical sector-based trade challenges and explore the capacity of the potential sectors to address the challenges of the sector with pragmatic steps. The article has explored the domestic pharmaceutical sector, market size and the export-import trend while addressing LDC graduation's impact on the pharmaceutical industry. The sudden outbreak of the pandemic in 2019 directly hit the healthcare and pharmaceutical sectors of Bangladesh, as sourcing API from China and other countries was hampered due to disruption in the supply chain.

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The study challenges and prospect of pharmaceutical sector, export and market diversification feature specially challenges that arises due to the implication of the TRIPS after graduation. The study explores worldwide import of pharmaceutical products HS code-wise to identify the export potential of products. Here, the potential area of market diversification is explored with the ITC export potential map. Along with this, 20KIIs are conducted by author the representatives of BAPI, Business Chamber and Association of pharmaceutical and API Industries, BSCIC, NBR and researchers as well as public and private sectors representatives of the industry for extracting the concerns of stakeholders.

The stakeholders have identified that over-dependence on API import, challenges related to API production, lack of R&D lab test, lack of uncertainty in gas connection in API park, lack of bioequivalence test facility, and having less patentable molecules create challenges for the sector. The study also explores that Bangladeshi products are quality and cost-effective and there is a huge demand for Bangladeshi medicines in the global market but dependence on Chinese and Indian API reflects the necessity for strengthening backward linkage in API production in Bangladesh. The export forecast for the pharmaceutical sector is prepared with the ARIMA model in the study. It is forecasted that the export of the pharmaceutical sector will be around US$335 million by FY2032 but there is potential to increase the export further if policy intervention is taken to address the challenges of the sector.

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2. LITERATURE REVIEW

The pharmaceuticals industry, the next multi-billion-dollar opportunity for Bangladesh, has grown significantly with a current market size of over USD 3 billion (BAPI) [2]. The sector has been growing at an annual rate of 16.7%and is expected to exceed USD 6 Billion by 2025 according to export data of EPB [3]. Asadujjaman, Hassan & Ratin [4] addressed that after the formulation of the National Drug Policy 1982, the industry become able to meet the major portion of local demand. Alam [5] urged that the industry meets 98% of the domestic demand and contributes around 1.8% to the Gross Domestic Product (GDP). The Bangladeshi drug is dominated by the branded generic drug, accounting for almost 80% of the drug produced locally and the top ten pharmaceutical companies produce 70% of the domestic market according to BAPI [2].

2.1 Domestic Market of Pharmaceutical Sector

EBL report [6] stated that the domestic manufacturers produce almost all types of medicine, including high-tech products like insulin, hormones, anti-cancer products, etc. and most of them have production facilities for tablets, capsules, liquid dry suspensions, injections, ointments, creams, nasal sprays, granules, etc.Specialized delivery products like a dry-powder inhaler and prefilled syringe/ lyophilized injection are the most citable products.Bangladesh Investment Development Authority (BIDA) [7] explored that the domestic pharmaceutical sector is expanding rapidly, some companies have been certified by different international regulatory bodies like US-FDA, UK-MHRA, Australia-TGA, EMA, Health Canada, TFDA, Taiwan, ANVISA, Brazil EU, etc. for quality products manufacturing. According to industry experts, the market size of pharmaceuticals may reach about BDT 330,000 million by 2024.

Currently, Bangladeshi pharmaceutical industry can source only 10% of the total API requirement, domestically[i] and the estimated market size of the APIs is around US$730 million. It is estimated that demand for APIs will reach around US$1,409 million in the year 2025 MRC [8]. At present, there are 26 API producers in the country, which produce around 40 API molecules according to author's interview with BAPI and private sector businesses. While domestic demand for APIs is growing rapidly, local production remains low in the place of demand, leading to significant API imports. BIDA estimated that approximately USD 600 million of API was imported into the country in FY 2018-19 [7].

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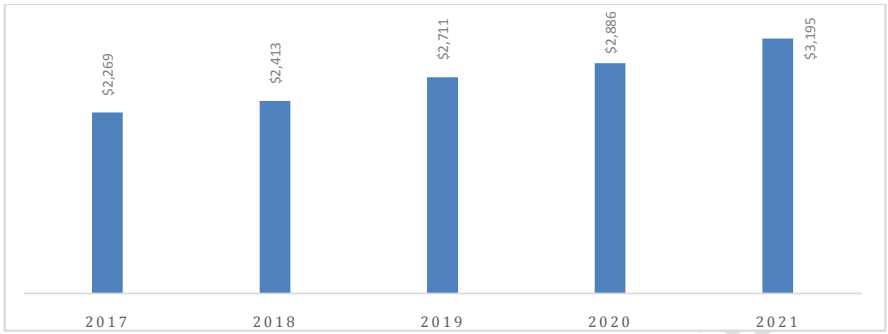
Figure 1: Revenue of BD Pharmaceutical Industry in million US$

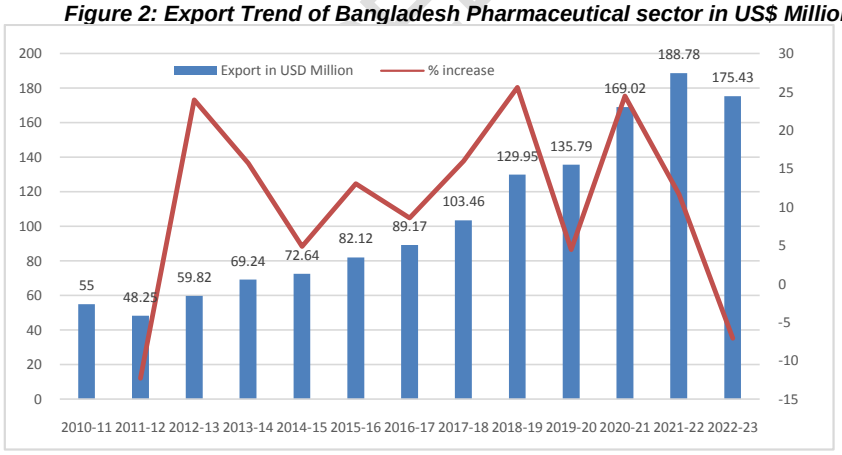


Source: BAPI 2021

2.2 Export & Import Trend of Pharmaceutical Sector

The contribution of the pharmaceutical sector to GDP is on the rise and it has become one of the largest potential sectors in Bangladesh to earn foreign currency and contribute to the national exchequer (MRC) [8]. After focusing on the domestic market for many years, Bangladeshi pharmaceutical companies have entered the global market in recent years. It is explored that around 1,200 products have been accredited for import by the authorities at the importing countries and are being exported to more than 150 countries including USA, UK, Canada, Australia, Germany, EU, etc. (Asadujjaman, Hassan & Ratin) [4]. Export is growing fast as the current export earning is more than $175.43 Million in FY 2022-23 as per EPB data [3].

Figure 2: Export Trend of Bangladesh Pharmaceutical sector in US$ Million



Source: EPB 2022-23

From the given data, it is shown that the market of pharmaceutical export is concentrated on the HS Code: 300490 (Other medicaments of mixed or unmixed products, for retail sale, nes) which is amounting to US$110.84 million in FY 2020-21 and US$ 124.40 million in FY2021-22. It is around 66% of the total export of pharmaceutical products. The trend over the past decade shows an incremental export growth of pharmaceutical products.

Table 1: HS Code wise Pharmaceutical Products Export in US$ million

HS Code	Product Description	FY2021-22
300120	Extracts of glands or other organs or of their secretions	0.000010
300190	Substances of human or animal origin, for prophylactic uses, nes	0.403
300220	Vaccines for human medicine	0.003
300230	Vaccines for veterinary medicine	0.044
300290	Human and animal blood; microbial cultures; toxins, etc, nes	0.091
300310	Medicaments of penicillins... or streptomycins..., not for retail sale	0.011
300320	Medicaments of other antibiotics, not for retail sale	21.377
300331	Medicaments of insulin, not for retail sale	0.000031
300339	Medicaments of other hormones, not for retail sale, nes	0.512
300390	Other medicaments with >2 constituents, not for retail sale, nes	9.878
300410	Medicaments of penicillins or streptomycins for retail sale	7.774
300420	Medicaments of other antibiotics, for retail sale	6.454
300439	Medicaments of other hormones, for retail sale, nes	13.493
300440	Medicaments of alkaloids or derivatives thereof, for retail sale	0.008
300450	Other medicaments of vitamins or other products of 29.36 for retail sale	1.210
300490	Other medicaments of mixed or unmixed products, for retail sale, nes	124.403
300590	Wadding, gauze, etc with pharmaceutical substances for retail sale, nes	0.000
300610	Materials for surgical sutures; laminaria; absorbable haemostatics	0.00002
300620	Blood-grouping reagents	0.000
300650	First-aid boxes and kits	0.258
300660	Chemical contraceptive preparations based on hormones or spermicides	1.840
300670	Gel preparations designed to be used in human or veterinary medicine.	0.834

Source: EPB Export data FY 2021, FY 2022

Rahman [9] identified that Bangladesh is highly dependent on imports of API, even 90%ii of API are recently imported from different countries and over dependence of Bangladesh on Chinese, Indian API and other sourcing countries reflects the necessity for strengthening backward linkage in API production of Bangladesh. Till 2017, approximately 40% of the raw materials came from China and 30% came from India, and the rest came from other countries like Korea and Germany according to MRC Report [7] but in FY 2021-22, Bangladesh sourced 34% of API from China and 32% of API from India according to Bangladesh Bank data [10]. Meanwhile, in analyzing 2-digit level HS Code of API products or organic chemicals, it was found that Bangladesh imports major API ingredients under HS Code 29 in FY 2021-22 is amounting to USD1247.62 million [10].

2.3Global Pharmaceutical Product Market

The pharmaceutical industry has grown significantly worldwide over the period and the global pharmaceutical market was valued at 1.48 trillion dollars in 2022. This represents a marginal increase from the market's 2021 valuation of USD 1.42 trillion according to(Statista) [11]. Statista's market outlook for 2022 has also explored that the commercial "blockbuster" drug can generate more than US$1 billion in a year. It implies that a single product can play a major role, as a certain segment of the market is driven by a small number of drugs. It is also forecasted that the largest market segment of pharmaceutical products is Oncology Drugs amounting to US$ 188.90 billion in 2022. Here, from ITC trade data, the top 20 imported products at a six-digit level in the world are shown and Bangladeshi exported products which are green colored fall under HS Code: 300190, HS: 300220, HS: 300230, HS: 300290, HS: 300390, HS: 300190, HS: 300590 and HS Code:300230(ITC) [12]. It shows that the Bangladeshi pharmaceutical sector's strength implies that if Bangladesh ensures minimum value addition conditions with domestic API invention and chemical synthesis, the sector will flourish more than the expectation.

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Table 2: Top 10 World Import of Pharmaceutical Products at Six-digit Level

Product HS code	Product label	Imported value in US$ Million 2021
300490	"Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic purposes	359528.17
300215	Immunological products, put up in measured doses or in forms or packings for retail sale (excl.	149165.61
300220	Vaccines for human medicine	125857.78
300439	"Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in	40587.92
300212	Antisera and other blood fractions	32499.67
300214	Immunological products, mixed, not put up in measured doses or in forms or packings for retail	22750.27
300420	"Medicaments containing antibiotics, put up in measured doses ""incl. those in the form of **...**	16147.37
300290	Human blood; animal blood prepared for therapeutic, prophylactic or diagnostic uses	12195.45
300431	"Medicaments containing insulin but not antibiotics, put up in measured doses ""incl. those	10301.84
300432	"Medicaments containing corticosteroid hormones, their derivatives or structural analogues **...**	10103.05
300390	Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic	6575.16
300190	Dried glands and other organs for organo-therapeutic uses, whether or not powdered; heparin	5313.23
300590	Wadding, gauze, bandages and the like, e.g. dressings, adhesive plasters, poultices, impregnated	5027.82
300230	Vaccines for veterinary medicine	4910.47
300610	Sterile surgical catgut, similar sterile suture materials, incl. sterile absorbable surgical **...**	4894.76
300450	"Medicaments containing provitamins, vitamins, incl. natural concentrates and derivatives thereof	4734.89
300510	Adhesive dressings and other articles having an adhesive layer, impregnated or covered with **...**	4647.09
300449	"Medicaments containing alkaloids or derivatives thereof, not containing hormones, steroids **...**	4483.29

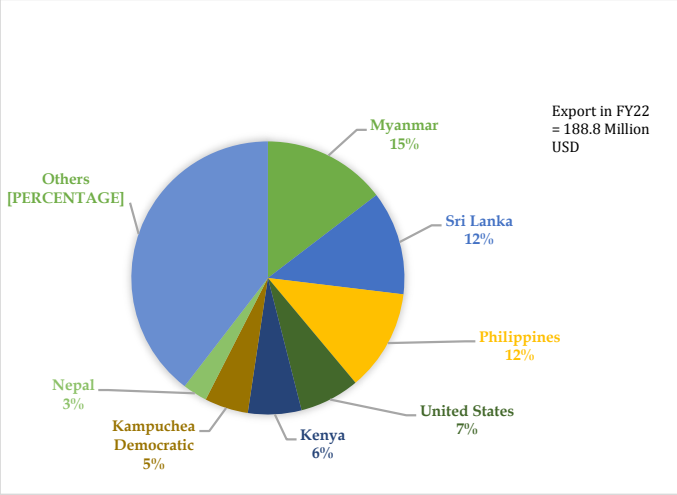
Product HS code	Product label	Imported value in US$ Million 2021
300213	Immunological products, unmixed, not put up in measured doses or in forms or packings for retail	4459.70
300630	Opacifying preparations for x-ray examinations; diagnostic reagents for administration to patients	3761.47

Source: *ITC Trade Data 2021 & EPB Data*

2.4 Pharmaceutical Export Market

Bangladesh can export to any country if the medicine is not under patent and has the export opportunity to another LDC or non-WTO country that has not implemented product patent protection (UN CDP) [13]. Bangladeshi pharmaceutical companies may export their products into markets that are regulated, such as those in the United States, Germany, Europe, and Developed Countries if their product is registered in those developed countries. It can be challenging for SMEs to register their product with drug regulators in such nations. Similarly, Bangladeshi firms can export into moderately regulated markets like Tanzania and Malaysia, which have moderate levels of regulation. Even though certain nations do not necessarily demand rigorous certification, a firm might get a competitive edge by becoming certified in a regulated market because it denotes quality. The majority of Bangladeshi medicines are sold to countries with markets that are not entirely regulated, including Bhutan, Pakistan, Sri Lanka, Nepal, Vietnam, and Myanmar. Exports from Bangladesh were on the rise but in 2022-23, the export in Sri Lanka, Myanmar and Pakistan is decreasing as per an interview with an industry insider and stakeholder of BAPI.

Figure 3: Top export destinations of pharma products from Bangladesh in FY2021-22



Source: EPB

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2.5Potential Export Market for Pharmaceutical Product

Except those countries cited in the figure 3, Bangladesh has the potential to export Russia, Switzerland, Belgium, Spain, Japan, Canada, United Kingdom, Saudi Arabia, France Italy Australia Poland Brazil United Arab Emirates Myanmar Netherlands and Mexico. The markets with greatest potential for Bangladesh's exports of pharmaceutical components are United States, Germany and China.

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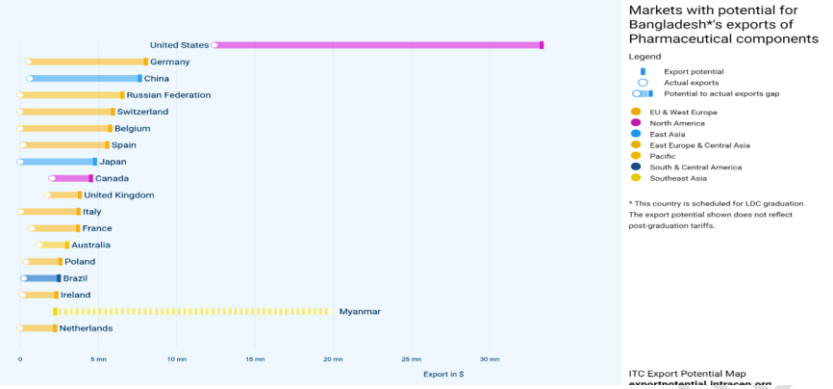
Figure 4: Export Potential Gap for top 20 Countries for Pharmaceutical Sector



The graphs show the largest absolute difference between potential and actual exports in value terms. It also explores that Bangladesh has extra potential for additional exports worth $21 million in the USA market. Accordingly, in Germany and China, there are 8-10 million export potential for Bangladesh while in the whole of Europe, as shown in Figure 4, Bangladesh has an export potential of about US$ 50 million. Similarly, in Myanmar, Bangladesh has the potential to export an extra US$15 million, which indicates diversification of the market needs to be enhanced, as there is huge export potential for pharmaceutical products.

2.5 Challenges of Pharmaceutical Sector after Graduation

Bangladesh would lose patent exemption on pharmaceutical products after 2026 and after graduation and according to Ministerial Conference (MC-12), the graduated countries have the probability to enjoy the benefit of TRIPS waiver till 2033 in patent right but it is not certain, as the conference has adopted the decision below:

> "An eligible member may apply the provisions of this Decision until 5 years from the date of this decision. The general council may extend such a period taking into consideration the exceptional circumstances of the Covid-19 pandemic"[iii]

As a result, numerous non-generic medication varieties will no longer be manufactured. Domestic manufacturers may be required to pay royalties on patents to continue the production process as is; failing to do so could result in patent infringement. The primary concern for Bangladesh is that the country's pharmaceutical industries are falling behind in terms of research and innovation, particularly in API manufacture and reverse engineering of medicine. Along with there are various internal and External factors, dragging behind the sector, which are as follows;

2.5.1 Manufacturing Cost and Maintaining Global Standard

Bangladesh benefits from cheaper labor costs, but it is at a disadvantageous situation when it comes to the main cost factors, relating to Active Pharmaceutical Ingredients (APIs). Bangladeshi pharmaceutical companies are unable to match international standards due to price and quality competition issues. Moreover, the production of APIs is being curtailed by multinational corporations (MNCs), which are also looking for new, less expensive API suppliers or developing nations, where they may complete the entire manufacturing process medicine. The health markets in Europe and the US are cost-constrained, and inventive

companies have limited product pipelines. As a result, generic firms expand more rapidly compared to non-generic firms (Kathuria &Malouche) [14].

2.5.2 Over Dependence on API Import

Pharmaceutical companies generally create branded generic drugs using imported API. About 80% of the medications sold in Bangladesh are generic, and 20% are patented according to EBLpublication [6]. Since Bangladesh's API capacity is negligible, businesses import 90% of their APIs. Sheel [15] informed that some Bangladeshi businesses have invested in high-quality raw materials, production techniques, and technical know-how to meet the growing demand for APIs, but the domestic markets lack regulatory framework means that inferior products receive more consumer attention than superior ones. Bumpas, Kostermans, and Nair [16] explored that due to insufficient regulation, consumers are not unable to distinguish between low-quality products and high-quality ones and cannot make quality product purchases when companies with small investment in quality are still selling drugs alongside those with significant investment in quality. As a result, businesses that invest in quality manufacturing processes and standards are to be penalized for their quality production.

2.5.3 LDC Specific Challenges

Bangladesh is allowed to produce patented generic pharmaceutical items to sell domestically and export to markets all over the world due to flexibility available for LDC under TRIPS agreement of WTO. The World Trade Organization granted developing and underdeveloped countries the freedom to create generic pharmaceuticals in 2001 under TRIPS without requiring them to obtain licenses or pay the patent holders for a set period of time [17]. Later it was extended to 2026 for graduated LDC and Bangladesh. Bangladesh is allowed to produce any patented medicines without taking prior permission from innovator companies who own patents the non-generic medicine. To compete on the global market, Bangladesh will need to rely on conventional business strategies that provide the highest quality product at the lowest price, which may be challenging due to over dependence on imported API and Molecules.

Bangladeshi pharmaceutical firms operate in a protected domestic market and moves to open the economy after graduation will most likely lead to cost & quality increment. The LDC flexibilities make it possible to export drugs at a lower cost to countries where the medicine is not covered by patents or producers do not pay royalties and do not incur the R&D costs borne by innovating firms in patent-protected markets. After graduation, Bangladesh will face a number of hurdles which are as follows:

i. Prices **and health care costs:** The South Centre urged, as a result of the reinstatement of patents, “the lack of competition could lead to a significant increase in the price of medicines, particularly for therapeutic areas concerning non-communicable diseases which will be among the major contributors to the disease burden of Bangladesh” [18].Along with less competition, production costs would increase as local producers would have to pay royalties and other costs for complying with intellectual property rights.

ii. **Impacts on API segment:** Bangladesh may also be forced to remove import restrictions, opening the local industry up to competition from large-scale producers with nations like China and India after graduation. These two countries earned profit from economies of scale and vertical integration and have already matured their API industries, whereas Bangladesh has only recently begun to do so. In near term, this could drive some product costs lower, but it could also drive local players out of the market.

iii. **Weakening of local players and industry consolidation:** Stronger patent protection, greater competition from imports and fewer restrictions on the participation of multinational players in domestic market could lead to a weakening of local producers, which in turn would have economic, employment and public health implications including higher prices.

iv. **Rule of Origin in different trade agreements:** There is a condition for concessionary value addition, and Bangladesh needs not comply with the value addition condition while exporting pharmaceutical products in a developed and regulated market. Following graduation, Bangladesh must meet criteria requiring a minimum of 40%–50% value addition before exporting any pharmaceutical product to overseas markets and therefore domestic self-sufficiency in API production is required.

Along with these, there are various challenging factors, dragging pharmaceutical sector behind from the expected growth. Addressing these problems, Sultana [19] underscored that a bioequivalence study center is necessary for the registration of an exportable product in both moderately and well-regulated markets. Bangladeshi pharmaceutical firms need to make significant investments to meet international manufacturing standards as per explanation of Hasan and Essar [20]. In addition, they have underscored that extra expense of importing API under COVID-19 places an additional strain on pharmaceutical companies trying to make medicines for the local market.

Bumpas, Kostermans and Nair [16) stressed that Bangladesh companies have lack of capacity in warehouse maintenance of pharmaceutical products. Internationalstandards dictate that warehouses must maintain the environmental standards stated on the product insert. If the insert indicates that the item must be stored “at less than 25 degrees Celsius,” the warehouse must also maintain the required temperature. Bangladesh’s warehouses are not air-conditioned and temperatures from May through July can reach 30 degrees Celsius, and higher. Similarly, the lack of cold chain facilities in airports for export, creates complexities in pharmaceutical product export from Bangladesh.

2.6 Potential of Pharmaceutical Sector

The proper utilization of this patent waiver flexibility made Bangladesh become the only LDC country with adequate pharmaceutical manufacturing ability and almost self-reliant. Albeit after graduation, such exemption will not prevail. The TRIPS agreement has turned Bangladesh into a center for affordable and high-quality generic medicines and contract manufacturing, with exports to potentially more than 100 countries across the world. Even, more than ten leading Bangladeshi pharmaceutical companies are exporting generics to international markets. A number of these firms are also evolving as contenders to high-

ranked Indian companies in certain areas. Muktadir [21] urged that pharmaceutical firms in the country are modernizing their factories and receiving certifications from the US, Australia, Canada, and EU. Along with these, there are other potentials which are described below:

The rapid rise of non-communicable diseases (NCDs) like cardiovascular diseases, cancer, chronic respiratory disease, diabetes in Bangladeshi population has led to growing demand for drugs used for NCDs' treatment according to EBL [6]. Such drugs for NCDs include anti-cancer, anti-diabetes, vaccines, insulin, etc. Although Bangladesh has some facilities to produce medicines for NCDs, they are still predominantly imported, giving the opportunity to enhance local production.

Since 2015, there has been a rapid increase in demand for APIs from the local drug formulation industry. It is estimated that demand for APIs will exceed USD 1,400 million by 2025, providing API producers with promises of stable market access as per MRC report [7]. By 2025, the global API market is anticipated to reach USD 319.07 billion. The scheduled patent expiry of blockbuster pharmaceuticals, the rise in healthcare costs, and government policies favoring generics drugs will all contribute significantly to the market expansion of APIs for generics. Additionally, China, one of the main producers of APIs, is relocating its production location due to worries about costs and sustainability. Many manufacturers are starting to move their factories to other cost-competitive areas as China's labor costs rise. Additionally, some API companies may think about broadening their supply-chain base in light of the Covid-19 pandemic's disruption to the supply chain.

Given the facilities and support provided by the government to the pharmaceutical sector, this sector is maturing over time and leading pharmaceutical companies have increasingly focused on expanding their business in highly regulated markets, including the USA, UK, Canada, Australia, Germany, EU, etc. These leading companies Square, Incepta, Beximco, Opsonin, Renata, Healthcare, ACI, Eskayef, ACME Laboratories Ltd., Aristopharma Ltd., and Drug International Limited, etc. have attracted huge attention from clients abroad, achieving nearly all major Good Manufacturing Practices (GMP) accreditation like USFDA, UK MHRA, EU GMP, Health Canada, TGA Australia, ANVISA Brazil, GCC, etc. They are now exporting medicine to highly regulated countries, including the USA, UK, Canada, Australia, Germany, Europe, etc. Regarding this issue,Islam, Rahman, & Al-Mahmood [22]urged a number of smaller companies are going to enter in highly regulated overseas market as the industry has ability to establish itself as rigorous export-oriented industry.

Bumpas, Kostermans and Nair [16) urged that pharmaceutical labor costs are approximately 30%iv less in Bangladesh than that of the India. At present, Pharmaceutical white collar workforce cost is less than other countries, implying the comparative advantage of the sector that that of competing countries. Contract manufacturing for a product that will be exported to a market under regulation is a new area of opportunity for expanding export in the world market. Recently, Square Pharmaceuticals company with a certified facility is starting a contract production agreement right now. Partnerships can be built up with Global Firms and MNCs, operating in a country in multiple ways, including foreign direct investment (FDI), contract manufacturing, joint ventures and strategic partnerships or licensing.

3. METHODS OF THE STUDY

The methodology of this study applied a Qualitative Approach and SWOT analysis has been used to identify major sectoral strengths, opportunities, weaknesses and threats. The study uses qualitative tools to evaluate the area of market and product diversification of pharmaceutical industry and finally used ARIMA model to forecast what will be the export figure after 2032 and what interventions are needed to be taken to reach the expected level of growth.

As Bangladeshi products are quality and cost-effective, there is a huge demand for medicine in the global market. We could have exported more but the export process is complex and time-consuming. Over the past two years, 1200 pharmaceutical items acquired export registration and are now being shipped to more than 150 nations, including the USA, UK, Canada, Australia, Germany, and the EU, etc. (BAPI) [2]. Here, using ARIMA Model the study determines the trend of future valuefollowing the model developed by Mohini, Prasad, Nguyen-Huy and Deo [24]. The AR model equation is:

$$y_t = c + a_1 y_{t-1} + \cdots\cdots\cdots\cdots + a_p y_{t-p} + u_t \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (1)$$

$y_t$is the observed time series and a_1, a_p are the AR parameters, c is a constant, p is the order of the AR, and u_t is the white noise i.e. sequence of random numbers. Similarly, the MA model is represented as:

$$y_t = \mu + u_{t+} m_1 u_{t-1} + \cdots\cdots\cdots\cdots + m_q u_{t-q} \cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots\cdots (2)$$

where $m, \ldots\ldots\ldots, m_p$ are the MA parameters, q is the order of MA, u_t, u_{t-1}, $\ldots\ldots\ldots\ldots u_{t-q}$ are the (error) terms, and μ is the expectation of y_t . By integrating these two models with the same training data, the ARIMA model becomes:

$$y_t = c + a_1 y_{t-1} + \cdots\cdots + a_p y_t - p + u_t + m_1 u_{t-1} + \cdots\cdots + m_q u_{t-q} \cdots\cdots\cdots (3)$$

where p and q are the autoregressive and moving average terms, respectively. Each component in ARIMA functions as a parameter with a standard notation. For ARIMA models, a standard notation would be ARIMA with p, d, and q, where integer values substitute for the parameters to indicate the type of ARIMA model used. The parameters can be defined as:

p: the number of lag observations in the model; also known as the lag order.
d: the number of times that the raw observations are differenced; also known as the degree of differencing.
q: the size of the moving average window; also known as the order of the moving average.

From fiscal year 2010-11 to 2021-22, EPB export data are used to forecast the normal growth of the sector till 2031-32. Four ARIMA models at different values of p, d, and q are estimated using theSPS Packages 26.0 to forecast the export growth of pharmaceutical industry. From this comparison, the ARIMA(1,1,1) model is the best fit model according to its following value:
List 1 :ARIMA models at different values

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Comment [BP30]: Kindly write it in full before you then put the abbreviation in a bracket. Autoregressive integrated moving average

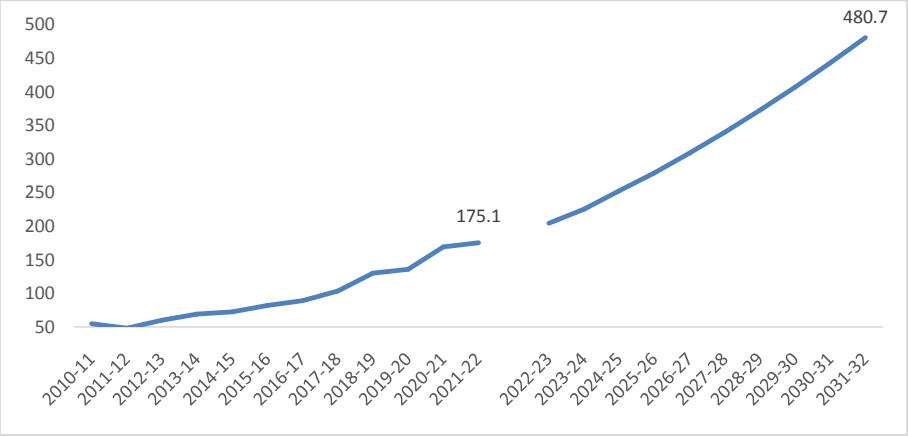
Comment [BP31]: This statement is not correct. You can simply say ' as a result of high quality and cost-effectiveness of Bangladesh pharmaceuticals products, there are usually huge demand for the products in the global market'.

Comment [BP32]: This should be SPSS, kindly check the name of the statistical package again

Model	Stationary R-squared	R-squared	RMSE	MAPE	MaxAPE	MAE	MaxAE	BIC
ARIMA(0,1,1)	**.672**	.979	6.980	5.716	20.181	5.168	10.732	**4.540**
ARIMA(0,0,0)	.929	**.929**	12.237	10.127	36.648	9.008	20.156	5.423
ARIMA(1,1,1)	.718	.982	**6.916**	**5.306**	20.459	**4.436**	**9.871**	4.740
ARIMA(1,1,0)	**.664**	.979	7.068	6.067	**19.324**	5.124	11.215	4.565

And it is expected that in FY2032, the export of pharmaceutical sector is expected to reach around US$ 480 million, if the current export trend continues without any intervention. However, there is possible negative impact in the current export growth as Bangladesh has to pay IP payment for non-generic medicine and higher price due to having no developed indigenous molecules. Moreover, majority market share of export from Bangladesh is concentrated on Developing countries and LDC who donot follow the intellectual right properly. Hence,government's interventions need to be ensured to secure the policy support for having self-reliant APA sector in Bangladesh. If pragmatic intervention is taken addressing the Graduation challenges, pharmaceutical sector would be the next billion-dollar industry.

Figure 5:Pharmaceutical Sector Export Projection in US$ Million from FY2022-23 to 2031-32



Source: Author Own calculation based on EPB Export Data From 2010-11 to 2021-22 and projected data from FY2022-23 to FY2031-32 is sourced by author own's calculation.

4. RESULTS

It was found in HS code analysis, Bangladesh earning from HS Code: 300490 (Other medicaments of mixed or unmixed products, for retail sale, nes) from the single pharmaceutical product is amounting to US$ 67% of the total export. It explores, Bangladesh lags behind in product diversification while majority of its market share concentrated on Sri-Lanka, Nepal, Mayanmar, Kenya, Khempuchia. Similarly, recent economic crisis amid Ukraine and Russiawas has lessened the pharmaceutical export to those countries in FY 2021-22.

Comment [BP33]: Kindly recheck this english

The pharmaceutical industry has grown significantly in the last five years. So does its export growth reach US$480.7 million by 2032 if the normal growth rate will continue against the challenges of LDC graduation. If the LDC graduation challenges affect the pharmaceutical sector due to IP right and API molecules, the cost of production will increase and the export growth cannot reach as expected level, though the domestic demand for drugs is on the rise due to incremental GNI per Capita, population growth, changing disease profiles, lifestyle changes and rapid urbanization.

Given the concern, the onus of the private sector is to invest more in R&D and reverse engineering for API to reap the demand of the domestic market while the responsibilities of the public sector are to expedite the trade facilitation as well as address the LDC graduation challenges. In addition to these, the operational API park along with infrastructure facilities can act as a turning point for this purpose, but activating all the utility facilities in the least possible time becomes a murky task. The sector needs to ensure as many as innovations and known molecules in the public domain as possible before graduation, to avoid implications of enforcement of the patent regime. In view of the above, establishing more research institutions capable of undertaking R&D activities and setting up institutions like NIPER and CDRI in India (e.g., Bangladesh Institute of Pharmaceutical Education, Research and Development – BIPERD) get priority. Accordingly, the capacity of Contract Research Organizations CROs needs to be enhanced to conduct clinical trials for biosimilar and biotech products and prepare trained professionals to undertake CROs for BE studies. These ramifications will continue to help the growth of the pharmaceutical industry. From stakeholder interview and literature review, the following SWOT Strength and Weakness along with Opportunities and Threats are found:

Table 3: SWOT Analysis of Pharmaceutical Sector

Strengths	**Weakness**
a) Lower white collar workforce costs b) Manufacturing Facilities for earlier import-dependent drugs c) Quality medicine at affordable price d) Many companies have international accreditation e) Export led improvement for quality control	a) More than 90% APIs are imported b) Insufficient investment in API, R&D, reverse engineering and technical know-how c) API park yet to be functional. d) Lack of skilled labour and technical workforce for API e) NBR reluctance to provide tax break as per National API Policy f) Lack of Synthesis Chemistry expertise g) Lack of know how about handling patent h) Unavailability of accredited bioequivalence study center or Contract Research Organization (CRO) i) Don't have any patentable molecules and API
Opportunities	**Threats**

a) Huge scope in world pharmaceutical market b) Tax Waiver, Export subsidies and cash incentive up to graduation c) Patent waivers for patented pharmaceutical products until graduation d) Protected domestic market & domestic demand e) Export Potential in the global API market	a) Ending WTO TRIPS agreement waiver after graduation b) Lack of protection option for domestic industry in IP and Patent act c) Incremental production price due to patent right orientation d) Globalization led extremely competitive international market e) Complex Biosimilar product registration guideline f) Cannot export to the market where patent is granted g) Lack of Cold chain facilities in airport for export

It was also found that exporting pharmaceutical products from Bangladesh is difficult task, because a company needs to adhere to each country's unique product rules, registration procedures, language requirements, cultural preferences, national packaging standards, and industry protection systems. Exporters also need to make a sizeable commitment in terms of money, time, and paperwork to register the product in the target country in order to start the registration procedure for entering the market. Here, supporting service from the commercial counselor of Bangladeshi embassy in different countries can facilitate export of pharmaceutical company.

5. STAKEHOLDERS OPINION

Stakeholders stressed that Bangladesh needs to accentuate self-reliance in API production, R&D, reverse engineering and technical know-how as well as make functional API Park, develop curriculum to have experts in Synthesis Chemistry and establish accredited bioequivalence study center or Contract Research Organization (CRO) to secure patentable molecules and API.

Stakeholders have opined that a pharmaceutical company must obtain registration from the country's drug or food administration body of the potential export destination country to export pharmaceutical products to international markets. From a KII with an official of the leading pharmaceutical industry, the author comes to know that the procedure for registering a product in a foreign country is so complex, that businesses frequently establish offices there to sell their products there. Here, the company must pay for the official costs as well as the logistical support of the office. Often small companies do not register their products on those markets which costs much to maintain their expenses and they find less profitability. Some hidden charges have to be paid by the Bangladeshi companies to register pharmaceutical products in LDC's countries.

Stakeholder underscored that Bangladesh currently has few resources available for bioequivalence research. According to a World Bank report, a company must conduct its bioequivalence test in a foreign nation at a significant testing expense of US$ 50,000–100,000 [15]. BAPI and pharmaceutical exporters first felt the necessity of having a bioequivalence test facility in Bangladesh and they proposed to set up a modern bioequivalence test center for the promotion of pharmaceutical export but no step has been taken till now, hampering overall export. Alternatively, the stakeholder in the interview urged

that pharmaceutical manufacturers are agree with government with the support of International Center for Diarrhoeal Diseases and Research in Bangladesh (ICDDRB) and/or Bangladesh Council for Scientific and Industrial Research (BCSIR) they can start bioequivalence test with reasonable cost.

Stakeholder has further stressed that there are practical difficulties associated with basic chemical import authorization for API since an entrepreneur must obtain authorization from seven to eight organizations in Bangladesh to import the product from foreign sources according to a representative interview from BAPI. For instance, a company must apply for permission from the Bangladesh National Authority for Chemical Weapons Convention, Department of Explosives, Department of Narcotics Control, Ministry of Industry, Ministry of Commerce, Directorate General of Drug Administration, etc. Recently in an interview with the author and stakeholder, it was proved that a renowned pharmaceutical company requires 11 months and another requires 9 months to get permission to import basic chemicals. The stakeholders of API industries have suggested preparing a one-stop service to facilitate the easier process of basic chemicals from sourcing countries.

Comment [BP34]: between

Comment [BP35]: 'a'

4.1 Challenges Related to API

Stakeholders further addressed only because of imported dependent raw materials, the cost of production becomes higher than that of India and China. That's why, Bangladesh cannot compete with the Indian and Chinese companies to offer export prices. Hence, setting the API park in motion is a very urgent issue.

Stakeholder underscored that due to the claims and urges of BAPI and pharmaceutical business entrepreneurs, the government of Bangladesh has taken the initiative to establish an API park near Dhaka. A long time has already passed after deciding on establishing an API park but still the park has not yet come effectively operational.

Stakeholdersinformed that domestic API companies are not getting tax breaks because of NBR's reluctance to facilitate tax breaks proposed in National API Policy 2018. According to API policy 2018, NBR is recommended to extend the tax break until 2032 under specific circumstances to make raw material suppliers eager and continue to invest 1% of their yearly revenue in R&D to maintain their eligibility for the tax exemption. Moreover, it is proposed in the National API policy that "if a company produces minimum three APIs or laboratory reagents in a year, they will get a 22.5% cut in corporate tax, meaning that they will pay 7.5% in tax" only remain in black and white in government gazette (SANEM)[23].

4.1 Challenges Related to API Park

With author interview, the business and association representative of pharmaceutical sector identified that fully in-operational API park become the major concern for API industry in Bangladesh. They listed the following problem and requested to addressed these issues at the least possible time:

- **Lack of uncertainty in Gas Connection:** Though internal gas connection and distribution line is prepared in the API industrial park; the gas connection is not linked with main line. The industry peoples have contributed to establish the Central

Effluent Treatment of the Plant (CETP) in the industrial park but it cannot become fully operational due to lack of gas supply.

- **Extra service charge imposed by BSCIC:** It was decided that Bangladesh Small and Cottage Industries Corporation (BSCIC) will remove 12.5% service charge and include 5% overhead cost for every plot[v]. Till now BSCIC has not issued any gazette or circular regarding this issue and hence a plot owner cannot pay the payment of plot because of uncertainty in determining the price of plot.

- **Inactive central fire extinguishing service:** In the industrial park, 1st class infrastructure for central fire extinguishing service was established with auto controlled fired hydrant system and fighting management but till now no workforce is employed to manage the system. Without active central fire extinguishing service, firms cannot operate its function.

- **Infrastructure related problem in the park:** In the park there is high voltage electricity pillar and poll in the distributed individual industrial plot which creates uneven risk. Besides, there are many places in the park downgraded to the normal level of road because of lack of sand fulfillment in the industrial plot. It is seen that around 4-8 feets of land are gone down from the normal level of land. Moreover, Boundary wall of the park needs to be elevated because after filling the sand in the plot many boundaries wall become low which can easily be crossed.

5. CONCLUSION

In the upcoming years, the government has to play a significant role for rapid growing pharmaceutical industry, providing policy support for easier drug approval, production, marketing and registration in the potential export destination. The full operational API Park with all other utilities will act as a turning point for this purpose. Along with these, the following area of activities especially for API & molecules production, self-reliance in API, expanding R&D, bio-equivalence test capacities are needed to be enhanced for the promotion of the industry.

1. As the industry lacks patentable molecules, it is imperative that many discoveries and well-known molecules are placed in the public domain before graduation to avoid the negative effects of implementing the patent regime.
2. Take meaningful steps in the patent regime to enhance capacities, especially in the areas of intellectual property law and patent law, chemical synthesis, patent examination, knowledge in synthesis chemistry, and accreditation specialists. Bangladesh should therefore utilize the pertinent research exemption provided by Section 38 of the National Patent Act of 2022.
3. Bangladesh needs to raise the capacity of Contract Research Organization (CROs) to facilitate clinical trials for biosimilar and biotech products. Accordingly, make available qualified CROs for Bioequivalence (BE) test & study and prepare trained professionals to undertake CRO for BE studies.
4. Establish research institutions capable of undertaking R&D activities and set up institutions like NIPER and CDRI in India (e.g., Bangladesh Institute of Pharmaceutical Education, Research and Development – BIPERD).

5. Take concrete measures to strengthen capacities, particularly in following areas like IP law and patent law, Chemical synthesis, Patent examination, Synthesis Chemistry expertise, Lab Technicians and Accreditation Specialists.
6. The regulatory authority should further review IP, API, and FDI policies and incentives in preparing the TRIPS compliance regimes following graduation in 2026.
7. Expedite registration and marketing authorization of pharmaceutical products in abroad, where the Bangladesh embassy may provide a catalytic support role to coordinate with the respective National Regulatory Authority (NRA).
8. The company's product registration process may be facilitated by additional assistance from the commercial counselor of the Bangladesh embassy in a foreign country as it can evaporate the cost of doing business as urged by a stakeholder.
9. Bangladeshi export of pharmaceutical products is concentrated on few products, implying the necessity for diversification. Hence, regulatory bodies and DGDA can suggest extra incentives for new product export and market diversification.
10. Government and funders can increase collaboration with businesses to produce goods by Good Manufacturing Practices (GMP) in pharmaceutical value chain.
11. The government might simplify regulatory requirements for new investments or encourage FDI in the API sector for firms, striving toward higher levels of quality improvement and working with the global industry through joint venture.

REFERENCES

1. UNCTAD. UNCTAD Handbook of Statics 2017. New York: United Nation Publication; 2018. Accessed 29 March 2022.Available: https;//unctad.org/system/files/official-document/tdstat42_en.pdf.
2. Bangladesh Association of Pharmaceutical Industry (BAPI). Bangladesh Pharmaceutical Industry Overview August 16, 2023. Accessed 29 April 2022.Available: http://www.bapi-bd.com/bangladesh-pharma-industry/overview.html.
3. Export Promotion Bureau (EPB). Product Wise-Country Wise Export (Goods) For the Month of July-June 2022-23.Accessed 29 April 2023. Dhaka: EPB. Available: http://epb.gov.bd/site/view/epb_export_data/-
4. Asadujjaman M, Khalid H, &Rahtin R. Overview of Pharmaceutical Industries in Bangladesh (Top 20 Pharma Companies). Moldova: LAP Lambert Academic Publishing; 2021.
5. Alam MZ. Bangladesh Pharmaceuticals Industry and Globaol Prospect. THE COST AND MANAGEMENT. 2019; 47(01):67-69.
6. Faisal MA. Pharmaceutical Industry of Bangladesh. Dhaka: EBL Securities Ltd. for August, 2022. Dhaka: EBL Securities Ltd. Accessed 22 August 2023. Available: http://www.eblsecurities.com.
7. Bangladesh Investment Development Authority (BIDA). Pharmaceuticals & API Report from International Investment Summit 2021 Bangladesh. Dhaka: BIDA. Accessed 3 October 2023. Available: https://bida.gov.bd/storage/app/uploads/public/616/6c2/000/6166c2000004a202755426.pdf.
8. MRC Bangaldesh Ltd (MRC). Review of Pharmaceuticals Sector in Bangladesh. Dhaka: Bangladesh: High Commission of India. 2016. Accessed 20 September 2023.Available:https://hcidhaka.gov.in/pdf/Report_on_Pharmaceuticals_Sector_in_Bangladesh(1).pdf.
9. Rahman MA, Yunsheng L & Sultana N. Analysis and prediction of rainfall trends over Bangladesh using Mann–Kendall, Spearman's rho tests and ARIMA model.

Meteorol Atmos Phys. 2017;129:409–424.https://doi.org/10.1007/s00703-016-0479-4.
10. Bangladesh Bank (BB). Annual Import Payment of Goods and Services FY2021-22. Dhaka: Bangladesh Bank.2022:1-443. Accessed 20 June 2023. Available: https://www.bb.org.bd/en/index.php/publication/publictn/0/9.
11. Statista: Global pharmaceutical industry - statistics & facts. Accessed 29 April 2023. Available: https://www.statista.com/:
12. ITC Trade Map: Trade Statistics for International Business Development, Accessed 3 October 2023. Available: https://www.trademap.org/Product_SelCountry_TS.aspx?nvpm=1%7c050%7c%7c%7c%7cTOTAL%7c%7c%7c2%7c1%7c1%7c1%7c2%7c1%7c1%7c1%7c%7c1.
13. United Nation (UN).UN CDP Background Paper on Trade Agreements and Policy Space for Achieving Universal Health Coverage (SDG Target 3.8) . Department of Economic and Social Welfare. New York: UN CDP. 2018. Available: https://www.un.org/development/desa/dpad/wp-content/uploads
14. Kathuria S. and Malouche MM. Attracting Investment in Bangladesh—Sectoral Analyses: A Diagnostic Trade Integration Study. Washington, DC: World Bank Group; 2016. doi:http://dx.doi.org/10.1596/978-1-4648-0924-8
15. Sheel SK. Problems of Export of Pharmaceutical Products from Bangladesh: An Analysis. Journal of Business Studies. 2015; 36(3): 23-37.
16. Bumpas J, Kostermans K and Nair D. Review of PUBLIC and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh. Washington, DC:South Asia, Human Development Department of World Bank. 2016: 1-54. Available:https://www.studocu.com/row/document/university-of-dhaka/history/public-and-private-sectore-approaches-to-improving-pharmaceutical-quality-in-bangladesh/19743580
17. Tazin F. Pharmaceutical Industry of Bangladesh: Progress and Prospects. The Millennium University Journal. 2016: 1(1): 19-30.
18. South Centre. The Loss of the LDC Transition Period for Pharmaceutical Products Under the TRIPS Agreement Upon LDC Graduation: Implications for Bangladesh. New York: United Nation CDP:2020. Accessed 20 September 2023. Available: https://www.un.org/development/desa/dpad/wp-content/uploads/sit.
19. Sultana J. Future Prospects and Barriers of Pharmaceutical Industries in Bangladesh. Bangladesh Pharmaceutical Journal. 2016; 19(1): 53-57.
20. Hasan MM, & Yasir ME. COVID-19 disruption to medicine supply in Bangladesh: Searching for a solution to drug shortages. Public Health in Practice. 2021; 50 (2):1-2.doi:https://doi.org/10.1016/j.puhip.2021.100134
21. Muktadir A. Opportunity and Challenges of Pharmaceutical Sector in the Context of LDC Graduation: Way Forward. Seminar on Pharmaceutical Sector in the Context of LDC Graduation. Dhaka: Economic Relation Division. 2022; (pp. 1-32).
22. Islam S, Rahman A, & Al-Mahmood AK. Bangladesh Pharmaceutical Industry: Perspective and the Prospects. Bangladesh Journal of Medical Science. 2018; 17 (04), 519-525. doi:http://dx.doi.org/10.3329/bjms.v17i4.36985
23. South Asian Network on Economic Modeling (SANEM). National API (Active Pharmaceutical Ingredients) and Reagents Production and Export Policy 2018. WTO Cell. Dhaka: Bangladesh Regional Connectivity Project-1; 2018.
24. Shobna M., Prasad M, Nguyen-Huy T. and Deo R. Chapter 12 - Support vector machine model for multistep wind speed forecasting, Predictive Modelling for Energy Management and Power Systems Engineering. Amsterdam: Elsevier Publisher. 2020: 335-389. Available: https://doi.org/10.1016/B978-0-12-817772-3.00012-4.

25MRC Bangladesh Ltd, *Review of Pharmaceuticals Sector in Bangladesh* (Bangladesh: High Commission of India: Bangladesh, 2016), https://hcidhaka.gov.in/pdf/Report_on_Pharmaceuticals_Sector_in_Bangladesh(1).pdf.

26 Mustafizur Rahman, "Review of Export of Pharmaceutical Sector upon LDC Graduation: Strategies & Way Forward", (Paper Presented at Seminar on Export of pharmaceutical Sector upon LDC Graduation: Strategies and Way Forward, Dhaka Chamber of Commerce & Industry (DCCI), July 23, 2022), 1-33

27 Ministerial Conference (MC12) of the WTO declaration

28 Bumpas, Kostermans and Nair, "Review of PUBLIC and Private Sector Approaches to Improving Pharmaceutical Quality in Bangladesh", 1-54.

29 Author interview with stakeholder from pharmaceutical company Healthcare Pharmaceutical, Beximco Pharmaceutical, Biopharma Pharmaceutical and Drug international Pharmaceutical,

Definitions, Acronyms, Abbreviations

ARIMA	Autoregressive Integrated Moving Average
Australia-TGA	Australian Therapeutic Goods Administration TGA
BCSIR	Bangladesh Council for Scientific and Industrial Research
CETP	Common effluent treatment plant
CIT	Corporate Income Tax
EMA	European Medicines Agency
ICDDRB	International Center for Diarrhoeal Diseases and Research in Bangladesh
MRC	Migrant Resource Centre
NBR	National Board of Revenue
NBR	National Board of Revenue
NCDs	Non-communicable Diseases
TFDA	Taiwan Food and Drug Administration
UK-MHRA	United Kingdom Medicines and Healthcare products Regulatory Agency
UNDESA	United Nations Department of Economic and Social Affairs
US-FDA	U.S. Food and Drug Administration