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Bangladesh Regional Connectivity Project-1

Probashi Kollayan Bhaban
Eskaton Garden, Dhaka-1000

Policy Review/Policy Study/Policy Paper Preparation on National API (Active Pharmaceutical Ingredients) and Reagents Production and Export Policy 2018

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on
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Preface

The final report intends to respond to the requirement according to the provision of the contract agreement signed between Bangladesh Regional Connectivity Project-1 (BRCP 1) and South Asian Network on Economic Modeling (SANEM) for conducting **"Policy Review/Policy Study/Policy Paper Preparation under the Bangladesh Regional Connectivity Project 1)"** in collaboration with International Development Association (IDA), The World Bank. The objective of this technical assistance project is to review the existing government policies related to trade to strengthen cooperation in trade, transport, and transit facilities and facilitate the economic empowerment of women traders. The ongoing context and challenges are compared with the existing policies. It has also analysed the best practices of regional comparators to promote and improve trade-related activities as well as the relevance of SHE trade with the existing policies. Finally, based on the findings, the recommendation for future policy has been identified.

Consultancy services for conducting the **"Policy Review/Policy Study/Policy Paper Preparation under the Bangladesh Regional Connectivity Project 1)"** was provided by the South Asian Network on Economic Modeling (SANEM), Bangladesh. The study team consists of four senior-level experts. The major objective of the study is to depict a clear picture of the current state of the implementation of the policies, and challenges and to provide suggestions for future policies. Furthermore, Reviewing and identifying the gaps in the existing policies were also aimed to be found for this study.

The review of the **National Active Pharmaceutical Ingredients (API) and laboratory reagents production and Export Policy 2018** has identified some specific areas including the overview of pharmaceuticals industries of Bangladesh, major and potentials countries for export pharmaceuticals products from Bangladesh diversification, challenges after LDC graduation, export promotion, incentives and infrastructural development for existing API industries, supporting existing exporters, promoting potential exporters, capacity building, skill development, and legal enforcement.

We are hopeful about the policy recommendations which would be beneficial for policymakers and other stakeholders for the improvement of the API industries as well as the pharmaceuticals sector.

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Acknowledgments

It is indeed a great pleasure that Bangladesh Regional Connectivity Project 1 (BRCP-1), Ministry of Commerce has entrusted International Development Association (IDA), and the World Bank to carry out "**Policy Review/Policy Study/Policy Paper Preparation".** The report of the study has been prepared based on a mixed methodology. The studies are 1) Patent and Design Act, 1911, 2) Bangladesh Tariff Commission (Amendment) Act, 2020, 3) National Active Pharmaceutical Ingredients (API) and laboratory Reagents Production and Export Policy 2018, 4) Free Trade Agreement Policy Guidelines, 2010.

The five policy papers contain objective, scope, and methodology for the studies, current context, and challenges, deviation from the international practices, and the relevance of the policies to the SHE trade. The consultants also described the best practices of regional countries adapted to facilitate trade-related activities. In the end, the findings from the analysis and recommendations for the upcoming policy papers are portrayed.

The authors wish to thank Md Mijanur Rahman, Project Director, Bangladesh Regional Connectivity Project 1, and Md Munir Chowdhury, National trade expert, BRCP-1 for their valuable comments and continuous support in undertaking the study.

We are also thankful to all the officials and participants who took part in the consultation meetings, both online and in-person, for helping us with their constructive criticism and valuable suggestions during the study period.

This work would not have been possible without the participation of the relevant stakeholders in the Key Informant Interviews (KIIs). Thanks are also due to all respondents of interviews, and KIIs who helped us by providing their information during the data collection period.

The contribution and support provided by everyone for the study are greatly appreciated.

Selim Raihan

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Executive Director, SANEM

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List of Acronyms

AI	*Artificial Intelligence*
AIT	*Advance Income Tax*
API	*Active Pharmaceuticals Ingredients*
BB	*Bangladesh Bank*
BAPI	*Bangladesh Pharmaceuticals Industry*
BIDA	*Bangladesh Investment Development Authority (BIDA)*
BRCP	*Bangladesh Regional Connectivity Project*
COVID-19	*Coronavirus disease of 2019*
DGDA	*Directorate General of Drug Administration*
DMF	*Drug Master File*
E-commerce	*Electronic Commerce*
Ecnec	*Executive Committee of the National Economic Council*
EPB	*Export Promotion Bureau*
FDI	*Foreign Direct Investment*
FGD	*Focus Group Discussion*
FTA	*Free Trade Agreement*
FY	*Fiscal Year*
GDP	*Gross Domestic Product*
GoB	*Government of Bangladesh*
GMP	*Goods Manufacturing Practice*
GSPA	*Global Strategy and Plan of Action*
HIC	*High-Income Country*
IMF	*International Monetary Fund*
IP	*Intellectual Property*
KII	*Key Informant Interview*
LDCs	*Least Developed Countries*
MNCs	*Multinational Corporations*
MoC	*Ministry of Commerce*
MSME	*Micro, Small, and Medium Enterprise*
NBR	*National Bureau of Revenue*
PCB	*Pharmacy Council of Bangladesh*
PHI	*Public Health, Innovation and Intellectual Property*
R &D	*Research and Development*
SDGs	*Sustainable Development Goals*
SOP	*Standard Operating Procedure*
SME	*Small and Medium Enterprise*
TDS	*Tax Reduction at Source*
TIN	*Taxpayer's Identification Number*
TRIPS	*Trade-Related Aspects of Intellectual Property Rights*
UMIC	*Upper Middle Income Country*

UNCTAD	*United Nations Conference on Trade and Development*
USA	*United States of America*
USD	*United States Dollar*
VAT	*Value Added Tax*
VDS	*VAT Deduction at Source*
WDI	*World Development Indicators*
WHO	*World Health Organization*
WTO	*World Trade Organization*
4D	*Four-Dimensional*
4IR	*4th Industrial Revolution*

Executive Summary

The Government of Bangladesh (GoB) has undertaken several policies to facilitate trade and trade-related activities. The circumstances have been changing over the years both domestically and globally. To keep up the pace with the global context modification of the existing trade-related policies has become mandatory for the country. Moreover, Bangladesh is expecting to be graduated from the LDC category within 2026, that's why reviewing the existing policies of the government of Bangladesh has become very much essential to keep pace with the world. The Government of Bangladesh has come up with the Bangladesh Regional Connectivity Project 1 (BRCP-1) in collaboration with the International Development Association (IDA) and the report has been propagated as an outcome. The primary concern of this technical assistance project lies in the progression of the institutional capacity related to trade activities, ensuring active and sustainable cooperation among trade-related stakeholders, and facilitating the economic empowerment of women traders. Formulation of effective trade-related policies and implementation is of much importance in the post-graduation period to maintain unimpeded performance.

SANEM has prepared this policy review on the National Active Pharmaceuticals Ingredients (API) and laboratory reagents production and export policy 2018 by using a mixed methodology including desk research, KIIs, and FGDs. Various issues have been addressed by this policy review paper inlining the complexities in implementation of the policy, the present situation of the prospective sectors, and relevance with the worldwide perspective with the existing scenario, and bottlenecks. Moreover, the policies of China, India, and Korea are compared with the existing policy. The relevancy of the SHE trade with the existing policy is also ascertained in this paper.

Chapter two of this paper discusses several facts which constitute the overview of the pharmaceuticals sector, a summary of the existing policy paper, its context of the present situation, challenges, and shortfalls. The changing trade environment in the impending context and the deviation of the policy from international practices are also overviewed here. n chapter two, of this paper, the current policy's context, challenges, general overviews, and trade-related provisions are investigated. The relevance of the National Active Pharmaceuticals Ingredients (API) Production and Export Policy, 2018, in the present changing trade scenario and the deviation of the policy provision from the regional comparators, are analysed.

The topicality of the propagated policy with the SHE trade is narrated in chapter three which discloses the facts about promoting the women mainstreaming the women entrepreneurs in international trade and global value chains. Several interviews were taken for finding out the actual situation in this sector. Based on the primary data (in-person meetings, KIIs), the findings of this study are depicted in chapter four which has uncovered various captivating issues.

Although the National API policy 2018 is a very recent policy, several issues have been unconcealed while conducting this study such as slow progress in the establishment of API parks, inadequate human resources in the relevant industry, and lack of investment in the API industry that results in few numbers of API firms, shortage of experts from the domestic

portion, high cost for producing molecules, implementation problem in the action plan, challenges that will be faced after LDC graduation, etc. The primary findings of this paper proclaim that the policy is progressive and compatible with our country's mainly the problem lies in the implementation stage. The nature of this policy is nonbinding in nature. Bangladesh government has formulated this policy in 2018 and the plan to establish the API industrial park was taken in 2008, although the API parks are not yet come to the light. The establishment of this API Park is necessary for attracting domestic as well as foreign API producers. The earliest opening of API Park has become a major challenge. Moreover, the pharmaceuticals sector is mainly technologically advanced and one of the prerequisites is the need for skilled human capital which is somehow inadequate in this sector. Developing new molecules requires extensive R & D. Some of the significant challenges to the effective function of the National API policy 2018 are the shortfall of inter-ministerial coordination, lack of awareness about the policy, shortage of experts in the relevant sector, insignificant number of API producing firms and policy harmony, etc.

Possible recommendations/action plans for the upcoming future policy are provided in chapter five with a detailed recommendation matrix. For securing the effectiveness and appropriate implementation of the policy, the focus should be paid to industry-related study and up-gradation of the existing syllabus in the universities, capacity building of the human resources, support from the government side, assigning regulatory bodies both from the public and private sector for smooth performance in this sector as well to assure accountability and credibility to maintain the sustainable progress in this sector. It is high time we focused on the development of a curriculum that is industry-relevant. Moreover, incentives (cash) should be provided to promote the R&D to promote not only this sector but also the interlinked industries. Surprisingly, among the LDCs Bangladesh has the potential to get advancement in this hi technologically dependent sector. For this reason, since the time length of the policy is based on the LDC graduation period and the progress is not that up to the mark for achieving this goal, Bangladesh might seek permission to extend the TRIPS flexibility for some more years for the preparation purpose for only this specific sector. In the end, the concluding remarks of the policy review are given in chapter six.

1. Introduction

1.1 Background

The pharmaceutical industry is considered to be one of the technologically advanced sectors which require skills. And this sector of Bangladesh has significant potential (BIDA, 2020). Few local firms and multinational companies (MNCs) initiated manufacturing pharmaceutical products in 1950. The most hi-technological sector of Bangladesh is the pharmaceutical sector there were only 210 licensed allopathic drug-manufacturing units in the country in 2000 but there are around 300 pharmaceutical industries currently manufacturing about 5,600 brands of medicines (Ahaduzzaman et al., 2017). Though the pharmaceutical industries have huge potential the dependency on the raw material is one of the major challenges (Sheel, 2015).

Since 1982's National Drug Policy the pharmaceutical industries are started to grow immensely as a result this sector can be able to meet the 98% local demand as well as around 1.8% contribution to the GDP came from this sector (BIDA, 2020; Chaudhuri, 2020). The 'Expert Committee' in 1982, identified that around one-third of the medicines were unnecessary as well as the MNCs were not entangled in producing APIs which were imported at bloated prices. However, when the regime of the military government had come to light, in March 1982 an expert committee had been formulated to develop a national drug policy. The expert committee tried to address problems of the objectives of industrial policy for ensuring the production of medicine from local firms and also aimed to reduce the non-essential products from the market by recommending a policy intervention for the API sector a manufacturing sector as well. Moreover, the 1982 ordinance banned reduced a major MNCs' significant role in the market and as a result, significant pressure was put on the government for not implementing the policy from MNCs (Chaudhuri, 2020).

On the other hand, significant API industries are needed for Bangladesh for further development as it is assumed that, by the development of the API industrial park in Munshigonj, industries' potential has multiplied. Moreover, the Munshigonj API industry can be able to save 70% of the cost of the import of raw materials. Moreover, there is also an absence of the facilities for bio-equivalency tests as a result this test has been conducted in European countries, Singapore, and Malaysia which eventually increases the cost of production (Sheel, 2015).

But some major challenges were not addressed by the 1982 ordinance, such as lack of technological assistance, lack of skilled workforce, and so forth. Without addressing these challenges, it will be quite difficult to enjoy the benefits of the policy of 1982. Moreover, the expert committee also recommended developing the API manufacturing sector, but the ordinance neglected this part as a result the MNCs did not manufacture API (Chaudhuri, 2020). Furthermore, according to Drug Control Ordinance 2006, a foreign manufacturer can manufacture any drug under licensing agreement and a local manufacturer can manufacture any drug under any written contact with any pharmaceutical manufacturing plant in Bangladesh.

However, the Bangladeshi drug market produces high branded generic drugs. Active pharmaceutical ingredients (APIs) are the most significant materials for pharmaceutical industries. While the demand for APIs in the domestic market is significantly increasing, the local production of APIs is not sufficient to meet the demand which leads to an increase in the rate of import of APIs. In FY 2018-19, it was estimated that approximately USD 600 Million APIs have been imported (BIDA, 2020). According to the recommendation of the Expert Committee developed in 1982, the abolishment of patent protection from pharmaceutical products needs to ensure the sustainable growth of this industry but this was not undertaken before 2008, as Bangladesh was not able to ensure the replacement of the British Act of 1911 and it simply emanated a notification in 2008 that the applications for the patent protection in the pharmaceutical industries would be ceased till 2016. After that, the suspension is continuing with the propagation of LDC graduation from 2016 to 2033 and after that, Bangladesh must have to produce patent protection before the achievement of LDC graduation (Chaudhuri, 2020).

Until 2016, the Agreement on Trade-Related Aspects of International Property Rights (TRIPS) provides the opportunity for limited export benefits and patent-free production rights, moreover, Bangladesh can be able to ensure the import of around 80% of its APIs for the local production and around 20-25% of which are patented. Furthermore, under TRIPS Bangladesh is enjoying several advantages, such as exporting to any country if the drug is not under patent, exporting to another LDC or non-WTO country that has not implemented product patent protection, export to a country where the patent holder has not filed for patent protection for the drug, export to a country that has issued a compulsory drug license and awarded the production contract to Bangladesh. Moreover, Bangladesh has patent law as well which is based on the Patent and Designs Act of 1911 and the Patents and Designs Rules of 1933, and the patent law offers both product and process patent rights for the products of pharmaceutical. In addition, the patent office issued around 40 drug formula patents and around 300 patents per year, and 90% of those are occupied by the MNCs (Bumpas et al., 2007).

But pharmaceutical industries of Bangladesh are also growing immensely despite having all the bottlenecks and can be able to introduce several patented products at low prices Though Bangladesh is being able to introduce several patented products due to the absence of product patent protection, India, China are not being able to formally export the patented APIs to Bangladesh. Therefore, due to the absence of patent protection, Bangladesh is not able to enjoy the benefit. Around 3% of the domestic market for the finished formulation is dependent on imports which is related to technologically intensive manufacture. In addition, the local industries are also starting to produce high-tech products (Chaudhuri, 2020).

However, there are mainly two drug regulatory authorities in Bangladesh, which are: a) The Directorate General of Drug Administration (DGDA) under the Ministry of Health and Family Welfare, and its responsibility is to monitor or regulate the activities which are related to export and import of raw materials, production, sales, packaging, licensing and so forth and b) The Pharmacy Council of Bangladesh (PCB) which aims to regulate or control the pharmacy practice in Bangladesh PCB was established under the Pharmacy Ordinance in 1976 to control pharmacy practice in Bangladesh (Moniruzzaman, 2016). Furthermore, a 10% cash incentive is provided by the authority to boost the pharma sector and customs duty on 40 raw materials

used in pharmaceutical industries was also reduced to 5% from a 10%-25% rate and most importantly, customs duty on 14 items used in anti-cancer drugs have been alleviated in the national budget 2014-15 (Mohiuddin, 2019).

Despite having regulatory authorities or policies the Bangladesh pharmaceutical industry is suffering from a lack of APIs industries and as a result, 90% of raw materials have to import (Moniruzzaman, 2016). Therefore, the standard API industry is one of the essential conditions for Bangladesh. On the other hand, research institute with the global standard for pharmaceutical industries also needs to be developed as early as possible and Bangladesh needs to transform its logistics to increase its research facilities by developing its intellectual property (Sultana et al., 2017).

China can be used as an ideal example that Bangladesh can follow as China has a significant domestic pharmaceutical manufacturing sector along with immense potential. China's pharmaceutical sector mainly developed during the period of China's isolation from the free-market economy and most of their industries are state-owned and supported by the government through significant incentives and development of their industrial zone as well. After that, China adopted a free market economy in the year of 1980 and joined WTO in late 2001 and that period, China's pharmaceutical industries experienced immense growth. China mainly focused on the development of the API industries and also ensured themselves as the leading suppliers of APIs in the global market currently, approximately 97% of drugs sold by local Chinese industries are generic along with that around 80% of the drugs sold on the Chinese domestic market are generic. Therefore, the development of the medicine regulatory framework is also responsible for the robust growth of China's pharmaceutical industries. These procedures which are followed in China are absent in Bangladesh which is necessary to be presented for the further development of Bangladesh's pharmaceutical industries development in the long run (WHO, 2017).

1.2 Objectives and Research Questions

The Ministry of Commerce has published this policy paper which is deemed as the first sectoral export policy paper that primarily focuses on encouraging domestic production of API and export of pharmaceutical products. Under the TRIPS, the LDCs enjoy certain exemptions, which have proven beneficial to ramping up their export share in the global market. And to avail of the benefits engendered by the exemptions, this policy was adopted. It has some particular objectives, incentives, and implementation strategies. Besides, it has a proper action plan. In the context of WTO rules and procedures, LDC graduation, and domestic Drug Law 2006 and Drug Ordinance 1982 the policy will be examined with the view to achieving the maximum benefit that Bangladesh can enjoy from the TRIPS exemption for the LDCs and also prepare itself to adjust with the post-graduation era. Through this review gaps in the existing mechanisms and innovative measures for promoting "SHE Trades" will also be addressed.

The key research questions that the research team will answer particularly for this study are as follows,

1. Do the objectives of the policy are in line with the present context? (LDC graduation, 8th five-year plan, graduating to Upper Middle Income Country (UMIC) category, and changing trade scenario due to Covid pandemic)
2. Do the measures stated in the National API (Active Pharmaceutical Ingredients) and Regents Production and Export Policy 2018, to achieve the objectives are consistent?
3. What incentives can be provided for female entrepreneurs in this sector?
4. How can the policy be updated to prepare Bangladesh for domestic production of API post-LDC graduation?
5. Which are the possible implementation/institutional challenges to achieving the objectives of the policy?

1.3 Methodology

Given the objectives and the key research questions of this study, the research team will primarily follow mixed methodologies in presenting the deliverables. The methodology will be based on two significant tasks in general:

(i) Rigorous desk research of all relevant policy documents, literature, and secondary data, and
(ii) Primary data collection and analysis by conducting Key Informant Interviews (KIIs) and Focus Group Discussions (FGDs) with stakeholders relevant to the study.

Therefore, the research methodology can be categorised as follows.

1.3.1 Desk research

Comprehensive desk research will be conducted by the research team. The desk research will include all pertinent documents and literature on the pharmaceutical industry, trade trends, international standards (laws, agreements, treaties, etc.), and female participation in the pharmaceutical industry. The research team will focus on the following documents for desk review,

- National API (Active Pharmaceutical Ingredients) and Reagents production and Export policy documents
- Domestic Drug Law, 2006 and Drug Ordinance, 1982
- Global best practices and WTO rules on TRIPS exemption for LDCs

During the desk research, the research team will follow the following steps,

- Inspection and scrutiny of the policy documents, which includes all relevant and existing acts, ordinances, legislation, agreements, treaties, and literature.
- Formulating the KII and FGD checklists based on the scanning of the stated documents.
- Substantiating and complementing the preliminary analysis with the findings from the primary data.
- Assessing the current pharmaceutical rules and practices in Bangladesh. Also, the study will consider pharmaceutical export data by using the UNCTAD database, as a

part of the secondary data analysis. Data from other sources, such as World Bank, IMF, etc. will also be examined.
- Comparing the policies with WTO standards.
- Comparing Bangladesh's pharmaceutical and pharmaceutical-related policies with global comparators.

1.3.2 Primary data collection

In collecting primary data, the research team has followed a qualitative approach. Social aspects that are mostly unrepresented in the quantitative data can be addressed through qualitative data, which are expected to provide in-depth information on social dimensions and characteristics. As part of the qualitative data, the team will conduct Focus Group Discussions (FGD) and Key Informant Interviews (KIIs).

Key Informant Interview (KII)

The KIIs are helpful for an in-depth understanding of the policies, assessment of projects, and identifying gaps. For this particular study, the research team has carried out a total of six KIIs.

List of KIIs for the policy review

Organisation/Association	Key informant
Representative from EPB	• Ms. Kumkum Sultana, Deputy Director (Policy & Planning Division), Deputy Director (Statistics & Research)-Additional Charge
Industry insiders	• Mr. ABM Jamaluddin (Active Fine Chemicals Ltd.) • Md. Anwar Morsalin (Chief Executive Officer, Gaco Pharmaceuticals Ltd) • Khairul Alam (Deputy Sales Manager, Orion Pharma)
Think Tanks	• Dr. Kazi Iqbal (Senior Research Fellow, BIDS)

The mode of contact for the KIIs was face-to-face interviews, virtual meetings, and telephone interviews, depending on the situation. A detailed list of the interviewees is provided in the annex section of this report.

1.4 Evaluation and Analysis

All the gathered data and information will be evaluated and analysed at this stage. This process will include:

- Identifying the gaps in existing information through rigorous desk research.
- Exploring the potential provisions of the existing policy for mainstream women entrepreneurs.
- Analysis of primary data through KIIs to evaluate the actual activities of the organisation and its actors in the present trade scenario.
- Identifying the weaknesses and implementational challenges of the existing policy from stakeholders' experiences, through KIIs.

- Comparing international best practices with the current provision of the policy.
- Providing possible legal recommendations about changes, alterations, exclusion, and extension of the current ordinance through consultation with legal experts, and recommendations of key informants.

1.5 Organization of the Study

In total there are six chapters in this study. In chapter two of this paper, the overview of the pharmaceuticals sector, current policy context, challenges, general overviews, and trade-related provisions is investigated. The relevance of the National API (Active Pharmaceutical Ingredients) and Reagents Production and Export Policy 2018, in the present changing trade scenario and the deviation of the policy provision from the regional comparators, are analyzed. Chapter three has discussed the relevance of the current policy in promoting and mainstreaming women entrepreneurs in international trade and global value chains. Chapter four provides findings from this study based on the interviews and meetings. In chapter five possible recommendations and a way forward are given and chapter six states the concluding remarks of this policy review.

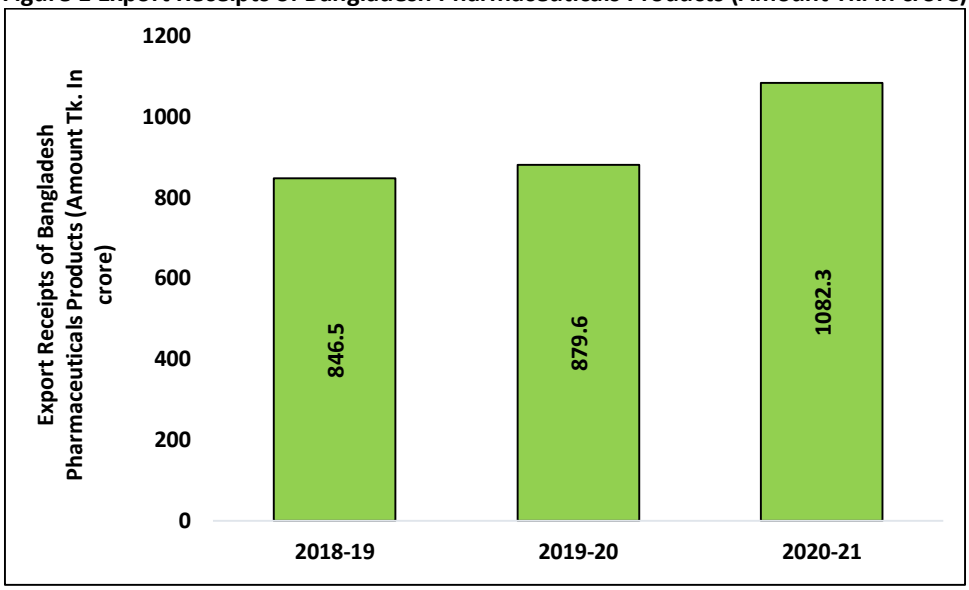
2. The National Active Pharmaceutical Ingredients (API) and Laboratory Reagents Production and Export Policy, 2018- Context and Challenges

2.1 Overview of the Pharmaceuticals Sector in Bangladesh

2.1.1 Export Receipts of Bangladesh

An increasing trend has been observed over the years in the export receipts of pharmaceutical products in Bangladesh. In FY 2018-19 the amount was 846.5 crore taka which rose to 1082.3 crore taka in FY 2020-21.[1] Bangladesh has a great advantage in boosting this sector.

Figure 1 Export Receipts of Bangladesh Pharmaceuticals Products (Amount Tk. In crore)



Source: Authors' Compilation from data of Bangladesh Bank

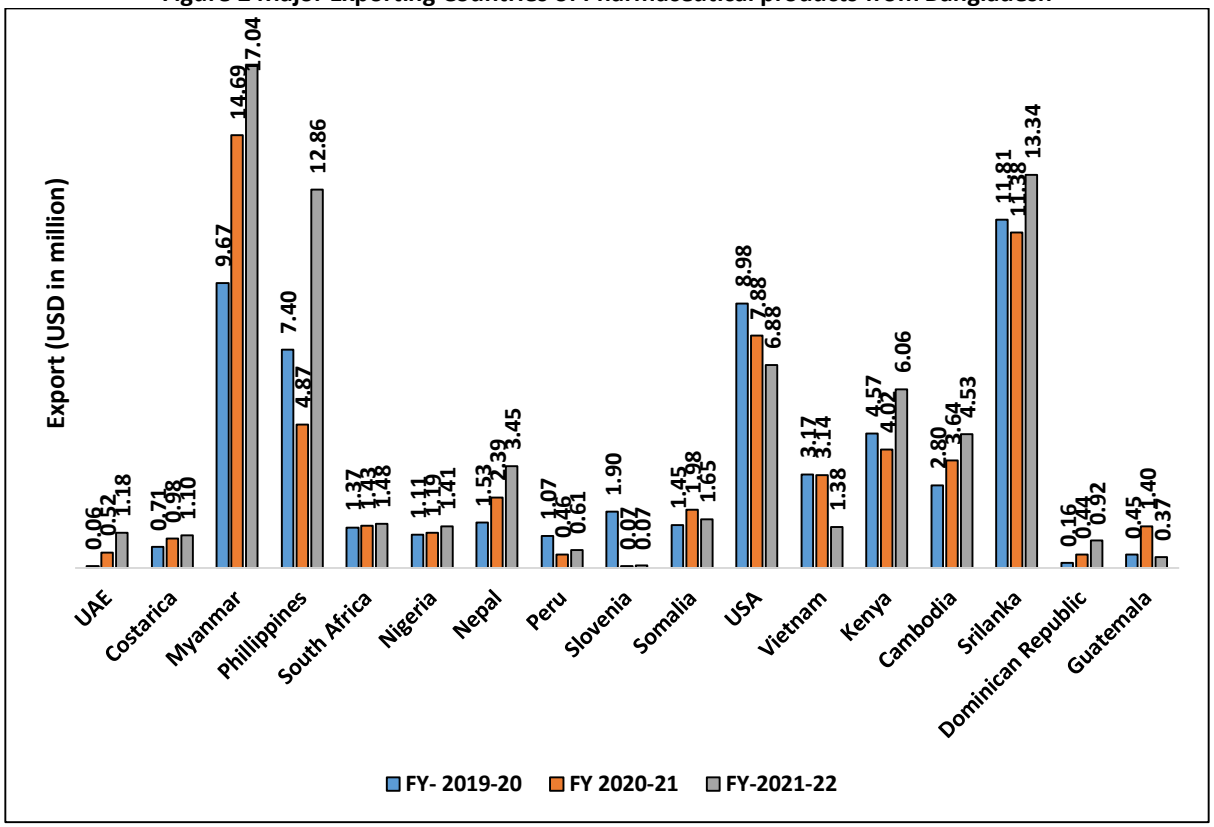
2.1.2 Major Export from Bangladesh

Bangladesh has been exporting pharmaceutical products to several countries and that is contributing to our economy a lot. The major exporting countries of pharmaceutical products from Bangladesh are Myanmar, Srilanka, the Philippines, the USA, Cambodia, Nepal, and Kenya. The potential pharmaceutical product exporting countries are the UAE, Nigeria, Costa Rica, South Africa, Peru, Dominican Republic, Somalia, Slovenia, and Guatemala (Figure-2). An upward trend is observable in the amount of the export of pharmaceuticals products over the years. In FY 2019-20, the export to Myanmar was USD 9.67 million which has become USD17.07 million in the FY 2020-21 (Figure-2).[2]

[1] Data from Bangladesh bank

[2] Information collected from Export Promotion Bureau (EPB)

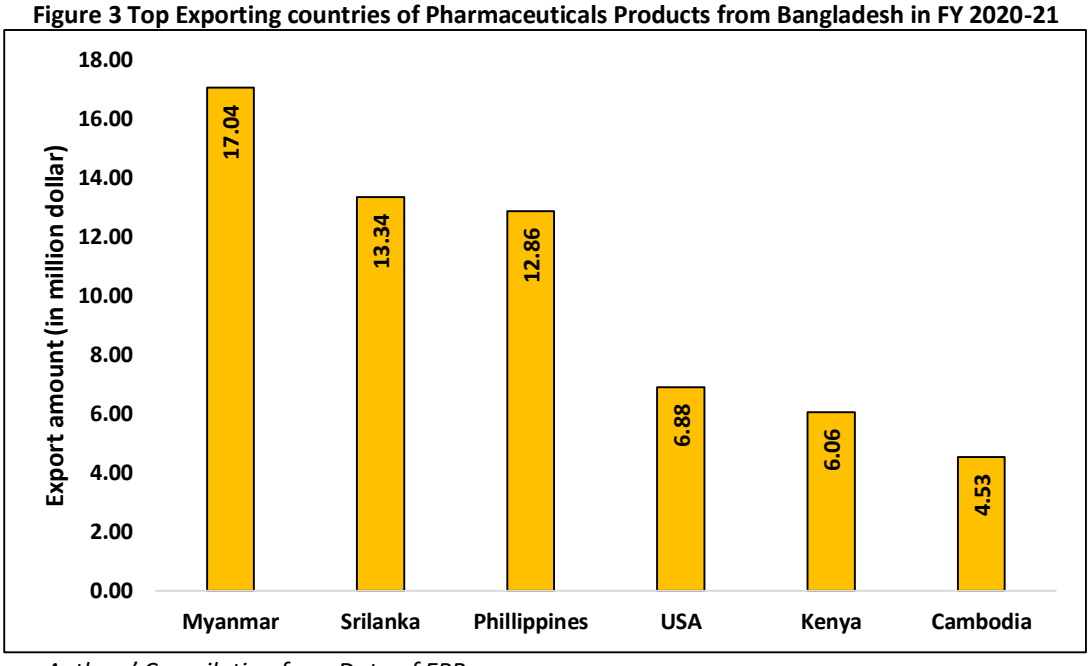
Figure 2 Major Exporting Countries of Pharmaceutical products from Bangladesh



Source: Authors' Compilation from Data of EPB

Bangladesh is now exporting pharmaceutical products to several countries. The top exporting countries of pharmaceuticals products from Bangladesh are Myanmar, Srilanka, Phillippines, USA, Kenya, and Cambodia (Figure 3). [3]

Figure 3 Top Exporting countries of Pharmaceuticals Products from Bangladesh in FY 2020-21



Source: Authors' Compilation from Data of EPB

[3]Export Promotion Bureau (EPB)

2.1.3 The Impacts of COVID-19 Pandemic on the Pharmaceutical Sector of Bangladesh

It does not take much for a country to experience the lesions of massive disasters in the present world economic order. Currently COVID-19 pandemic has started to spread its massive consequences all over the world and the poorer countries must feel the bite the most. Globalization has brought distinguished amenities to many countries of the world; Bangladesh is one of the countries among them. But due to the COVID-19 pandemic, the benefits of globalization will be hurt. The most possible adverse impacts mainly depend on the duration of the crisis. According to IMF, a potential global recession will fade out by Q4 2020, which will be worse but shorter-lived than the global financial crisis of 2008. As a least developed country, Bangladesh also has to feel the bite of the COVID-19 pandemic and almost every sector of Bangladesh has experienced the adverse impacts of Bangladesh. Though the need and essentiality of the pharmaceutical sector of Bangladesh have come to light during the period of the COVID-19 pandemic due to the lack of capacity, this sector also has to suffer from the adverse impacts of the pandemic.

Bangladesh is already being able to ensure the three thresholds for graduation from the least developed country (LDC) and hopefully, Bangladesh will achieve the status of LDC graduation by 2026. But due to the pandemic, the investment scenario and the overall structure of economic growth in Bangladesh have been changed, therefore, developing strong and capable API industries will be quite tough for Bangladesh. The development of strong API industries needs an extensive investment but due to the pandemic, the investment procedure will be harmed. Hence, it will need more time for API policy to be implemented as now the most priority of the government is to address the challenges of the COVID-19 pandemic.[4]

2.2 Brief Overview of the Legislation

This policy was formulated back in 2018 to utilize all the benefits of the TRIPS agreement. The pharmaceutical sector of Bangladesh has become the fastest-growing export sector in the world. The National API and Laboratory Reagent production and export policy 2018 has two sections.

The section-one is the main part where the details of the policy paper are discussed. In section two, the background documents of the policy paper are elaborated. In section one, there are eight chapters. Chapter one has the headline of the policy which states that the policy would be named ''National Active Pharmaceuticals Ingredients and laboratory reagents production and export policy''. The objectives of the policy paper are mentioned in chapter two, chapter three includes the implementation strategy, imposition, and circumference are stated in chapter four. Policies regarding the payable incentives are mentioned in chapter five which includes provisions about corporate tax holidays, VAT exemption, cash incentives, foreign exchange support, Easing the Import Process, Providing duty-free goods exemption facility, Facilitation of import of raw material samples, Government Procurement, and Prioritising land allocation. Provision about the support side is mentioned in chapter six. As Bangladesh is only the one country from LDC that export pharmaceutical products there is a huge

[4]Sarkar, S. (2020, March 30). Economic Fallouts from Covid-19. *The Financial Express.* Retrieved from https://thefinancialexpress.com.bd/views/economic-fallouts-from-covid-19-1585582385

opportunity for FDI in this sector. That's why chapter seven discusses the risk evaluation to cope with LDC graduation. The action plans are discussed in chapter eight.

The goal and objectives mentioned in the policy are summarized below in Table-1:

Table 1 Goal and objectives of the National API and laboratory reagents production and export Policy, 2018

Topic	Remarks
The Desired Goal	Achieving the highest possible production capacity in the API and laboratory reagent manufacturing sector by 2032, taking full advantage of the benefits of the TRIPS Agreement, and implementing the SDG's third goal (Good Health and Well-Being for People) and export diversification targets outlined in the 7th Five-Year Plan.
Objectives	**General Objective**
	Reducing import dependence through the development of API and laboratory reagent sector and meeting domestic demand and increasing export through the production of API and laboratory reagent locally by creating a competitive market.
	Particular Objective
	• Reduction of import dependence on API and laboratory reagent sector, increase in the production and diversification of export. • Assurance of entrance of new investors in the API and laboratory reagent sector within 2022 and promotion of foreign investment to an additional one billion dollars. Also bringing the necessary technology and additional impact. • To make the production cost of API and laboratory reagents in Bangladesh competitive in the international market. Significant reduction in imports of API and laboratory products by 2032 and ensuring the supply of quality API and laboratory reagents produced in the country at affordable prices. • Achievement of production capacity of more than 370 Lifesaving API molecules approved by the Drug Master File(DMF) and vital for export to advance production locally. • Creation of opportunities for 500,000 jobs in this sector from 2032.
	Administrative objective
	• Increasing the contribution of API and laboratory reagents to GDP from 0.0121% in 2016 to 0.025 by 2032. • Enhancement of the number of locally produced API molecules and laboratory reagents from 41 in 2016 to 125, 230, and 360 by 2021, 2028, and 2032 respectively. • Reduction in the dependency on imports from 97% in 2016 to 80% in 2032. • Raising the export from 1.5 lakh in 2016 to nine lakh dollars in 2032.

Source: Authors' Compilation from National API and laboratory reagents production and export policy, 2018

Section two of this paper narrates the background document of this policy paper. By applying and following the five steps of the Evidence-Informed Policy Making (EIPM), several aspects of the policy papers are explained, and by analysing the possible policy options, the most perceptible policy option is taken here. In chapter one of this section, the beneficiaries under this policy are mentioned which are also disclosed in the following table:

Table 2 Beneficiaries under the policy

Beneficiaries	Remarks
Primary	• Producers of API and laboratory reagents and API-related ingredients • Small and Medium Entrepreneurs (SME), Agriculture, and Backward linkage industries
Intermediate	• Bangladesh API and Intermediate Manufacturers Association (BAIMA) • Bangladesh Association of Pharmaceuticals (BAPI) • Pharmaceuticals industries of Bangladesh • Directorate General of Drug Administration (DGDA)

Source: National API Policy 2018

Chapter two discusses the nature of the problem e.g. analysis of the causes and effects of backwardness in the pharmaceutical raw material industry, discussion of the current policy of API industry of China, India, and Bangladesh, diagnosing strengths, weaknesses, (problem tree, comparison of the policy options, projection on API import, demand, and production, multi-criteria analysis, etc.).

2.3 Current State and Bottlenecks

Bangladesh has been exporting to more than 160 countries in the world. The annual market size of the pharmaceuticals industry was 170 crore taka in 1982 which rose to 26000 crore taka now. There's no doubt that the pharmaceutical sectors have rapidly flourished but the problem lies in the large dependency on the import for API demand. Around 90% of the raw materials are imported from China, India, and Korea for meeting domestic demand. Local entrepreneurs need to import around 90 percent of raw materials from China, Korea, and India to meet domestic demand. Making the self-abundant API sector by producing about 370 important molecules for export has been set as the target of this API policy. The amount of locally produced API molecule and laboratory reagents was 41 in 2017.[5]

2.3.1 Absence of a business-friendly environment

One of the major objectives of API Policy-2018 is to bring new entrepreneurs to this sector by 2022. There are some preconditions which need to be assured before ensuring the entry of new businessmen in any sector, such as firstly, the business environment needs to be friendly and cooperative for the newcomers, secondly, financial incentives or tax holidays should be provided, thirdly, infrastructure development with utility services as well as the introduction of one-stop service and policy support from government are the major preconditions for attracting the freshers in this sector. But in the context of Bangladesh, due to cumbersome bureaucratic problems, poor infrastructure and utility facilities, high rate of tax and other duties, and so forth, these preconditions are not being able to provide by the government yet, which will discourage the freshers from involved in pharmaceutical or any other sector.

[5] NBR to review API manufacturers' tax holiday proposal. (2021, July 17). *New Age | The Most Popular Outspoken English Daily in Bangladesh*. https://www.newagebd.net/article/144011/nbr-to-review-api-manufacturers-tax-holiday-proposal

2.3.2 Lack of investment

As there is a lack of a business-friendly environment in Bangladesh, which often discourages the investors both local and foreign to invest in any sector of Bangladesh. Moreover, if any country cannot be able to assure a business-friendly environment for the local investors then it is quite tough to attract foreign direct investment (FDI). Several feasible incentives, government support, support from the Bangladesh Investment Development Authority (BIDA), National Board of Revenue (NBR), and other relevant authorities are absent in the context of Bangladesh. Consequently, in this circumstance, these are the major challenges to the path of ensuring more investment in developing API industries for the further development of the pharmaceutical industries of Bangladesh.

2.3.3 Poor infrastructural development

Poor infrastructural development is one of the major challenges to the path of further development of pharmaceutical industries and this is not only the challenge for this sector, rather than this is the major labyrinth for the industrial sector of Bangladesh. As a least developed country, Bangladesh does not have sufficient utility services, transportation facilities, a strong communication system, and so forth. Due to this barrier, Bangladesh also is not able to ensure a significant amount of investment and FDI as well. Therefore, the poor infrastructure facility is one of the major labyrinths in the path of the development of the API industry.

2.3.4 Burden of tax

According to the API Policy-2018, the Bangladesh government has announced a 100% corporate tax holiday from 2016-17 to 2021-22, and then from 2023-2032 according to the qualification the tax holiday will be enjoyed by the industries. Therefore, it is quite tough for the industries to grow without the financial incentives as due to the pandemic several additional challenges have also emerged. Besides, in Bangladesh, there is an additional vat on the manufacturing of raw materials and importing several necessary primary goods, which eventually impose a burden on the manufacturer. For example, China is one of the ideal examples, with strong and sufficient API industries, and the industries of China have got immense support from the government through subsidies and financial assistance. The relevant authority of the Bangladesh government also should provide this type of support to the pharmaceutical industries.

2.3.5 Lack of skilled manpower

Lack of skilled manpower is another challenge for the implementation of the API policy- 2018, in the context of Bangladesh there is a lack of skilled manpower which is one of the major preconditions for the implementation of the policy. Currently, workers who are engaged in this sector are mostly low-skilled or semi-skilled. Technical and vocational education and training might play an important role to supply the skilled workforce in the pharmaceutical sector. However, there is a widespread belief that the curriculum in the TVET institutes is not need-based as there is a gap between the educational institutes and industry. As in the era of globalization, the pharmaceutical sector requires some modern technical up-gradation, the relevant stakeholders need to be equipped with technical experts to provide technical support to the industries as well as supply a skilled workforce.

2.3.6 Institutional incapacity to develop a strong API industrial zone

Institutions are the tool that mainly shapes the rule of the game of the society and eventually, it significantly influences the rule and environment of doing business. Like the other developing and least developed countries, Bangladesh's institution has a great impact on its industries. As the RMG sector's contribution to the GDP cannot be denied, therefore, institutional support is always there for the RMG sector. The fondness of the institution toward the RMG sector is not unwelcomed but it leads to developing an uneven field to play the game for other industries. On the other hand, most of the developing and least developed countries must face the challenges that emerged from institutional incapacity for having weak institutions. As a result of weak institutions, the implementation of policy is not up to the mark, and being able to make any positive change as well leads to constructing a complex and cumbersome business environment. Consequently, the less support from formal institutions often makes the ease of doing business more difficult for the domestic industries and as a result, it discourages the foreign and local investors to invest in the API industries.

2.3.7 Lack of policy support

Feasible policy support is indispensable for this sector. Though the policy document in Bangladesh is well written, the rules and regulations are not business-friendly. The procedure for submitting VAT is very cumbersome and the relevant government employees lack efficiency as they often fail to understand the products to be taxed. The burdensome regulations particularly regulations related to the cross-border clearance processes and licensing are considered a major barrier to unlocking the trade potential of this sector. There is also a lack of coordination between the government and the industries. The policies taken are not well communicated with the industries and other stakeholders which adversely affects the entrepreneurs. Due to these cumbersome rules and lack of coordination, the entrepreneurs face harassment which works as a disincentive for them to invest.

2.3.8 Delay in construction of API Park

In the Executive Committee of the National Economic Council (Ecnec), the project of API park got approval in 2008 still it didn't come to light as it was expected. The location selected for this API Park is Munshiganj comprising 42 plots with 200 acres of land. Some of the leading companies secured their plots in the API industrial park such as Beximco, Square, Incepta, and Acme. The construction plan includes several infrastructural development and facilities such as CETP, waste dumping yard, etc.[6]

2.3.9 Lack of awareness about the policy[7]

Although this policy came to light in 2018, a great number of relevant stakeholders lack knowledge about this policy. If the majority of the stakeholders are unaware of this policy, it will be cumbersome for our country to rip the maximum benefit from this sector.

[6] Wing, L. A. (2021, August 3). *Active Pharmaceutical Ingredient (API) Manufacturing: The Next Growth Driver of The Bangladesh Pharmaceutical Industry*. LightCastle Partners. Retrieved January 24, 2022, from https://www.lightcastlebd.com/insights/2021/08/active-pharmaceutical-ingredient-api-manufacturing-the-next-growth-driver-of-the-bangladesh-pharmaceutical-industry/

[7] KII with stakeholder

2.4 Changing Nature of the World Trade and Relevance of the National Active Pharmaceutical Ingredient (API) and Laboratory Reagents Production and Policy 2018

Though API Policy-2018 is well documented due to the several implementation challenges, this policy is not able to come to light with its immense potential. Some of the major challenges of API policy are identified through the analysis of the context of Bangladesh as well as through existing literature that is relevant to the API policy.

2.4.1 LDC graduation and TRIPS agreement

Due to LDC graduation, benefits from reverse engineering will be lifted. Hence, Bangladesh will start to phase out the preferential treatment criteria due to no longer being a low-income country.

The main global enactment working with intellectual property protection across the member countries is the WTO's agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of 1994. According to this agreement, developing countries are exempted from product patents and waivers on drug production. In Bangladesh, using the benefits of this agreement, the pharmaceuticals sector has developed gradually.

The flexibility of the TRIPS agreement will be effective for the LDCs till July 1, 2034. When Bangladesh will be graduated in 2026 from the LDC status, the benefit of the World Trade Organization (WTO) waiver from the Agreement on Trade-Related Aspects of International Property Rights (TRIPS) will be discontinued which connotes that the countries which cannot produce medicines themselves would have to fully rely on the import under mandatory licenses.

Moreover, the fees imposed for intellectual property on the import of APIs and raw materials for drugs and medicines will go up might create an ambivalent impact on our API as well as the pharmaceuticals industry.[8]

2.4.2 Absence of expertise in the relevant field[9]

The skill gap has become a vital issue in terms of comparing others. The capacity the domestic manpower has become a crucial factor for value addition in the pharmaceutical sector. The country much is relied on the formulators and experts from our neighboring countries, especially India. The prerequisite of sustaining this sector in the upcoming future requires an intensive focus on R&D. And our country has limitations on this side.

2.4.3 Reliance on the local market

The waiver from the TRIPS agreement was mainly to facilitate the LDCs to give scope to enter the global market as the production of drugs and medicines are dependent on the intellectual property rights issue. This facility also qualified the local producers to exhibit generic medicines at a very cheap price which is responsible for the growth of the local industry. Also, the producers find it convenient to sell the medicines in a certain domestic market and make a profit rather than selling the products in a highly regulated market. This type of facility

[8] https://www.lightcastlebd.com/insights/2021/08/active-pharmaceutical-ingredient-api-manufacturing-the-next-growth-driver-of-the-bangladesh-pharmaceutical-industry/

[9] Information from KII

encourages the firms in producing generic medicines rather than invest in technologically commencing industries like the API industry. [10]

2.4.4 Backward linkage

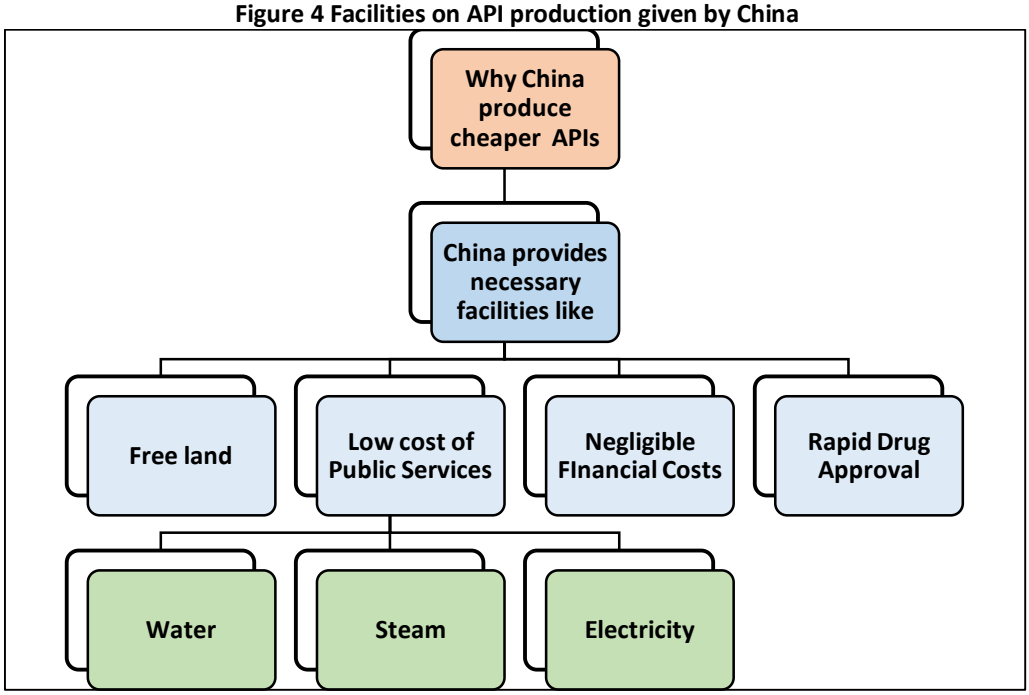
The absence of a strong backward linkage industry (including the API industry) can be responsible for attracting larger markets globally. In India, all the leading exporters produce their APIs while Bangladesh is still largely dependent on the import from China and India for producing the final products.[11] At present, the domestic production of local APIs carries out a 20% share while the rest of the 80% is imported from neighbouring countries like India, and China.[12]

2.5 Deviation from the International Practices (By Comparators)

2.5.1 China's Pharmaceuticals Industries at a glance

The API industry of China is well known for its cheap rate around the world which is one of the leading raw material manufacturing countries. China has taken remarkably convenient measures to improve and take lead in this particular industry. Support has been provided by the government through various initiatives such as low-cost funding, active public funding models tax incentives, etc. The Financing cost of China range from 6 to 7%, moreover facilities such as the low cost of water, steam, and electricity attract investors in this industry (Vyas, N., et al., 2020). Figure-4 shows the reason behind the cheap production cost of APIs in China.

Figure 4 Facilities on API production given by China



Source: (Vyas, N., et al., 2020)

[10] Information from KIIs

[11] https://thefinancialexpress.com.bd/trade/backward-linkage-lag-inhibits-export-of-pharma-products-1550286458

[12] Mohiuddin, A. K. (2019). AN AZ of Bangladesh pharmaceutical industry. *Marketing Research*, *1*, 2.

There is an extensive dependency on China's APIs in the global market economy as well as the pharmaceuticals industry worldwide. Table- 3 shows the global distribution of Chinese API exports around the globe and the top countries are also listed here with the main products they are importing.

Table 3 Global distribution of Chinese API exports[13]

Country	Sum Share (%)	Main Products
United States	20.22	Vitamins, amino acids, sweetening agents
India	8.88	Antibiotics, hormones
Germany	8.43	Antibiotic vitamins
Japan	7.12	Enzymes, amino acids, activated carbon
Netherlands	5.15	Vitamins, amino acids, antibiotics
Korea	4.15	Antibiotics, Sulfamido, Natural extracts
Belgium	3.61	Vitamins, amino acids, organic acids
Spain	3.19	Vitamins, amino acids, antibiotics
Italy	3.07	Antibiotics, hormones, citric acid
UK	2.32	Vitamins, amino acids

Source: www.pharmaexcil.com

2.5.2 India's Scheme for promotion of domestic manufacturing of critical KSMs/ DIs / (APIs)[14]

In terms of volume, the pharmaceutical industry of India is the third-largest globally. Moreover, 3.5% of total drugs and medicines are exported from India worldwide. Although India relies on the import of pharmaceuticals raw materials are imported heavily. That's why the government of India has introduced a scheme which is known as the Production Linked Incentive (PLI) Scheme for the promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India. On October 29, 2020, the Government of India published guidelines. To decline the dependency on the import of raw materials, the scheme has been established to provide financial incentives to the selected applicants for the eligible products. The following table highlights some key points regarding the incentives and takeaways for Bangladesh.

[13] This information was collected from:
https://www.ijper.org/sites/default/files/IndJPhaEdRes_54_4_835_0.pdf
[14] https://plibulkdrugs.ifciltd.com/docs/BD%20Guidelines.pdf

Table 4 Guidelines for the Production Linked Incentive (PLI) Scheme for Promotion of domestic manufacturing of Critical KSMs/ Dis/ APIs in India

Topic	Highlights	Take away
Definitions	**Empowered Committee (EC)**: A committee constituted by DoP and comprising of the following members: CEO, NITI Secretary, Secretary, Secretary, Secretary, Secretary, Secretary, Aayog (Chairman) Department of Pharmaceuticals Department of Chemicals and Petrochemicals Department for Promotion of Industry & Internal Trade Department of Commerce Ministry of Environment, Forest and Climate Change Department of Health & Family Welfare **Greenfield Project:** Project(s) wherein investment equal to or more than the threshold investment is proposed to be made by the applicant under this Scheme in a new production facility or a new plant on the premises of an existing production facility. Separate records shall however be maintained for the new plant(s) on the premises of an existing production facility for the Scheme. **Key Starting Material (KSM):** A raw material, intermediate, or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement, or produced. **Target Segment:** Target Segment shall mean one of the four segments viz.: Key Fermentation based KSMs I Drug Intermediates ii. Niche Fermentation-based KSMs/ Drug Intermediates I APIs iii. Key Chemical Synthesis based KSMs / Drug Intermediates iv. Other Chemical Synthesis based KSMs I Drug Intermediates / APIs	• Inclusion of the definitions such as empowered committee, Greenfield project, KSM, target segment, etc. • Specification of the eligible products for the scheme. • The applicant should have a minimum annual production capacity/threshold investment for eligible products under the scheme. • Providing documents /certificates a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, and purchase agreements in respect of the cost of technology, Intellectual Property Rights (IPRs), patents, and copyrights.
Eligibility	4.1.4 The applicant should not have been declared as bankrupt or wilful defaulter or defaulter or reported as fraud by any bank or financial institution or non-banking financial company. 4.2.2 A selected applicant will have to separately meet the eligibility criteria of minimum annual production capacity and threshold investment for each of the eligible products, for which approval has been granted under the Scheme.	
Investment for determining eligibility	6.2.1 Expenditure incurred on new Plant, Machinery, and Equipment as defined in Clause 2.20.1 of these guidelines shall be considered as an Investment for determining eligibility under the Scheme.	

Topic	Highlights	Take away
	6.3.2 The applicant shall provide a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, and purchase agreements in respect of the cost of technology, Intellectual Property Rights (IPRs), patents, and copyrights	• Eligibility to apply for more than one product if the applicant has that capacity and for each eligible products, and separate fees for each products. • Regardless the minimum bar, the applicants may produce more than the minimum amount of production if they can. • Specification of own domestic manufacturing sites. • Establishment of a project management agency (PMA) for regulating the state and progress of the applicants. • Inclusion of online portal for the application which will be maintained and regulated by PMA. Moreover, upon the successful submission, unique Application ID for the
Application	7.3 An applicant can apply for more than one eligible product. However, a separate application along with the application fee is required to be submitted for each eligible product. 7.4 An applicant may commit annual production capacity higher than the minimum annual production capacity. However, the capacity committed shall be in whole-number multiple of the minimum annual production capacity, along with the commitment to invest the corresponding multiple of threshold investment, as specified in Appendix B. For example, in the case of Penicillin G, the minimum annual production capacity eligible for the incentive is 5,000 MT and the threshold investment is Rs. 400 crores. An applicant may commit 10,000 MT annual production capacity along with the commitment to invest Rs. 800 crores. 7.5 An applicant shall specify its own other domestic manufacturing sites, if any, used to manufacture KSMs/Dls, which are proposed to be used by the applicant for the manufacture of eligible products.	
Online portal	8.1 All applications will be submitted through an online portal maintained by the PMA. In case, the portal is not available, applications may be submitted in physical form to the PMA. 8.2 Upon successful submission of an application, PMA will issue a unique Application ID to the applicant for all future references about the Scheme. 8.3 Application can be made on the online portal	
Project Management Agency (PMA)	9.1 The Scheme will be implemented through a Project Management Agency (PMA) which will be responsible for providing secretarial, managerial, and implementation support and carrying out other responsibilities as assigned by the DoP from time to time. 9.2 The PMA shall be responsible, inter alia, for: i. Receipt of application, examination and processing of applications, and issuing acknowledgments.	

Topic	Highlights	Take away
	ii. Fortnight submission to DoP, the status of applications received and processed under the Scheme. iii. Making appropriate recommendations to the Empowered Committee (EC) in line with Annexure 3 for approval of applications under the Scheme Verification of thresholds for determining eligibility for disbursement of incentive. iv. Examination of claims for disbursement of incentive and making appropriate recommendations to the EC. v. Verification of the reconciliation of disbursement claims with prescribed documents. vi. Compilation of data regarding progress and performance of the Scheme through Quarterly Review Reports as per Annexure 5 and other information I documents. vii. Providing secretarial and other support to the TC for carrying out its responsibilities 9.3 PMA may seek inputs from Technical Committee on a technical issue related to the Scheme, as may be deemed necessary. 9.4 The PMA may request additional information, details, and documents from the applicant as deemed necessary. 9.5 The PMA will have the right to carry out a physical inspection of an applicant's manufacturing units and offices through a site visit.	applicants that will be issued by the PMA. • Inclusion of 8 physical inspection rights to the manufacturing sites, units for PMA. • Establishment of Technical committee, empowered committee comprised by the Department of Pharmaceuticals or relevant authority of Bangladesh. • The technical committee should be comprised of skilled personals relevant to the specific sector such as person form govt. organization having the insights and knowledge on API/DI/KSM, experienced person, experienced in regulating API industry, expert on R & D/ manufacture.
Technical Committee(TC)	10.1 A Technical Committee constituted by the DoP will assist the Empowered Committee in discharging its functions. TC will also give its comments on any technical matter referred by DoP. The composition of the committee is as given below: i. One person, from a Government organisation, knowing in the manufacture of API/DI/KSM and or experience in the regulation of the API industry. ii. One representative from CSIR with knowledge in the process development / R&D / manufacture of API. iii. Two experts having knowledge and experience in the process development /R&D / manufacture of API (New technologies) from relevant institutions (NIPER, llSc, lIT, CCMB, NCL, or similar institutions).	

Topic	Highlights	Take away
Empowered Committee (EC)	11.1 The EC shall meet as often as necessary to ensure timely consideration of applications and disbursement claims and conduct periodic reviews of the Scheme. 11.2 The EC will consider applications, as recommended by the PMA for approval under the Scheme. The EC may seek such additional information, as considered necessary for approval 11.4 The EC will conduct a periodic review of selected applicants concerning their investment, employment generation, and production under the Scheme. 11 .5 The EC will consider claims for disbursement, as examined and recommended by the PMA, for disbursement of incentives. 11.6 The EC may carry out any amendments in the Scheme and these guidelines except revising the incentive rates, ceiling, or eligible products. 11.7 In case of a Force Majeure Event, the EC may amend, modify or withdraw any Clause under the Scheme.	• Separate approval letter for the applicants who have applied for more than one eligible products. • FInalisaton of the application within 90 days from the closing date of the application. • Providing authority to the Ec for conducting periodic review of the applicatnts who are approved under the scheme and to monitor their investment, employment generation and the production. • Inclusion of budgetary provisions for disbursing the incentives by PMA should be made by relevant authority based on the requirements of PMA on quarterly basis. • Specification of the rate of incentives based on the Fermentation based
Approval under the Scheme	12.4 All the applications will be finalized within 90 days from the date of closure of the application window. 12.7 The bank guarantee will be released once 90% of the committed investment in the project is made. 12.8 The bank guarantee will be invoked and an approval letter will stand withdrawn if the following timelines and the corresponding investment schedule are not strictly adhered to from the date of issuance of the approval letter: i. Not more than 10% of the committed investment is made within 180 days ii. Not more than 30% of the committed investment is made within 365 days iii. Not more than 90% of the committed investment is made within 720 days 12.9 In case, an applicant is selected for multiple eligible products, separate approval letters will be issued for each eligible product.	

Topic	Highlights	Take away
	12.11 If a selected applicant is found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines, etc. of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason, the envisaged incentive claim of such selected applicant shall be forfeited and the bank guarantee shall be invoked (if not released in line Clause 12.7), and the offer letter issued shall stand canceled. In such a case, the offer shall be extended to the waitlisted applicant for the period remaining.	products: and Chemically synthesized products. • Inclusion of provision for the applicants in case they fail to meet up the requirements.
Post Approval	13.1 PMA shall monitor the progress of the project made by the selected applicant as and when required concerning the investment committed. 13.2 The applicant shall complete the investment as stated in the project report before commercial production. The applicant shall be eligible for the incentive only after investing the entire investment committed and after setting up the entire committed annual production capacity, as per the approval letter. 13.3 PMA shall monitor the rollover of the bank guarantees and shall take timely action for releasing/ invoking the bank guarantees as per these guidelines.	
Calculation of incentive	14.2 The annual incentive to be disbursed to the applicant shall be subject to the ceiling of the annual incentive, as stated in the approval letter. 14.3 The sale price quoted in the application form shall be a maximum price on which the applicant can claim incentive and shall remain fixed throughout the tenure of the Scheme. However, it is clarified that the price quoted by the applicant is only for the calculation of incentive and there are no conditions I restrictions under these guidelines on the actual sale price of the eligible product. 14.4 (g) Rate of incentive: I. Fermentation based products: • FY 202 3-2024 to FY 2026-2027: 20%, • FY 2027-28: 15% and • FY 2028-29: 5% II. Chemically synthesized products: FY 2022-2023 to 2027-2028: 10%	

Topic	Highlights	Take away
Disbursement of incentive	15.2 An applicant may submit a claim for disbursement of incentive only on a half-yearly or annual basis that is for the sales made from April to September and October to March or April to March. Claims for any period shall be made only once unless withdrawn, and no subsequent party claims shall be allowed for the said period. 15.4 Claims for disbursement of incentive shall be filed by the applicants within 9 months from the end of the financial year to which the claim pertains. 15.5 The PMA will examine the disbursement claims as submitted by an applicant. The PMA shall verify eligibility and assess incentive payable to an applicant based on the method laid down in these guidelines and the approval letter issued to the applicant. The applicant is required to submit the calculation of Domestic Value Addition with every claim, along with a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable. 15.10 The PMA shall disburse funds after completion of all pre-disbursal formalities by the applicant and approval from EC. 15.13 The PMA shall verify the aforesaid reconciliation. In case of excess claims disbursed, the applicant shall reimburse DoP for any incentive amount refundable along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually (for the period between excess payment and date of refund by the applicant). 15.15 DoP shall make budgetary provisions for disbursal of incentives by the PMA under the Scheme. The PMA will submit budgetary requirements to the DoP as a consolidated amount quarterly.	
Review	16.1 Periodic reviews will be undertaken by the Empowered Committee (EC) with respect to the progress and performance of the Scheme. 16.2 All approved applicants shall be required to furnish self-certified Quarterly Review Reports (QRRs) within 30 days from the end of each quarter in the format provided in Annexure 5 of these guidelines.	

Topic	Highlights	Take away
Residual	17.1 An applicant shall intimate the PMA of any change in the shareholding pattern during the tenure of the Scheme, after updating with the Registrar of Companies (RoC). 17.2 Any change in the shareholding pattern of an applicant leading to a successor-in-interest during the tenure of the Scheme, shall be intimated by PMA for approval of the EC to consider for disbursal of incentives. 17.5 To obviate any malpractices in the financial matters where disbursements are made to the industry by the Government, it has been decided to provide a deterrent against corrupt practices for the promotion of transparency and equity. Therefore, keeping in view the sensitivities involved in the process and taking a cue from the instructions of the Central Vigilance Commission regarding the adoption of an Integrity Pact in the matter of procurement, it has been decided to obtain undertaking(s) from applicants under the Scheme.	

Source: Compiled byAuthors from Guidelines for the Production Linked Incentive (PLI) Scheme for Promotion of domestic manufacturing of Critical KSMs/ Dis/ APIs in India

2.5.3 Korea's Pharmaceuticals Affairs Act[15]

The Pharmaceuticals Affairs Act of Korea was enforced on July 16, 2019, and was partially amended on January 15, 2019.

Table 5 Pharmaceuticals Affairs Act

Topic	Highlights	Takeaways
The Pharmaceutical Association and the Oriental Pharmacy Association	Article 11 (The Pharmaceutical Association) 5) The Pharmaceutical Association shall establish the Ethics Committee to deliberate and decide on requests for revocation of a license or suspension of qualifications prescribed in Article 79-2.	• Formulation of an Ethics Committee by the Pharmaceuticals Association and the matters regarding operations and organisation of the Ethics Committee will be guided by the

[15] *Statutes of the Republic of Korea*. (2019b). https://elaw.klri.re.kr/. https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG

Topic	Highlights	Takeaways
	(6) Matters regarding the organization, operation, etc. of the Ethics Committee shall be prescribed by Presidential Decree Article 15 (Training and Education) (1) The Minister of Health and Welfare may order pharmacists and oriental medicine pharmacists to undergo training and education for the improvement of their qualities. (2) Matters necessary for training and education under paragraph (1) shall be prescribed by the Ordinance of the Ministry of Health and Welfare Article 17 (Subsidisation) Where the Minister of Health and Welfare deems that programs of the Pharmaceutical Association or the Oriental Pharmacy Association are necessary for the improvement of national public health, or orders or entrusts such Association to conduct education, investigation, and research concerning pharmacists or oriental medicine pharmacists, he or she may fully or partially subsidize necessary expenses.	Ministry of Health. • The relevant ministry of the government may order training and education to improve the qualities of the relevant stakeholders of the sector. • Govt can take programs that deem essential for the improvement of the research concerning the pharmaceuticals sectors and may fully or partially subsidise the necessary expenditures. • Inclusion of impact assessment to measure the progress of the sector. • Disclosure of the necessary information upon the request from the relevant authority from the government. • Publishing the result after the impact assessment procedure. • Assigining pharmaceutical inspectors and the qualifications should be mentioned by the relevant authority.
Manufacturing Business of Drugs	Article 31-2 (Registration of Drug Substances) (1) A person who intends to manufacture and distribute a drug substance of a new drug or a drug substance determined and publicly notified by the Minister of Food and Drug Safety may file for registration of the matters prescribed by Ordinance of the Prime Minister, such as its ingredients, name, and manufacturing method, with the Minister of Food and Drug Safety, as prescribed by the Ordinance of the Prime Minister.	
Impact Assessment	Article 50-11 (Impact Assessment) (1) The Minister of Food and Drug Safety shall analyze and assess the impact	

Topic	Highlights	Takeaways
	of the matters prescribed in this Chapter, such as the prohibition of distribution and permission for preferential distribution of items under Article 50-6, on the domestic pharmaceutical industry, health policies, fluctuations of employment, etc. Where deemed necessary for the impact assessment referred to in paragraph (1), the Minister of Food and Drug Safety may request the relevant administrative agencies, education and research institutions, etc. to provide necessary data. In such cases, the heads of the relevant administrative agencies, education, research institutions, etc. upon receipt of the request for the provision of data shall comply therewith unless there is a good cause. (3) Where the impact assessment is conducted pursuant to paragraph (1), overseas cases shall be analyzed. (4) The Minister of Food and Drug Safety shall disclose the result of the impact assessment conducted under paragraph (1) and report it to the National Assembly. (5) Matters necessary for the standards, methods, procedures, etc. for the impact assessment referred to in paragraphs (1) through (4) shall be prescribed by Ordinance of the Prime Minister.	• Government may designate institutions or organizations with appropriate personnel, facilities, etc., such as universities and research institutions, as a professional training institution and have them provide necessary education and training.
Supervision	Article 78 (Pharmaceutical Inspectors) (1) Pharmaceutical inspectors shall be assigned to the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, or Sis/Guns/Gus (Gus refer to	

Topic	Highlights	Takeaways
	autonomous Gus of the Special Metropolitan City and Metropolitan Cities) in order to perform the duties of pertinent public officials under Articles 69 (1) and 71 (2). (2) Pharmaceutical inspectors shall be appointed by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the Mayor/Do Governor, or the head of a Si/Gun/Gu from among the members of the Ministry of Health and Welfare, the Ministry of Food and Drug Safety, Cities/Dos, or Sis/Guns/Gus. (3) Qualifications and appointment of pharmaceutical inspectors and other necessary matters shall be prescribed by the Ordinance of the Prime Minister following consultation with the Minister of Health and Welfare	
Supplementary Provisions	Article 83-2 (Training of Professional Personnel) (1) For the enhancement of national health and the promotion of the pharmaceutical industry, the Minister of Health and Welfare and the Minister of Food and Drug Safety shall endeavor to train professional personnel. (2) In order to train professional personnel prescribed in paragraph (1), the Minister of Health and Welfare and the Minister of Food and Drug Safety may designate institutions or organizations with appropriate personnel, facilities, etc., such as universities and research institutions, as a professional training institution and have them provide necessary education and training, as prescribed by Presidential Decree.	

Topic	Highlights	Takeaways
	(3) The Minister of Health and Welfare and the Minister of Food and Drug Safety may fully or partially subsidize expenses incurred in training for the professional training institutions designated pursuant to paragraph (2) within budgetary limits, as prescribed by Presidential Decree. (4) Standards, procedures, etc. for designation of professional training institutions under paragraph (2) shall be prescribed by Presidential Decree	

Source: Compiled by Authors from various sources

3. The National API Policy 2018 and Relevance to the SHE Trades

One of the acquainted words of the present time is women empowerment and the struggle for women empowerment has been discovered in several sectors and this case is visible in a developing country like Bangladesh. Several policies have been formulated to put forward women of our country. According to the data of the World Bank (2020), 49.445% of the total population is women which means half of the population of our country is women. So for inclusive growth and development participation of women in trade and trade-related activities are indispensable for the context of Bangladesh. The policies should be focused on targeting this half of the population.

The National Active Pharmaceuticals Ingredients and laboratory reagent production and export policy were formulated in 2018 to enlighten the potential new export sector in Bangladesh. The policy is well written and crafted and it is not a gender-biased policy. The main aim of this policy is to flourish a new export sector in Bangladesh to diversify the export basket of this country. The provisions of this policy are neither gender-discriminatory nor women-friendly. In the case of employment in the pharmaceuticals sector, it has been found that a lot of women are working in the pharmaceutical industry such as quality control department and R & D. In case of the entrepreneurship in the API industry the number is not that significant. Several provisions might be included to facilitate women's entrepreneurship such as easing the funding opportunities for women and creating awareness about this policy for women's inclusion in this sector.

4. Findings of the Study[16]

4.1 Shortage of Skilled Manpower

There is a lack of technical experts and leaders who can lead the sector. There is a lack of soft skills, such as communication skills, leadership skills, and so forth. Science graduates are expected in this sector. There is a gap on both sides as qualified students are not getting their expected jobs and as well as on the other side the industrialists are not finding their expected workers. In Bangladesh, in terms of pharmacy education, three types of education are available which are a university degree, a diploma, or a certificate. Although it has been found that in Bangladesh the pharmacy education of Bangladesh is not up to the mark. (Alam, Shahjamal, Al-Amin, & Azam, 2013). That is why there is a shortage of skilled manpower and expertise in this sector.

Moreover, there is a relationship between skills and salary. Skilled workers demand better payment. There is also a lack of on-job training programs for the laborers. Moreover, as several training programs are expensive hence the small and medium industries cannot be able to afford them.

Though there is an opportunity for the female workers the rate of participation is lower than that of male workers due to the unfavorable socio-economic circumstance.

4.2 Insufficient API Firms

For developing a sector adequate numbers of firms are required though only 15 local companies in Bangladesh are currently producing APIs. Around 40 APIs are produced by the top API producing firms in Bangladesh which are Square Pharma, Beximco Pharma, Active Fine, ACI Limited, Globe Pharma, Gonoshasthaya Pharma, Opsonin Pharma, Drug International, and Eskayef. Only Active Fine doesn't generate finished medicine and is an expert in the manufacturing of the APIs among others.[17]

4.3 Inadequate Focus on the Industry-Related Study

There is a gap between the curriculum and the industry-related issue. The syllabus of the curriculum doesn’t perfectly fit the industry level. The modification of the existing curriculum is essential for the growth of this technically advanced sector.

4.4 High Production Cost for Producing Molecules

Production of a molecule requires a lot of time and effort. Moreover, a huge sum of money is needed to produce a single molecule. It takes about three billion dollars to produce one molecule. The high production cost often discourages the firms to invest in this purpose.

[16]Information from KIIs and FGDs

[17]https://www.lightcastlebd.com/insights/2021/08/active-pharmaceutical-ingredient-api-manufacturing-the-next-growth-driver-of-the-bangladesh-pharmaceutical-industry/

Furthermore, technologically skilled manpower is also required for this purpose and Bangladesh does not have that many skilled human resources for this.

4.5 Shortage of experts from the domestic side

The production of API requires skilled manpower as this requires technical expertise. Due to a lack of technological assistance, and skilled manpower it is quite difficult to produce APIs. There is a lack of skilled manpower due to a lack of knowledge and appropriate curriculum at the university level. To address the challenges that emerged due to the fourth industrial revolution there is a lack of skilled manpower.

4.6 Implementation issue

There are several implementation challenges. The lack of coordination connectivity and effective dialogue between the industrialists and the relevant authority is absent. Moreover, there is a lack of monitoring and regulatory bodies for the implementation process. Specific committees and authorities are needed to smoothen up the implementation process.

4.7 Lack of Cooperation between Govt and Industries

Cooperation is essential for a better outcome. Government alone cannot initiate and flourish the sector with the policy. The lack of cooperation between the government and the industries hampers the growth and development of this sector.

4.8 Construction of API Park

The project of API park got approval in 2008 In the Executive Committee of the National Economic Council (Ecnec), the project API park got approval 2008 still didn't come to light as it was expected. The location selected for this API park is Munshiganj comprising 42 plots with 200 acres of land. Some of the leading companies secured their plots in the API industrial park such as Beximco, Square, Incepta, and Acme. The construction plan includes several infrastructural development and facilities such as CETP, waste dumping yard, etc

4.9 Lack of Knowledge of API Policy

Although there is an existing API policy, the majority of the relevant stakeholders are not aware of the objectives and outcomes of the policy. The majority of the stakeholders are much more concerned about producing the drugs rather than the raw materials of the drugs and medicine.

4.10 Challenges after LDC Graduation

After LDC graduation, several challenges will emerge, such as a burden for the consumers as the price of medicine will increase which will eventually increase the health expenditure. The waiver for patented medicine will be excluded after 2032. This will cause a great obstacle in this industry and the growth of this sector will be shunned. Although the policy was

formulated back in 2018 to accelerate the growth and development of this sector the production cost of manufacturing API is relatively cheaper than in India and China.

5. Recommendations and Way Forwards

This is incontrovertible that the policies of Bangladesh are eminent in terms of crafting. And the National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018 is of no difference. While formulating the policies, tremendous efforts, interlocution, and opinions from the relevant stakeholder were kept in mind. This policy was formulated back in 2018[18].

The policy has been formulated in 2018 by targeting the year 2032. This policy will be valid till 2032. Different economic changes have been observed in these years, so a follow-up by reviewing the existing policy has become the demand for the time. Various issues and anomalies have been brought to light. The whole world is moving forward with technological advancements such as 4IR that will create new challenges for Bangladesh. To keep up the pace with the global context, it is necessary to revise the policy.

Diversified issues have been unfolded with the comprehensive desk research, in-person interviews, meetings, and interlocution with extensive desk research, meetings, and consultation with relevant stakeholders. The goal and objective of the policy are consistent with the present era through the problems that lie in the evolvement and implementation.[19]

Moreover, the insignificant number of API-producing firms and lack of skilled manpower protract from achieving the ultimate objectives. The policy is itself gender inclusive but the provisions are not non-discriminatory at all. Specific provisions focusing on the empowerment of women in this leading sector might be added up in the upcoming policy. As half of the population of our country is women, the country cannot go forward without the active participation of women in trade-related activities.

Based on the findings which have been gathered from the KIIs and FGDs, this chapter will provide some recommendations for the upcoming National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018.

[18] National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018
[19]Information from KII with stakeholders

5.1 Focus on the industry-related study

Academicians and industrials should work together in developing the curriculum. As there is a mismatch between the curriculum and the work field of this sector.

5.2 Capacity building in human capital

Since there is a shortage of skilled human resources in this sector, the industrials are hiring experts from abroad to maintain the activities. A huge amount is remitted every year from our country. Capacity-building programs should be introduced to ameliorate the labor force of the home country so that a huge volume of money will stay in our economy.

5.3 Support from the government side

Cooperation and coordination among both stakeholders are mandatory to thrive in a sector. But the main lead should be taken by the government. The government of Bangladesh has been working reluctantly for the development of the country and the flourishing sectors, which includes the formulation of several policies to develop specific sectors. Indeed the formulation and provisions of the National API policy 2018 is the reflection of tremendous velocity, the government should regulate and monitor the implementation of the policy and follow up on the progress.

5.4 Assigning Regulatory Body from Public and Private Sector

The formulation of the policy shows the true endeavor of the government in the development of the pharmaceuticals and API industries. But appropriate implementation is required for the improvement of this sector proper monitoring and regulation are needed to follow up on the progress. The government should assign regulatory authority both from the public and private sectors to maintain the balance.

5.5 Incentive for Research and Development

Government should provide cash incentives for the research and development for the elevation of the API and pharmaceuticals industries. Bangladesh Association of Pharmaceutical Industries (BAPI) and the Directorate General of Drug Administration (DGDA) might work collaboratively on the formulation for research and development of API and pharmaceutical industries. The government might provide cash incentives for this purpose.

5.6 Establishment of API Parks

After 2032, according to the TRIPS Agreement, the waivers on patented products will be ceased and Bangladesh will lose the advantage as it would raise the cost of import raw materials and

APIs. The API Park must be fully functional as early as possible to stave off the challenges of the rising cost.

5.7 Extending the TRIPS Flexibility

Bangladesh might work on the negotiation power in trade-related activities, as flexibility of TRIPS waiver will be ceased in 2032. The country should pursue augmentation of the flexibility of TRIPS as it might help to minimise the cost for a while and add up a while for preparation.
Opportunities to use the Maldives precedent for extension of the transition period exist as Maldives had received a two-year general extension from the TRIPS Council in 2005

Table 6, on the next page, provides a detailed recommendation matrix for future policies.

Table 6 Recommendation Matrix for National API Policy

Chapter	Stated Provision in National Digital Commerce Policy 2018		Unchanged	Proposed Extension	New inclusion
Chapter One Headline	This policy will be entitled the ''National Active Pharmaceutical Ingredients (API) and laboratory Reagents Production and Export Policy''		Yes	N/A	N/A
Chapter Two Objectives of the Policy	2.1 The **Desired Goal** Achieving the highest possible production capacity in the API and laboratory reagent manufacturing sector by 2032, taking full advantage of the benefits of the TRIPS Agreement, and implementing the SDG's third goal (Good Health and Well-Being for People) and export diversification targets outlined in the 7th Five-Year Plan.		Yes	N/A	N/A
	2.2 **General Objective** Reducing import dependence through the development of API and laboratory reagent sector and meeting domestic demand and increasing export through the production of API and laboratory reagent locally by creating a competitive market.		Yes	N/A	N/A
	2.3 Particular Objective	2.3.1 Reduction of import dependence on API and laboratory reagent sector, increase in the production, and diversification of export.	Yes	N/A	N/A
		2.3.2 Assurance of entrance of new investors in the API and laboratory reagent sector within 2022 and promotion of the foreign investment to additional one billion dollars. Also bringing the necessary technology and additional impact.		Assurance of entrance of new investors in the API and laboratory reagent sector within 2024.	
		2.3.3 To make the production cost of API and laboratory reagents in Bangladesh competitive in the international market. Significant reduction in	Yes	N/A	N/A

Chapter	Stated Provision in National Digital Commerce Policy 2018		Unchanged	Proposed Extension	New inclusion
		imports of API and laboratory products by 2032 and ensuring the supply of quality API and laboratory reagents produced in the country at affordable prices.			
		2.3.4 Achievement of production capacity of more than 370 Lifesaving API molecules approved by the Drug Master File (DMF) and vital for export to advance production locally.	Yes	N/A	N/A
	2.4 Administrative objective	2.4.1 Increasing the contribution of API and laboratory reagents to GDP from 0.0121% in 2016 to 0.025 by 2032.	Yes	N/A	N/A
		2.4.2 Enhancement of the number of locally produced API molecules and laboratory reagents from 41 in 2016 to 125, 230, and 370 by 2021, 2028, and 2032 respectively.	Yes	N/A	N/A
		2.4.3 Reduction in the dependency on imports from 97% in 2016 to 80% in 2032	Yes	N/A	N/A
		2.4.4 Raising the export from 1.5 lakh in 2016 to nine lakh dollars in 2032.	Yes	N/A	N/A
		2.4.5 Creation of opportunities for 500,000 jobs in this sector in 2032	Yes	N/A	N/A
Chapter Three Implementation Strategy	3.1 Expenditure on research and development of at least 1% of the annual turnover of all API and laboratory reagent producers for the expected molecular production.		N/A	N/A	• Support from government in training and skill development program to train up the people of relevant sector

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	3.2 For the next five years from FY 2017-18, all registered (domestic and joint venture) API and Laboratory Vendor manufacturers in Bangladesh will get unconditional corporate tax holiday benefits, but after FY 2021-22, this facility will be provided only based on capacity. For this purpose, two groups will be created for measuring the capacity: **Group A:** After the surpassed of the first 5 years (after FY 2021-22), registered producers registered (domestic and joint venture) in Bangladesh who will be able to produce at least five molecules per year, will get a 100% corporate tax holiday till 2032. **Group B:** After the surpassed of the first 5 years (after FY 2021-22), registered producers registered (domestic and joint venture) in Bangladesh which will be able to produce at least three molecules per year, will get a 75% corporate tax holiday till 2032.		• Revising the molecule production bar (as it requires much capital to produce) • For group A, the extension of the period to 2022-23 and 3 molecules per year with a 100% corporate tax holiday • For group B, the extension of the period to 2022-23 and 2 molecules per year with an 80% corporate tax holiday	
	3.3 Exemption from AIT (Advance Income Tax) and TDS (Tax Deduction at Source) till 2032	Yes	N/A	N/A
	3.4 20% cash incentive will be provided for the export of registered API and laboratory reagent producers (domestic and joint venture) in Bangladesh; In this case, minimum 20% value addition is required. However, after 2026, the government may review the issue of value addition.	Yes	N/A	N/A
	3.5 Source inspection and quality audit of imported APIs and laboratory reagents should be made mandatory in the same way as domestic API and laboratory reagent		N/A	Source inspection and quality audit of potential exported

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	manufacturers are subject to source inspection and quality audit. The objective of this source inspection and quality audit is to assure GMP is in the top 20 laboratory reagents.			APIs and laboratory reagents should be made mandatory to maintain the quality of the products and sustainability in the global market.
	3.6 VAT and VDS waiver on purchase and sale of API and laboratory reagents, all types of raw materials, fixed assets, and other goods, services, and products produced by registered manufacturers(domestic and joint venture) in Bangladesh till 2032.	Yes	N/A	N/A
	3.7 Increase the involvement of this industry with academic and research institutes to increase the growth in the industry. Establishment of API and Laboratory Reagents Association and establishment of academic and research institutes with the productive masses under the initiative of this association.			• The public-private partnership may be created for maintaining the productive initiatives
Chapter Four Imposition and Periphery	4.1 The National API and Laboratory Reagent Production and Export Policy will be effective till 31 December 2032. The Government will review and amend this policy from time to time.	Yes	N/A	N/A
	4.2 All the detailed plans for the implementation of this policy should be adopted and followed with the participation of all the concerned Ministries / Departments / Agencies. A high-powered committee will	Yes	N/A	N/A

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	be formed to review the implementation and progress of these policies and plans on a semi-annual basis.			
	4.3 The policy will be applicable in all areas of Bangladesh including the Export Processing Area, Proposed API Park, Bangladesh Economic Zone, and Private Export Processing Area.	Yes	N/A	N/A
	4.4 DGDA's rules/regulations will apply to the production, distribution, supply, purchase, sale, import, and export of API and laboratory reagents.	Yes	N/A	N/A
Chapter Five Payable Incentives	5.1 **Corporate Tax Holiday** 5.1.1 100% Corporate Tax Holiday for FY 2017-18 to 2021-22 for Bangladesh Registered API and Laboratory Reagent Manufacturers. (National Board of Revenue & Ministry of Commerce) 5.1.2 From 2023 to 2032, the API and laboratory reagent manufacturers registered in Bangladesh will be given a corporate tax holiday only based on eligibility. From 2023, those who can produce at least five molecules locally per year will get 100% by 2032 and those who can produce at least 3 API molecules per year will get a 75% corporate tax holiday till 2032. In this regard, the certificate has to be submitted properly as per the overall rules of the Department of Drug Administration. 5.1.3 Bangladesh Registered API and Laboratory Reagent Manufacturers will be given 100% IT exemption till 2032 for the purchase and sale of raw materials and parts.	N/A	• Change of the bar of molecule production • 100% waver for producing 3 molecules • 80% waver for producing 2 molecules. • Relaxation for the time length of the 100% corporate tax holiday period and extending it to FY 2022-23 to attract more API-producing firms.	

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	5.2 **VAT Exemption** 5.2.1 VAT and VDS on purchase and sale of API and laboratory reagent manufacturers registered in Bangladesh will be waived till 2032. 5.2.2 VAT and VDS on purchase and sale of raw materials and parts for API and laboratory reagent manufacturers registered in Bangladesh will be waived till 2032.	Yes	N/A	N/A
	5.3 **Cash Incentive** 20% cash incentive to provide export incentives to registered API and laboratory reagent manufacturers in Bangladesh.			• Assigning a regulatory and monitoring authority from the GoB or affiliated ministry to monitor the production and export-related activities. • Creation of a range for the export volume and classifying the range with a specific percentage of tax.
	5.4 Foreign exchange support 5.4.1 Delay in payment for import of raw materials will be allowed from 180 days to 360 days.	Yes	N/A	N/A

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	5.4.2 Delay in payment for the purchase of equipment will be allowed for 360 days in case of bullet payment and 3 years in case of non-payment, which is applicable in the RMG sector. 5.4.3 Manufacturers of API and laboratory reagents will be able to borrow from foreign funds (offshore) 5.4.4 The mandatory credit report limit for the purchase of spare parts will be increased from the current 10,000 to 20,000. 5.4.5 In the case of factories and machinery, term loans will be allowed for up to 12 years instead of 6 years 5.4.6 API and laboratory reagent producers will be able to keep 40% of their crop as a replacement quota. 5.4.7 Single borrower caps will not be applicable in case of borrowing by API and Laboratory Reagent Sector Banks like Power Sector. 5.4.8 In case of advance payment of outbound remittance, post-facto notification of Bangladesh Bank will be approved 5.4.9 Issuance of BIDA, DoE, and other certificates will be facilitated through fast track			

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	5.4.10 Back-to-back LC facilities like the RMG sector will be provided to encourage the export of API and laboratory reagent manufacturers.			
	5.5 **Easing the Import Process** Blocklist approval and approval of imported chemicals and raw materials (Acid, Acetone, Acetic anhydride, Toluene, Paraformaldehyde) for making API and reagent will be facilitated through fast track.	Yes	N/A	N/A
	5.6 **Provide duty-free goods exemption facility** A duty-Free Discount facility will be provided through undertaking before inclusion in SRO 26A of the National Board of Revenue.	Yes	N/A	N/A
	5.7 **Facilitation of import of raw material samples** API and laboratory reagent manufacturers can import up to 10 kg per molecule (maximum) as the raw material sample for making drugs, valued at up to Tk 10 lakh per molecule (per molecule) annually.		• API and laboratory reagent manufacturers can import up to 15 kg per molecule (maximum) as the raw material sample for making drugs, valued at up to Tk 12 lakh per molecule (per molecule) annually	
	5.8 **Government Procurement** Government Pharmaceutical (Military and civilian) The policy objectives should be reflected in the procurement of API and laboratory reagent products. According to the	Yes	N/A	N/A

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	policy of Government Procurement, priority should be given to those industries which are presently capable of maximizing value addition in the country. In the case of government procurement, there is an urgent need to reduce purchases from existing APIs and industrial companies that rely on laboratory reagent products imported from abroad.			
	5.9 **Prioritizing land allocation** Preference will be given to API and laboratory reagents for allotment of land in government existing and under-implemented industrial parks and economic zones for setting up industrial plants.	Yes	N/A	N/A
Chapter Six Support side	Like the readymade garments and leather sector, Bangladesh has high potential in API and laboratory reagents. API and laboratory reagent production can add more value to the pharmaceutical sector which is much higher than other industries like garments. As a result, there is a possibility of higher income in the API and laboratory reagent sector.	Yes	N/A	N/A
Chapter Seven Risk Evaluation	As one of the least developed drug exporting countries, implementation of this policy will significantly attract foreign direct investment. However, as soon as the TRIPS agreement expires, Bangladesh will no longer be able to take advantage of these foreign investors who wish to invest in Bangladesh, if given a 20% cash incentive on their exports, are expected to bring the necessary knowledge and skills in exchange, which will help us			• Special treatment and facilities may be introduced for foreign venture capital by prioritising joint

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	acquire 370 API molecules in the API sector. To encourage the acquisition of this knowledge and skills, foreign investors must enter into joint ventures with API and laboratory reagent manufacturers in Bangladesh. This joint venture has been made mandatory in this policy opportunity and the rate of foreign investment may fall sharply.			ventures • Priority might be given to foreign investment by establishing more API parks with standard infrastructure.
Chapter Eight Action Plan	1. Mandatory investment in R&D of at least 1% of the annual turnover of API and laboratory reagents and producers and acceptance of certification of invented molecule numbers. 2. Mandatory accuracy testing of all APIs and laboratory reagents and establishment of DTL for quality monitoring. 3. Conduct academic and research activities for the development of API and laboratory reagents 4. Pay 100% corporate tax holiday (AIT and TDS exemption) in the API and laboratory reagent sector. 5. 15% VAT waiver (and VDS) on API and laboratory reagents. 6. Provide a 20% cash incentive on API and laboratory reagent exports. 7. Provide foreign exchange policy assistance 8. Facilitate the import approval process 9. To provide duty-free goods exemption facility			• Establishment of a research centre for fostering academic and research activities • Aligning the curriculum of the university level with industries • Introduction and implementation of skill

Chapter	Stated Provision in National Digital Commerce Policy 2018	Unchanged	Proposed Extension	New inclusion
	10. Facilitate the import of raw material samples 11. Proper implementation of government policies regarding the procurement of drugs, APIs, and laboratory reagents. 12. Priority in allotment of land to API and laboratory producers.			development program for skilled human capital in the pharmaceuticals sector by the government of Bangladesh. (such as the creation of training centers for skilled manpower in API and pharmaceuticals industries)

Source: Authors' compilation from various sources, KIIs, FGDs

6. Conclusion

Several elements are used in producing drug products such as a tablet, capsules, etc, the biologically active component is termed the Active Pharmaceuticals Ingredient (API), which is used for treating and medicating purpose of various diseases related to oncology, cardiology, CNS, and neurology, orthopedic, pulmonology, gastroenterology, nephrology, ophthalmology, and endocrinology. In generating a sustainable healthcare system, APIs can help to produce and introduce unprecedented potential by introducing new drug products.[20]

Since the 80s, the transformation and development of the pharmaceutical sector have been started and over the last four decades, this sector has been booming. The only LDC that has a flourished pharmaceutical sector, is Bangladesh.[21]

By using a mixed methodology, in the end, a thorough review of the National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018 is conferred. Diversified issues have been addressed such as challenges in execution, topicality with the present global context, and trade scenario from desk review, KIIs, and FGDs the National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018. Insights from the global policies (China, India, and Korea) are also compared with the policy of our country. The review has also considered the gender aspect of mainstreaming women traders by the existing provisions of the National Active Pharmaceutical Ingredient (API) and laboratory reagent production and export policy 2018.

Since the policy was formulated back in 2018, the National API and laboratory reagent production and export policy 2018 is a very updated and a time being policy for the pharmaceutical sector. With a view to the flourishment and the ameliorating of the API industry, this policy came to light in 2018. Moreover, it is a more updated policy in Bangladesh, that's why while formulating many issues have been already addressed in the policy and it is well thought out and crafted according to that.

The elemental findings of this policy have pointed out that the provisions of the current policy are pertinent. Since the policy was formulated in 2018, some modifications and changes are required for maintaining the pace to achieve the ultimate goal and objectives of the policy. The intended objectives of this policy are prominent but the successful accomplishment of these objectives will help to sustain the local and the global market. This sector needs to be more prepared and more coordination is needed for the successful completion of the objectives mentioned in the policy. Major drawbacks in implementing the policy are lack of proficient manpower, the insignificant number of API industries, the extensive cost in the production of molecules, insufficient experts/human resources in the sector, poor infrastructure, and lengthening in the construction of API parks, etc.

[20]Biocon. (2021, January 27). *Active Pharmaceutical Ingredient (API)*. https://www.biocon.com/businesses/generics/api-overview/

[21]http://www.bapi-bd.com/bangladesh-pharma-industry/overview.html

Furthermore, the policy was formed keeping in the mind the context of LDC graduation, the current policy doesn't address the present changing trade and business dynamics such covid recovery issue. The necessity of the API in the pharmaceutical industry can be well felt in the scenario of COVID 19. The whole world was suffering and the fate was also the same for Bangladesh. Other countries were trying to come up with the formula for the remedy to the COVID-19. Moreover, the countries that were highly dependent on imports for the raw materials for medicines and drugs suffered a lot and Bangladesh was no exception. Due to the restriction and limitation of API export to the rest of the world, a crisis was observed in producing medicine, the price was hiking due to that. This disaster has taught us the importance of self-reliance in producing the raw materials for drugs also known as active pharmaceutical ingredients. To be a pioneer in this sector Bangladesh needs to work more reluctantly to be self-reliant in this sector and for this purpose in 2018 the National API policy was formulated. Also, the investment in the API industry is not as significant as it was expected to be as the majority are much interested in investing in the production of drugs and medicines by using the formula developed by other nations. Apart from these, the focus on the industry-based study is insufficient in Bangladesh. Also, there is an absence of cooperation between industries and the government reading this.

Against these findings, some specific recommendations have been proposed for the upcoming National API policy. Firstly, as the time limit for graduating from the LDC is shortening, the prior focus should be working on the TRIPS agreement. Bangladesh can seek an extension in the TRIPS flexibility. Secondly, the industry insiders and academicians should work together in developing the curriculums of pharmaceutical-based studies for the evolvement of this sector as there is a gap between the current syllabus pattern and the industrial activities. So, alignment is much needed for advancement in the future. This will also result in the development of human capital in this sector since this sector relies on expert manpower. Thirdly, tracking down the progress of the objectives and the action plan of the policy monitoring and regulation is very crucial. Assigning regulatory bodies both from the public and the private sector might play an indispensable role in this case. Fourthly, for research and development regarding API as well as pharmaceuticals industries, cash incentives might be provided from the government side. The pharmaceuticals association as well as the DGDA can work collaboratively for R&D purposes. Finally, the successful completion of the construction of the API park will propagate the activities not only for API industries but also for the overall pharmaceuticals sector in Bangladesh. The development of the API industries will flourish the pharmaceuticals sector and will reduce the dependency on the imports for raw materials for producing the medicine and will help Bangladesh to be self-reliant on pharmaceuticals in the upcoming future.

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Annexure

List of KIIs

Organisation/Association	Key informant
Representative from EPB	• Ms. Kumkum Sultana, Deputy Director (Policy & Planning Division), Deputy Director (Statistics & Research)-Additional Charge
Industry insiders	• Mr. ABM Jamaluddin (Active Fine Chemicals Ltd.) • Md. Anwar Morsalin (Chief Executive Officer, Gaco Pharmaceuticals Ltd) • Khairul Alam (Deputy Sales Manager, Orion Pharma)
Think Tanks	• Dr. Kazi Iqbal (Senior Research Fellow, BIDS) • Dr. Mozibur Rahman (Former Chairman, BTTC)

Team Composition:

Name of staff	Area of expertise relevant to the assignment	Designation for this assignment	Assigned tasks or deliverables
Dr. Bazlul Haque Khondker	Economist, Institutional analysis expert, Survey expert, FGD and KII expert	Team Leader	Finalize questionnaire, FGD, and KII checklists, Evaluation, and analysis, Draft synthesizing summary, Draft short summaries Finalizing reports
Dr. Selim Raihan	Economist, Political economy and institutional analysis expert, Survey expert, FGD and KII expert	Co-Team Leader, Trade Expert	Coordinating and monitoring the team, monitoring all the activities performed by the team members, finalizing questionnaire, FGD, and KII checklists, Evaluation, and analysis, Draft synthesizing summary, Finalizing reports.
Mahtab Uddin	Policy analysis and evaluation, Survey expert, FGD and KII expert	Policy Analyst	Monitoring all the activities performed by the team members, finalizing questionnaire, Coordinating FGDs and KIIs, Evaluation and analysis, Draft synthesizing summary.
Mohammad Golam Sarwar	Legislative consultant, development law practitioner	Legal Expert	Analysing the legal terms and provisions of the study, identifying the possible grounds for alterations, extensions, and exclusion of current legal provisions, and providing legal recommendations.
Recardo Saurav Antor Halder	Data analyst, Survey Experts	Senior Research Associate	Desk review, analyzing secondary data, designing questionnaires for KIIs, supervising and conducting FGDs, analyzing primary data, and drafting the reports.

Name of staff	Area of expertise relevant to the assignment	Designation for this assignment	Assigned tasks or deliverables
Mir Ashrafun Nahar	Data analyst, Survey Experts	Senior Research Associate	Desk review, analysing secondary data, designing survey questionnaires for KIIs, supervising the survey, conducting FGDs, analysing primary data, and drafting the reports.
Zareen Tasnim	Data analyst, Survey Experts	Research Associate	Research and analysis of relevant literature, primary and secondary data, supervising and conducting KIIs and FGDs.
Afia Mubasshira Tiasha	Data collection and Supervision	Research Associate	Desk Review, developing KII questionnaire, assisting in conducting the KIIs, conducting FGDs.
Shithee Ahmed	Data collection and drafting	Intern	Conducting KIIs and FGDs, and transcripting

SANEM
RESEARCH I KNOWLEDGE I DEVELOPMENT

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