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CONCESSION ON TARIFF GIVEN TO RAW MATERIAL USED IN PHARMACEUTICAL

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ACRONYMS

ACD	Additional Custom Duty
API	Active Pharmaceutical Ingredient
BE	Bioequivalence
CAGR	Compound Annual Growth Rate
CBSCR	Center of Bioequivalence Studies and Clinical Research
CD	Custom Duty
CEO	Chief Executive Officer
CRAMS	Contract Research and Manufacturing Services
CRO	Contract research organizations
DRAP	Drug Regulatory Authority of Pakistan
DTL	Drug Testing Laboratory
ECI	Economic Complexity Index
EU	European Union
FBR	Federal Board of Revenue
FDA	Food and Drug Administration
FED	Federal Excise Duty
GATT	General Agreement on Trade and Tariff
GAVI	Global Alliance for Vaccine and Immunization
GBM	Global Bench Marking
GDP	Gross Domestic Product
GIFF	Growth Identification and Facilitation Framework
GMP	Good Manufacturing Practices
GSK	GlaxoSmithKline
GST	General Sales Tax
HVAC	Heating, Ventilation and Air Conditioning
IP	Intellectual Property
IQVIA	IMS Health-Quintiles
ISO	International Organization for Standardization
IT	Income Tax
LDC	Low Developing Country
MBCO	Manufacturing Bonds Program
MD&MC	Medical Devices & Medicated Cosmetics

MFN	Most Favored Nation
MIS	Management Information System
MNC	Multinational Company
MNHSR&C	Ministry of National Health Services, Regulation and Coordination
MOU	Memorandum of Understanding
MRP	Maximum Retail Price
NCLB	National Control Laboratory for Biologics
NEML	National Essential Medicine List
NLC	National Logistics Cell
NOC	No Objection Certificate
NTB	Non-Tariff Barriers
NTM's	Non-Tariff Measures
OTC	Over-the-Counter
PBC	Pakistan Business Council
PCP	Pharmacy Council of Pakistan
PDTRC	Pakistan Drug Testing and Research Centre
PE&R	Pharmaceuticals Evaluation & Registration
PIC/S	Pharmaceutical Inspection Corporation Scheme
PIRIMS	Pakistan Integrated Regulatory Information Management System
PO's	Procedural Obstacles
PPMA	Pakistan Pharmaceutical Manufacturers' Association
PTA	Preferential Trade Agreement
QA	Quality Assurance
R&D	Research and Development
SBP	State Bank of Pakistan
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authorities
SRO	Statutory Regulatory Order
ST	Sales Tax
TRIPS	Trade-Related Aspects of Intellectual Property Rights
US	United States
USFDA	United States' Food and Drug Administration
WHO	World Health Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The value of the pharmaceutical sector in Pakistan was estimated at USD 3.2 billion in 2020-21, doubling from USD 1.64 billion in 2011. Including institutional sales, the industry is showing that the sector is becoming a retail market worth USD 4 billion. Total imports of Pharmaceuticals for 2020-21 were USD 781 million while total exports stand at USD 235.75 million, up from USD 44.4 million in 2003. Exports to the sector accounted for only 0.9 percent of Pakistan's total exports in 2021. Pharmaceutical sector contribution in GDP is 1.17% while share in FDI is 2.8%. The Industry insiders say exports of the sector could reach USD 0.5-1 billion in about three to five years - after reaching this critical figure, export growth could be strong. This study provides a detailed look on concession on tariff given to the raw material used in the pharmaceutical industry in Pakistan. Typical custom duties on APIs and excipients range from 5 per cent to 25 per cent. On custom duties of 25 per cent, an additional sales tax is also levied despite an absence of a sales tax on the sale of medicines. In addition, an advance income tax of 5.5 per cent of import value is also levied. Import duties on medicines range from 0 per cent to 10 per cent. Medicines for the treatment of cancer, transplants and heart diseases have no custom duty, yet have an advance tax at 5.5 per cent on import value. A comprehensive effort could be launched that could help Pakistan become a cost-effective manufacturer of generic drugs, and transform into more profitable products such as vaccines. However, with stakeholder inputs some policy steps are recommended to improve export situation in Pakistan. The recommendations aim to help the government and private sector to create an enabling environment for private-sector development and improve pharma export competitiveness in Pakistan. Pakistan import almost 90% of pharma raw material, therefore by giving concession on raw material used in pharmaceuticals, Pakistan can increase its exports.

Pakistan imports almost 90% of raw material used in pharmaceutical sector. Pakistan pharmaceutical industry is only able to make up 5% of its APIs locally whereas, the rest of the ingredients are being imported. Low emphasis on research and development by local companies is the major reason behind significant reliance on imported raw material. Nature of APIs and medical devices requires sensitive handling, proper storage and transport facilities. Hence, efficient supply chain is of utmost importance for pharmaceutical companies. Switzerland is the largest exporter of pharmaceutical products to Pakistan followed by Belgium, Germany, China, France, India and Italy. This significant reliance on imported raw material increases the inherent risk of supply chain disruption. However, non-reliance on any single country for imported APIs provides some comfort against potential disruptions in the supply chain. Due to higher imports of raw material from Switzerland, Germany, Belgium, India, China etc. The cost of manufacturing pharma products increases. Pakistan's share in these markets is negligible due to industry's inability to comply with non-tariff barriers, such as US FDA regulations. Currently Getz's pharma has spent PKR 300mn on its manufacturing plant to bring itself compliant with FDA regulations in order to penetrate the US market. As majority of Pakistani companies are unable to comply with FDA regulations, they lose the opportunity to export to USA along with other places in Europe. Pakistan pharmaceutical market has huge structure, but still Pakistan exports minimum quantity to countries like Afghanistan, Srilanka, Philippines, and Vietnam. Linked to quality control, Pakistan must obtain WHO accreditation for its major public laboratories, first through DRAP's National Control Laboratory for Biologics (NCLB), without which, all NCLB testing, registration and extraction of biodiversity is not known worldwide.

CHAPTER 1 AN OVERVIEW OF WORLD PHARMA

1.1 An Overview of Pharmaceutical Sector:

The pharmaceutical industry is responsible for the research, development, production, and distribution of medications. The market has experienced significant growth during the past two decades, and pharma revenues worldwide totaled 1.27 trillion U.S. dollars in 2020-21.

During the COVID-19 pandemic, the focus of pharmaceutical sector was diverted towards viral vectors in the biotherapy and vaccine sectors in delivering effective vaccines and pharmaceutical treatments. After the vaccine, the pharmaceutical sector will return back to pre-COVID projects. Many of these projects will benefit from lessons learned by the sector during the COVID-19 outbreak, helping to speed up their successful development. North America was the largest region in the global pharmaceutical market, accounting for 46% of the market in CY20-21. Asia Pacific was the second largest region accounting for 26% of the global pharmaceutical market. Africa was the smallest region. The manufacturing side of the pharmaceuticals is expected to receive an even greater boost. Aging population in developing countries, amplified focus on elderly and pediatric patients, high incidence of cardiovascular disorders, growing demand for home-based healthcare and increased cancer and diabetes cases are further propelling the pharmaceutical manufacturing expansion across the globe. The global pharmaceutical manufacturing market is expected to garner growth at a noteworthy CAGR of 13% from CY21 to CY30.

The pharma industry is comprised of some major multinational companies. Based on the prescription drugs market, Pfizer is one of the world's leading pharmaceutical companies. The company, which has its global headquarters in New York City, generated total revenues of around 51.7 billion U.S. dollars in 2019, the majority of which was derived from sales of its products. However, the company saw a heavy drop in revenues in 2020, after the spin-off of its Upjohn generics business. Other top global players from the United States include Johnson & Johnson, Merck & Co., and AbbVie.

1.2 Raw Material Used in Pharmaceuticals:

The pharmaceutical industry faces many challenges and has different capabilities, making it stand out at a different level among other types of industries. The Pharma industry requires extreme precision and care in every step from collecting pharma materials to finding a product ready for delivery.

Generally, Pharmaceutical raw materials can be divided into the following three categories:

1. **Active Pharmaceutical Ingredients (APIs):**
2. **Inactive ingredients or Excipients:**
3. **Packing Raw Materials:**

1. ACTIVE PHARMACEUTICAL INGREDIENTS (APIS):

The API is one of the key components of a pharma drug that works medically and is responsible for drug action. There are certain levels of API capability for each drug. Manufacturers are required by the FDA to prove the effectiveness of their products in labs and in real life with patients.

Active Pharmaceutical Ingredients global market is expected to reach 198.8 billion US dollars by 2022 with a CAGR of 6.4%. The main factors contributing to this growth are the disappearance of patents, government programs, entry, and growth of the elderly.

2. INACTIVE INGRIDIANTS OR EXCIPIENTS:

Excipients are also called inactive ingredients or drug carriers. Pharma substances used as chemicals contain solutions and other substances. There are guidelines on overseas pharmaceutical manufacturing standards to qualify as a customer. Industry analysts predict that the excipients market will reach a CAGR of 6.53% by 2021 to 7.7 billion US dollars by 2022 worldwide.

3. PACKING RAW MATERIALS:

Materials used for packaging in the pharmaceutical industry include plastics, polymer, glass, aluminum foil, paper and more. Packing is done with a different pharma category due to the use of different materials. The demand for the global pharmaceutical packaging market is estimated to reach more than 80billion US dollars by 2020. The regions of North America and Europe play a major role in the pharmaceutical packaging market.

1.3 The World's Pharma Trade: Which Countries Buy & Sell the Most Drugs?

The pharmaceutical industry is incredibly valuable and is continuing to grow. But just how much of the world’s imports and exports involve pharmaceuticals? To understand the impact of the pharmaceutical industry on the world’s economy, we created two visualizations to demonstrate pharmaceutical imports and exports by country.

World's Largest Pharmaceutical Exporters

Following countries are largest exporters of pharmaceuticals in world.

World's Largest Pharmaceutical Exporters

Germany: $84.7 billion	Switzerland: $71.7 billion	United States: $49.7 billion	Belgium: $45.7 billion	Ireland: $40 billion

Source: ITC

World's Largest Pharmaceutical Importers

United States: $99.7 billion	Germany: $53.7 billion	Belgium: $36.7 billion	United Kingdom: $33.8 billion	Switzerland: $29.3 billion

Source: ITC

CHAPTER 2 PHARMACEUTICAL SECTOR IN PAKISTAN

2.1 Introduction:

Pharmaceutical sector recorded a revenue of PKR 453bln during FY20 with YOY growth of 9% (FY19: PKR~416bln). The revenue was impacted by the closure of Outpatient Departments (OPDs) as the sector registered a growth of only 4% in 4QFY20. Despite the large number of registered companies (700+), the sector is dominated by top Local and Multinational Companies (MNCs). Top 100 companies hold 97% of the total market share whereas, remaining more than 500 companies hold only 3% market share. Moreover, top ~50 companies hold 80% of market share.

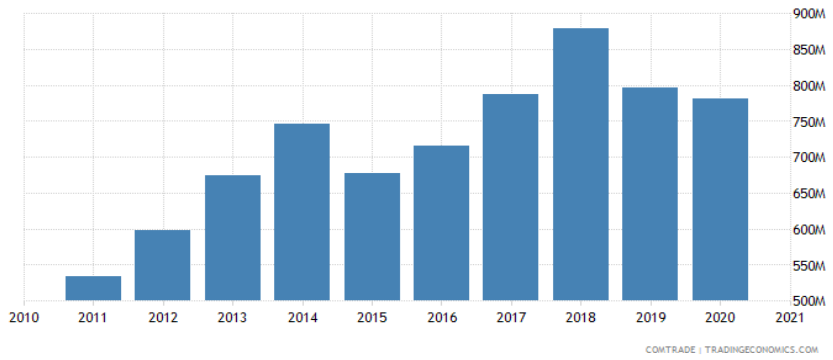
The sector is highly dependent on imports to meet the demand of basic raw material – APIs. As per the estimates, 95% of the APIs requirements are met through imports while the remaining 5% is being manufactured domestically. Heavy reliance on the imported raw material significantly increases the inherent risk of supply chain disruption and price fluctuations. Pharmaceutical sector is critically important for the health and lifestyle of any country and its population. The average world health expenditure per capita stands at USD 1,100/capita while the average health expenditure per capita in Pakistan is significantly lower standing at USD 43/capita (WHO).

On the international front, Pakistan is a net importer of pharmaceutical drugs since inception, with imports valued at USD 781 million vis-à-vis exports of USD 235.75 million in 2021, leaving a deficit of USD 545.25 million. Figures below provides a snapshot of the export and import of pharmaceuticals in Pakistan.

Pakistan Imports of Pharmaceutical products was US$ 781.48 Million during 2020, according to the United Nations COMTRADE database on international trade.

Figure 1

Pakistan's Imports of pharmaceuticals products in USD

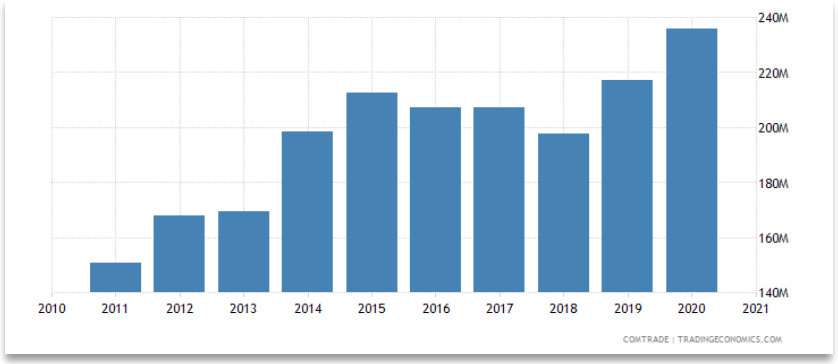


Source: COMTRADE

Pakistan exports of pharmaceutical products was US$235.75 Million during 2020, according to the United Nations COMTRADE database on international trade.

Figure 2

Pakistan's Exports of pharmaceuticals products in USD



Source: COMTRADE

2.2 Drug Regulatory Authority of Pakistan (DRAP):

Pharmaceutical products in Pakistan are governed under the Drug Rules 1976 which oversee labeling, packaging, licensing, registration, import, export and research of pharmaceuticals in Pakistan. Pharmaceuticals can include generics and brand medications. The regulatory body is Drug regulatory Authority of Pakistan. The industry is also regulated by Ministry of National Health Services Regulations and Coordination's (MNHSRC). The major association of pharmaceuticals firms in Pakistan is Pakistan Pharmaceutical Manufacturers Association (PPMA).

2.3 Economic contribution and performance of pharmaceutical sector of Pakistan:

Table 1

Contribution of pharmaceuticals to Pakistan's Economy

Variable	Contribution to National Economy
Share in GDP	1.17 percent
Employment (direct and indirect)	240,000
Share in national exports	0.9 per cent
Cost savings due to import substitution	USD 2 billion
Share in FDI	2.8 percent
Net indirect taxes (2005-06)	Rs. 1.5 billion
Share in industrial value addition	4.2 percent*

Source: COMTRADE

2.4 Duties and Taxes:

Pakistan's SRO 567 (1) 2006 abolishes the import duty on all medicines for cancer, kidney dialysis, hepatitis and cardio vascular diseases.

2.4.1 Custom Duties

Chapter 30 of the Pakistan Customs Tariff deals with import duty on pharmaceutical products. Under the 5th Schedule of the Customs Act, 1969 the government has reduced custom duties to provide relief to the pharmaceutical sector. Typical custom duties on APIs and excipients range from 5 per cent to 25 per cent. On custom duties of 25 per cent, an additional sales tax is also levied despite an absence of a sales tax on the sale of medicines. In addition, an advance income tax of 5.5 per cent of import value is also levied. Import duties on medicines range from 0 per cent to 10 per cent. Medicines for the treatment of cancer, transplants and heart diseases have no custom duty, yet have an advance tax at 5.5 per cent on import value.

Table 2

Duties and Taxes

		Custom duty	Sales tax	Income tax	Additional custom duty
API	FY21	11%-20%	17%	11%	2%-7%
		Custom duty	**Sales tax**	**Income tax**	**ACD**
Excipients	FY21	3%-90%	17%	11%	2%-7%
		Custom duty	**Sales tax**	**Income tax**	**ACD**
Drugs	FY21	0%-20%	0%-17%	0%-11%	0%-7%

2.4.2 Taxation:

Sales Of locally manufactured medicines fall under the Normal Tax Regime (NTR) whereas the Income Tax on sale of imported finished medicines falls under Final Tax Regime (FTR). In the case of exports, the entire export proceeds, whether of locally manufactured medicines or imported medicines also fall under FTR (Institute of Chartered Accountants of Pakistan ICAP, 2018).

Promotional Spend FBR reviews the sales promotional spending of pharma companies.

According to the Drug Act, sales promotional spending is limited to 5% of turnover.

Transfer Pricing The issue of transfer pricing involves MNC pharmaceutical companies where the local affiliate purchases Active Pharmaceutical Ingredients (API) from its parent company worldwide.

Sales Tax The pharmaceutical industry has exempt status in GST. There is no sales tax on sale of pharma products.

2.5 HS Codes of Pharmaceutical Products:

The Harmonized commodity description and coding system also known as the Harmonized System (HS) of tariff nomenclature is an internationally standardized system of names and numbers to classify traded products. The pharmaceutical products are represented by HS-30. The majority of pharmaceutical products lies between HS 3004 & HS 3003.

The full HS description is given below:

Medicaments consist of Mixed or unmixed products (HS 3004)

Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packing's for retail sale. (A prophylactic is a medication or a treatment designed and used to prevent a disease from occurring. Therefore, if the drug is administered before disease onset, it is considered prophylactic, otherwise it is considered therapeutic)

Medicaments consist of two or more constituents (HS 3003)

Medicaments consisting of two or more constituents mixed together for therapeutic or prophylactic uses, not in measured doses or put up for retail sale.

At 6-digit level, the majority of Pakistan's pharmaceutical exports lies within HS Codes 300490, 300439 and 300339.

The full HS product description is given below

HS 300490 (Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses (excluding medicaments including antibiotics, medicaments containing hormones, or steroids used as hormones**)**.

HS 300439 (Medicaments containing hormones or steroids used as hormones but not antibiotics, put up in measured doses "incl. those in the form of transdermal administration" or in forms or packing's for retail sale**)**

HS 300339 (Medicaments containing hormones or steroids used as hormones, not containing antibiotics, not in measured or put up for retail sale (excluding those containing insulin**)**.

CHAPTER 3: PAKISTAN TOP MARKETS

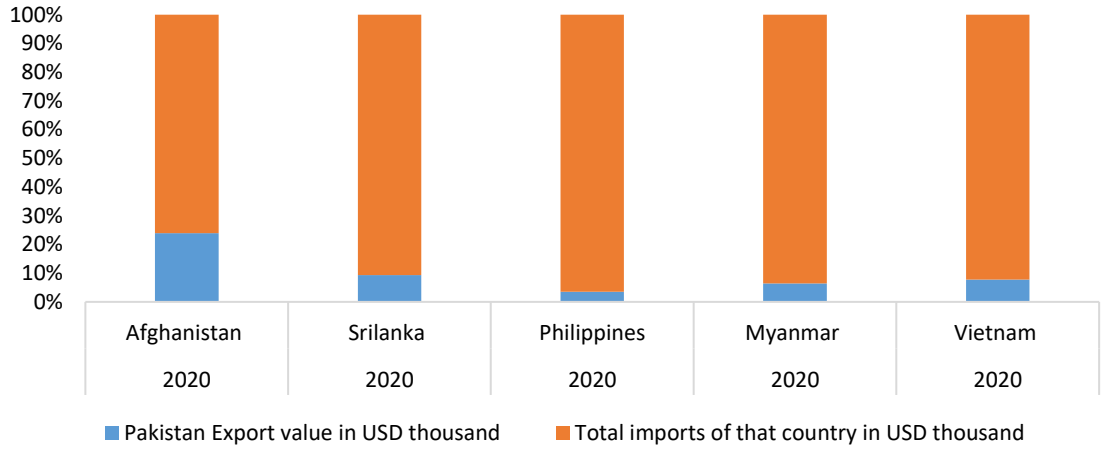
3.1 Pakistan's Exports of Pharmaceuticals:

Exports of medicaments from Pakistan amounted to USD 235mn (UNCOMTRADE 2020). The majority of pharmaceutical exports to Central Asia, Africa, and South Asian markets. Highly regulated markets such as, Germany, Switzerland, USA, Belgium, Europe have been less penetrated by Pakistan's pharma products due to the fact that they do not meet the requirements of FDA.

Pakistan pharmaceutical ranks 49th in terms of volume and 16th in value of global share.

Figure 3

Top markets for Pakistan exports of pharmaceutical products



Source: ITC

Over the past three to four years, the top markets for Pakistan's pharmaceutical exports have not been varied much. Afghanistan, Srilanka, Philippines, Myanmar, Vietnam, South Sudan are biggest market for exports. This statistic shows inability of exporters to approach and find new markets.

3.2 Pakistan's Top Markets of Pharmaceuticals In 2020:

Top markets for Pakistan exports of pharmaceutical products are as under

Table 3 Top Pharmaceutical Markets of Pakistan

Year	Country	Pak Exports	Imports of country	Pak Share	Avg Tariff for Pak	Avg distance
		USD (1000)		Percentage		Km
2020	**Afghanistan**	73,838	235,141	31	2.5	1215
2020	**Philippines**	22,300	1703,647	1.3	3	5698
2020	**Sri Lanka**	21,215	496,693	4.2	0.3	2769
2020	**Myanmar**	10,780	592,482	1.8	1.3	2808
2020	**Vietnam**	8361	3553,973	0.2	1.7	4367

Source: ITC

Pakistan exports most of its pharmaceutical products to Afghanistan and Sri Lanka, but this share can be increased by arranging trade agreements with both countries. As the 7th and 8th Afghanistan-Pakistan Transit Trade Coordination Authority (APTTCA) meetings were held in which bilateral and transit trade issues were discussed. Besides, Afghanistan Pakistan Transit Trade Agreement was extended for three months beyond 11th February 2021. The first meeting of Joint Working Group on Trade and Economic Affairs was held at Tashkent to discuss Preferential Trade Agreement and connectivity through Afghanistan through road and railway corridors.

The Free Trade Agreement (FTA) between Pakistan and Sri Lanka came into effect in July 2005 after being signed in August 2002. Under the FTA, Sri Lanka was given immediate duty-free market access for 206 products. Pakistan, on the other hand, received duty-free access for 102 products. Further concessions were agreed in November 2010. The 7th Session of Pakistan, Sri Lanka Commerce Secretary Level Talks, was held on 18th February 2021 wherein both countries renewed the resolve to further deepen bilateral ties and to work on resolving technical issues by reviving the platform of Joint Working Groups. Pakistan also held its first ever Trade and Investment Conference in Colombo on 24th February 2021 on the side-lines of visit of the Prime Minister of Pakistan to Sri Lanka (Z, A 2021).

3.3 Pakistan's Pharmaceutical Competitors in Major Markets:

Table 4

Pakistan's Competitors in top markets:

Year	Pak Major Markets	Competitors	Export value USD	Import Share	Average Tariff faced	Avg Distance
			1000	Percentage		Km
2020	**Afghanistan**	India Turkey China	84,337 15,672 5124	**36%** 7% 2%	2.5% 2.5% 2.5%	1850 2939 331
2020	**Srilanka**	India Switzerland UK	242,167 16,778 64,20	**49%** 3% 1%	0% 0.3% 0.3%	110 8040 5541
2020	**Philippines**	India Germany France	280,149 224,826 106,326	**16%** 13% 6%	1.3% 3.6% 4%	4622 10311 11,100

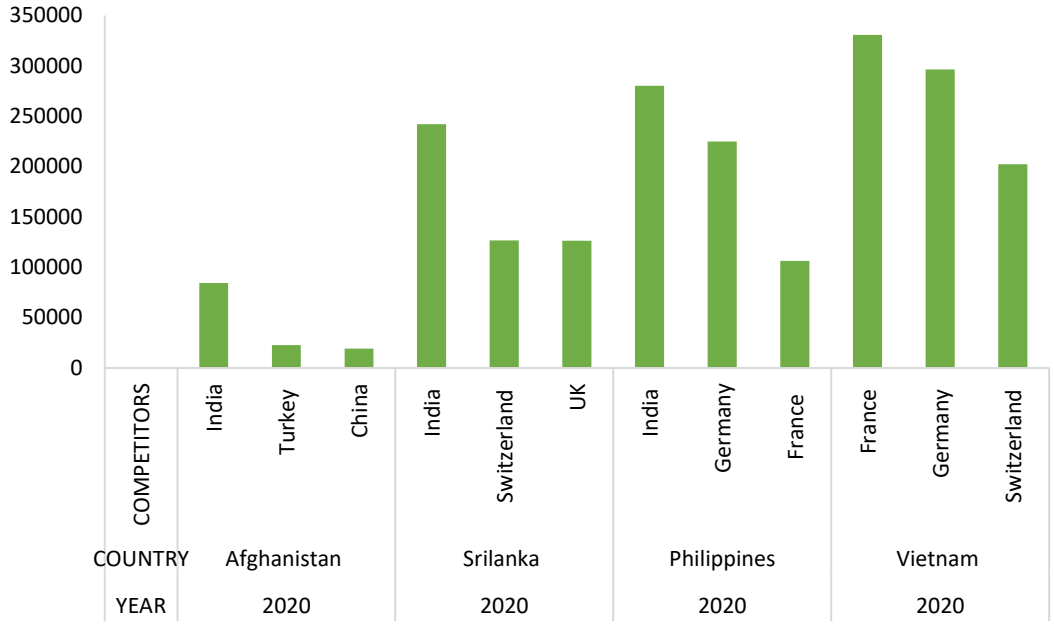
Source: ITC

The above table 4 shows Pakistan's competitors in major markets. In Afghanistan the major competitors are India and turkey with share of 36% and 7% respectively versus Pakistan 31%.

In Srilanka, the major competitors are India, Switzerland and UK with market share of 49%, 3% and 1% against Pakistan's 4.1%. Pakistan's advantage in Srilankan market is due to its geographical proximity and free trade agreement. In Philippine's, the major competitors of Pakistan are India, Germany and France with market share of 16%, 13% and 6% vs. Pakistan 1.3%.

Figure 4

Pakistan's Competitors in Top Markets



Source: ITC Trade map

3.3.1 Price Analysis of Pakistan and its Competitors in Major Markets:

Table 5

Price Analysis of HS 3003 In Major markets

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Afghanistan	Pakistan 7142* (1497)**	Turkey 16,000* (02)**	India 14,250* (08)**
Srilanka	Pakistan 17,085* (47)**	India 10,645* (425)**	Switzerland -
Philippines	Pakistan 12,441* (59)**	India 19,804* (235)**	Germany 262,000* (03)**

*Pakistan's export price per ton in USD Source: COMTRADE

**Total quantity exported in ton

According to table 5, In case of Afghanistan and Philippines, Pakistan charge lower prices as compared to its competitors India and Turkey. Pakistan should get advantage from price difference and increased its exports to both of these countries. While in case of in Srilanka, Pakistan charge higher prices as compared to India, which might be a reason that Srilanka imports almost 50% of pharmaceutical products from India.

Table 6

Price Analysis of HS 3004 In Major markets

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Afghanistan	Pakistan 10,825* (5,829)**	Turkey 10,991* (1,442)**	India 14,887* (4,752)**
Srilanka	Pakistan 14,440* (1413)**	Switzerland 325,432* (37)**	India 45,708* (4,527)**
Philippines	Pakistan 13,736* (1541)**	India 45,112* (5,097)**	Germany 25,568* (7,931)**

*Pakistan's export price per ton in USD Source: COMTRADE

**Total quantity exported in ton

Table 6, shows that in case of HS 3004, Pakistan is charging lower prices from Afghanistan, Sri Lanka and Philippines. On the basis of price analysis, Pakistan has an absolute advantage as compared to its competitors.

CHAPTER 4: POTENTIAL MARKETS

Potential Markets of Pharmaceutical for Pakistan:

The following potential markets have been identified to promote Pakistan's exports of pharmaceutical products.

4.1 Egypt:

Egypt is Pakistan's 5th largest African exports destination of Pakistan. Pakistan's overall exports to Egypt stands at US $ 71 million during 2019-20 against US $ 85 million in 2016-17 showing a decline by 8 %. Egypt total imports of pharmaceuticals from world is USD 226 million while Pakistan's share is just 0.1% in these imports.

Table 7

Pakistan's Pharmaceutical exports to Egypt

Country	**Pakistan Exports**	**Imports of Egypt**	**Pakistan's share (%)**	**Tariff faced by Pakistan**	**Distance factor**
	USD(1000)		Percentage		Km
Egypt	2580	226,4286	0.1%	1.9%	3,763km

Source: COMTRADE

4.2 Pakistan's Competitors in Egypt:

Switzerland and Germany are the major competitors of Pakistan in Egypt.

Table 8

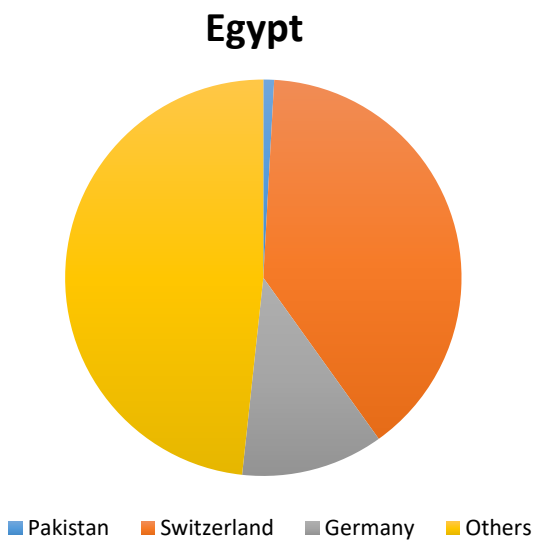
Pakistan's Pharmaceutical competitors in Egypt

Pakistan's competitors	**Competitors exports**	**Competitors share**	**Tariff**	**Distance factor**
	USD (1000)		Percentage	
Switzerland	895,062	39%	1.5%	2974 km
Germany	264,786	12%	0.1%	3203 km

4.3 Comparison of Pakistan with its Competitors in Egypt Market:

Figure 5

Pakistan's comparison with its competitors in Egypt



Source: Author's work

Fig 5 shows that Pakistan share in Egypt imports of pharmaceuticals is negligible, while Switzerland and Germany has huge share.

4.4 South Africa:

South Africa is Pakistan's second largest export destination in the African region. Total pharmaceutical imports of South Africa from world is USD 2.4 Billion. This indicates that South Africa is an emerging exports market for Pakistan in the Africa region.

Table 9

Pakistan's Pharmaceutical exports to South Africa

Country	**Pak Exports**	**Imports of South Africa**	**Pakistan Share**	**Tariff faced by Pak**	**Distance factor**
	USD (1000)		Percentage		Km
South Africa	5115	240,1518	0.2%	0.1 %	8359

Source: ITC

South Africa imports for pharmaceutical products is increasing with time, while Pakistan's

share in is imports too much low, while tariff faced by Pakistan is 0.1%. There is need to promote exports in South Africa.

4.5 Pakistan's Pharmaceutical Competitors in South Africa:

India and Germany are Pakistan's major competitors in pharmaceutical in South Africa.

Table 10

Pakistan's Pharmaceutical Competitors exports to South Africa

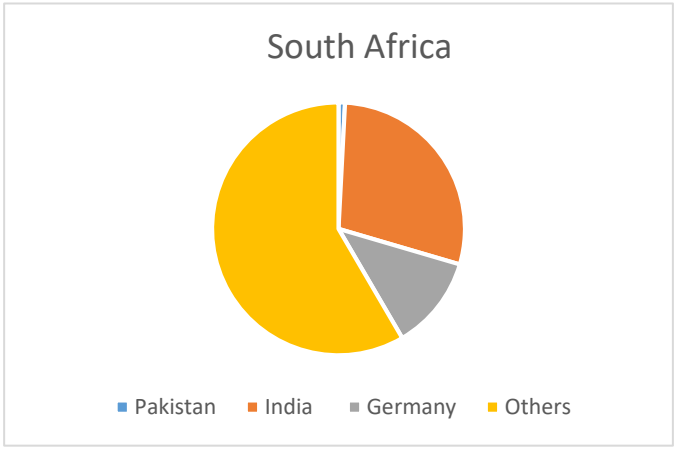
Pakistan's competitors	**Competitors exports**	**Competitors share**	**Tariff**	**Distance factor**
	USD(1000)	Percentage		Km
India	693,779	28%	0.1 %	8250
Germany	291,139	12%	0.1 %	12,963

Source: COMTRADE

4.6 Comparison of Pakistan with its competitors in South African market:

Figure 6

Pakistan's comparison with its Pharmaceuticals competitors in South Africa



Source: Author work

4.7 Price Analysis of Potential Markets for Pakistan with Its Competitors: (HS 3003 & 3004)

Table 11

Price Analysis of Pakistan and its competitors in Egypt and South Africa for HS 3003

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Egypt	Pakistan - 	Switzerland 47,764* (212)**	Germany 203,353* (51)**
South Africa	Pakistan 7000* (07)**	India 56,325* (40)**	Germany -

*Pakistan's export price per ton in USD Source: COMTRADE

**Total quantity exported in ton

Table 11 shows that, Pakistan is not exporting pharma product lies in HS 3003, while Egypt import these products at higher prices from Switzerland and Germany.

Table 12

Price Analysis of Pakistan and its competitors in Egypt and South Africa for HS 3004

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Egypt	Pakistan 15,542* (166)**	Switzerland 10,45709* (494)**	Germany 46,273* (4180)**
South Africa	Pakistan 19,328* (262)**	Germany 20,729* (10,453)**	India 85,817* (7,963)**

*Pakistan's export price per ton in USD Source: COMTRADE

**Total quantity exported in ton

Table 12 shows, Pakistan is charging lower prices for HS 3004 products as compared to Switzerland and Germany. Pakistan should focus on these two potential markets and promote exports.

CHAPTER 5: WEST AFRICAN REGION

5.1 West African Region With 0% Tariff Rate:

There are various countries in west Africa where Pakistan pharma company can increase their exports, and in these countries Pakistan face 0% tariff rates, but unfortunately our exports to west Africa is lower.

Pakistan's Pharmaceutical Exports to West African Region:

Table 13

Top markets of West Africa for Pakistan exports of pharmaceutical products:

Country	**Pakistan Exports**	**Imports of that country**	**Pakistan's share**	**Avg Tariff**	**Distance Factor**
	USD (1000)		Percentage		Km
Nigeria	4077	2982578	0.1%	0%	6689
Ghana	321	310867	0.1%	0%	7677
Mali	36	225410	0.01%	0%	7461
Mauritania	29	45741	0.06%	0%	7946

Source: ITC

Nigeria is Pakistan's 7th largest exports destination economy in the African region. Pakistan's exports stand at US $ 29 million during 2019-20. Nigeria is identified with 25 non-tariff barriers including technical measures, non-technical measures and export related measures. Nigeria's NTBs are applied to the World (all countries) therefore, Pakistani exports pass through the Nigeria's NTBs. Around 12 % of Nigerian NTMs are applied on machinery and mechanical appliance, 8.3 % of the reported Nigerian NTMs applies to fish and crustaceans, 8.1 % on electrical equipment and 7.9 % of Nigerian NTMs are applied to preparation and vegetables.

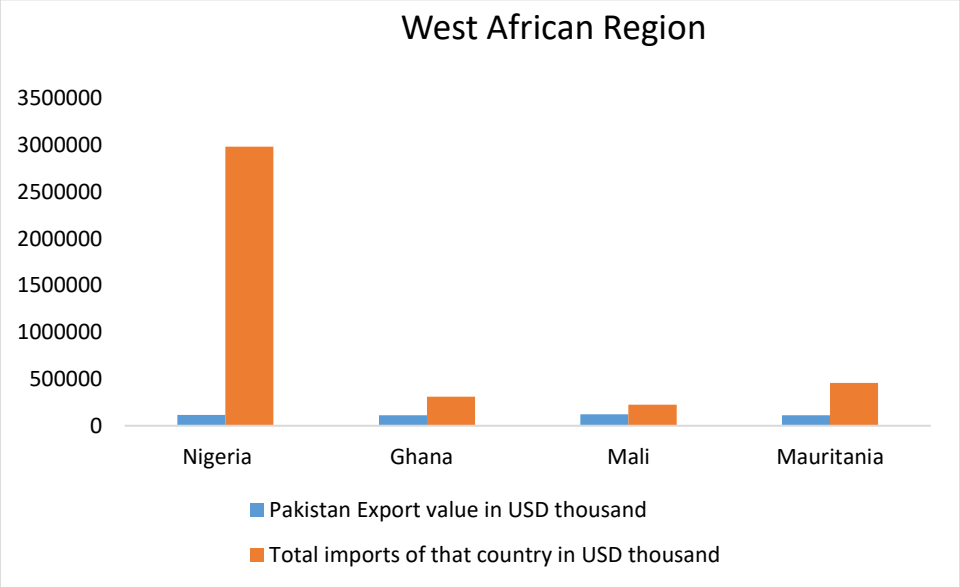
Ghana is Pakistan's 13th largest destination of Pakistani exports in the Africa region. Pakistan's exports to Ghana increased to US $ 51 million during the financial 2019-20 from US $ 12.64 million during the financial year 2016-17, showing an increase by US $ 38.26 million (227 %) – the second top exports destination in Africa in terms of increase in exports in US $ million. Pakistan's top exports to Ghana include ethyl alcohol (ethanol), fibers, wearing apparels, rice, instruments and appliance and medicaments etc.

Like Nigeria, Ghana is the other largest imposing Non – Tariff Barriers. It imposes total 31 types of NTBs, including non-technical measures, technical measures and export related measures on a number of tariff lines. Around 8.7 % of NTBs are imposed on 'fish and Crustaceans', followed by organic chemicals, which to (7.5 % of the NTBs applied and then vehicles and other railway products.

Mali is also another largest imposing Non-Tariff Barriers. Pakistan's export to Mali is very low as less than US $ 1 million during the financial year 2019-20, while the global imports of Mali is around US $ 5 billion. Mali has higher demand for pharma products and it import US $ 225 million of pharma products from the world while Pakistan share is too much less as of just 0.01%.

Figure 7

Pakistan's Pharmaceutical exports to West African region



Source:ITC

5.2 Pakistan's Pharmaceuticals Competitors in West Africa:

India and China are Pakistan's major pharmaceutical competitors in West African region

Table 14

Competitors of Pakistan in West Africa

Year	Pak Major Markets	Competitors	Exports value	Share in imports	Tariff faced by Competitors	Distance Factor
			USD(1000)	Percentage		Km
2020	**Nigeria**	India China	410,156 179,774	13% 6%	0% 0%	7607 9903
2020	**Ghana**	India	115,231	37%	0%	8655
2020	**Mali**	China India	37036 28,863	16% 12%	0% 0%	10441 8618

Source: ITC

Figure 8

Export value of Pakistan pharmaceutical competitors in West Africa

Source: COMTRADE

As shown in figure 08, India and china has a huge share in these West African regions while Pakistan's share is negligible.

5.3 Price Analysis of Pakistan with Its Competitors in West African Region With 0% Tariff Rate: (HS 3003& 3004)

Table 15

Price Analysis of Pakistan and its competitors in West Africa Region for HS 3003

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Nigeria	Pakistan 17,375* (16)**	China 5440* (75)**	India 13,175* (97)**
Ghana	Pakistan -	China 3682* (66)**	India 17,667* (46)**
Mali	Pakistan -	China 7000* (05)**	India 26,000* (01)**

*Pakistan's export price per ton in USD Source: ITC

**Total quantity exported in ton

China has an advantage in its exports due to lower prices in these West African regions, because China is world's biggest exporter of pharmaceuticals raw material. Pakistan is charging high prices because Pakistan imports raw material and then prepare medicine which increase cost. As shown in table 16, Pakistan is not exporting HS 3003 products to Ghana and Mali.

Table 16

Price Analysis of Pakistan and its competitors in West Africa Region for HS 3004

Importing Country	Exporting Country	Exporting Country	Exporting Country
Nigeria	Pakistan 10,210* (372)**	China 6521* (24,846)**	India 30,206* (11,741)**
Ghana	Pakistan 14,857* (21)**	China 5665* (1,865)**	India 15,951* (676)**

*Pakistan's export price per ton in USD Source: ITC

**Total quantity exported in ton

CHAPTER 6: CENTRAL ASIAN COUNTRIES

Pakistan has a great opportunity to increase its pharmaceutical exports in central Asian countries such as, Uzbekistan, Kazakhstan and Kyrgyzstan etc.

6.1 Pakistan's Pharmaceutical Exports to Central Asian Countries:

Table 17

Pakistan Pharmaceutical Exports to Uzbekistan, Kazakhstan and Kyrgyzstan

Year	**Country**	**Pakistan Exports**	**Imports of that Country**	**Pakistan's Share**	**Average Tariff**	**Distance Factor**
		USD (1000)		Percentage		Km
2020	**Uzbekistan**	7556	115,2949	0.6%	5%	1295
2020	**Kazakhstan**	2335	155,7776	0.14%	2%	1972
2020	**Kyrgyzstan**	936	204,277	0.4%	0.7%	1298

Source: ITC Trade map

Pakistan's share in Pharmace4utical exports in central Asian countries is below than 1%, while these countries imports high quantity from the world. Pakistan has edge in distance factor and it's easy to approach these countries.

6.2 Pakistan's Competitors in Central Asian Countries:

Table 18

Pakistan Pharmaceutical Competitors Exports to Uzbekistan, Kazakhstan and Kyrgyzstan

Year	**Pak Major Markets**	**Competitors**	**Exports value**	**Share in imports**	**Avg Tariff**	**Distance Factor**
		USD (1000)		Percentage		Km
2020	Uzbekistan	India	167,738	14%	5.3%	2677
2020	Kazakhstan	India China	83272 25609	5% 1.6%	2.5% 2.5%	3233 3323
2020	Kyrgyzstan	India China	136,20 3844	7% 2%	1.2% 1.2%	2324 2725

Source: ITC

Countries in Central Asia such as Uzbekistan, Kazakhstan, and Kyrgyzstan are potential markets for Pakistan pharmaceuticals. Most of pharmaceutical imports of these countries based on OTC drugs such as Unani medicine, Homeopathic, Paracetamol, cough syrups etc. while Pakistan export them a very little quantity of OTC drugs. These countries require quality products and most of them have low NTBs which wok in Pakistan favor. IMS health estimates that Uzbekistan and Kazakhstan pharma spending will grow at 14%to 15% in 2023. Pharmaceuticals exports growth is primarily dependent on population and these regions are attractive mostly due to geographical proximity to Pakistan and low requirements which can be met by Pakistani companies.

6.3 Price Analysis of Pakistan with Its Pharmaceutical Competitors in Central Asian Countries: (HS 3003& 3004)

Table 19

Price analysis of Pakistan with its pharmaceutical competitors in Uzbekistan, Kazakhstan and Kyrgyzstan for HS 3003

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Uzbekistan	Pakistan 9023* (216)**	China 16561* (57)**	India 19,857* (28)**
Kazakhstan	Pakistan 10,269* (67)**	China 62,056* (36)**	India 83,056* (18)**
Kyrgyzstan	Pakistan 12,294* (72)**	China -	India 11,667* (356)**

*Pakistan's export price per ton in USD Source: ITC

**Total quantity exported in ton

As shown in table 19, Pakistan is charging lower price as compared to its competitors India and China in these regions. India and China mostly export all those products which Pakistan can export also, the need of hour is to make some agreements with these central Asian countries regarding pharmaceuticals.

Table 20

Price analysis of Pakistan with its pharmaceutical competitors in Uzbekistan, Kazakhstan and Kyrgyzstan for HS 3004

Importing Country	**Exporting Country**	**Exporting Country**	**Exporting Country**
Uzbekistan	Pakistan 10,354* (528)**	China 5502* (3,909)**	India 37,994* (3,601)**
Kazakhstan	Pakistan 13,472* (106)**	China 1770* (2961)**	India 50,045* (1,545)**
Kyrgyzstan	Pakistan 7014* (34)**	China 3133* (909)**	India 33,396* (06)**

*Pakistan's export price per ton in USD Source: ITC

**Total quantity exported in ton

China is charging lower prices as compared to Pakistan for HS 3004 products, the reason is simple that China has all those raw materials used in these products while Pakistan has to imports these raw materials, that increased cost of production.

6.4 A Case Study of Pakistan's Trade with Tunisia:

The Republic of Tunisia is located between Libya and Algeria on the shores of the Mediterranean Sea. It covers an area of 163, 610 Km and a coastline of 1,148km. It has a population of 11.50 Million, of which 99% are Muslims. Due to its strategic location, Tunisia has been a center of trade between Europe and Africa for more than 2,000 years. Tunisia is the 72nd largest export economy in the world and the 69th most difficult economy according to the ECI. Pakistan's overall exports to Tunisia dropped from US $ 21 million (2017-18) to US $ 12 million (2019-20). Top exports to Pakistan in Tunisia include cotton, man-made fibers, beverages, cereals (especially rice), green skins and skins as well as tractors and tractor parts etc. Tunisia has huge market structure and high demand for pharmaceuticals products. But unfortunately Tunisia is not importing pharmaceutical products from Pakistan. Pakistan's pharmaceuticals exports to Tunisia is zero while Tunisia imports pharmaceuticals of 446 million USD.

6.4.1 Tunisia imports of Pharmaceutical's products:

The following table shows Tunisia imports of Pharmaceutical products from world

Table 21

Tunisia imports of Pharmaceutical products from world:

Country	Exports to Tunisia	Tunisia imports from world	Share in exports	Tariff	Distance factor (km)
	USD (1000)		Percentage		
Pakistan	0	446,749	0%	6.3%	5562
Switzerland	72,584	446,749	16%	0%	1715
Germany	51,681	446,749	11%	0%	2293
Belgium	38,695	446,749	9%	0%	2342
USA	9253	446,749	2%	6.8%	5570
India	8581	446,749	1.9%	6.8%	6892

Source: ITC Trade map

6.5 Pakistan-Tunisia Preferential Trade Agreement (PTA)

Currently, Tunisia and Pakistan are in the process of negotiating a Preferential Trade Agreement (PTA) which was expected to be signed in 2021 as reported by the Tunisian Ambassador to Pakistan Adel Elarbi. A PTA could be potentially beneficial for both countries. Pakistan can gain better access to large markets like North Africa, the Middle East and Europe while Tunisia could gain access to Asia. The identified potential areas of cooperation between the two countries are agriculture, textiles, electronics, tourism and services. Pakistan could also export rice, surgical, pharmaceutical, leather and sports products to Tunisia.

CHAPTER 7

7.1 Pharmaceutical Imports of Pakistan:

Pakistan pharmaceutical industry is only able to make up 5% of its APIs locally whereas, the rest of the ingredients are being imported. Low emphasis on research and development by local companies is the major reason behind significant reliance on imported raw material.

• During FY20 pharmaceutical imports were recorded at PKR 158bln (FY19: PKR 148bln) with YOY growth of 7%. Imports reached PKR~135bln during 9MFY21 (9MFY20: PKR 118bln) up 14% YOY.

The following table shows pharmaceutical imports of Pakistan

Table 22

Pharmaceutical imports of Pakistan:

Country	**Import Value**	**Total Imports**	**Share in Pak imports**	**Tariff applied by Pakistan**
	USD (1000)		Percentage	
Switzerland	123,615	781,484	16%	11.1%
Belgium	92,912	781,484	12%	11.3%
Germany	86,935	781,484	11%	11.3%
India	64,232	781,484	8%	8.7%
USA	51,641	781,484	7%	11.9%

Source: COMTRADE

Nature of APIs and medical devices requires sensitive handling, proper storage and transport facilities. Hence, efficient supply chain is of utmost importance for pharmaceutical companies. Switzerland is the largest exporter of pharmaceutical products to Pakistan followed by Belgium, Germany, France, India and Italy. This significant reliance on imported raw material increases the inherent risk of supply chain disruption. However, non-reliance on any single country for imported APIs provides some comfort against potential

disruptions in the supply chain.

Pakistan's share in these markets is negligible due to industry's inability to comply with non-tariff barriers, such as US FDA regulations. Currently Getz's pharma has spent PKR 300mn on its manufacturing plant to bring itself compliant with FDA regulations in order to penetrate the US market. As majority of Pakistani companies are unable to comply with FDA regulations, they lose the opportunity to export to USA along with other places in Europe.

7.2 Tariff, Custom Duties & Taxation on Pharmaceuticals in Pakistan:

7.2.1 Tariff:

Tariffs are an important policy tool for economic growth, protection of the domestic industry, income generation, productivity, and consumer welfare (Adam, C 2006). Tariffs provide value for goods on locally produced goods in addition to imported goods of the same nature and create a difference between domestic and international prices.

Tariffs are generally divided into three categories i.e.

- MFN
- Preferential
- Bound tariffs.

The Covid-19 epidemic has highlighted the importance of international trade in the acquisition of all kinds of medical devices, with many areas experiencing a shortage of essential medical supplies due to various trade barriers. Although there is no vaccine or effective treatment available for the disease, it turns out that its rapid global spread will be a major global problem. Any trade barriers that unnecessarily delay the distribution of drugs and increase their value should be identified and rejected.

Drug taxes are taxable as they take a higher share of the income of the poor than they take on those who rise in the rate of income - in fact, the prices of medicines are doubled as the main ones affecting the poor are suffering from disease. The need to reduce drug prices has been particularly pressuring in the ongoing Covid-19 epidemic.

7.2.2 Custom Duties

Typical custom duties on APIs and excipients range from 5 per cent to 25 per cent. On custom duties of 25 per cent, an additional sales tax is also levied despite an absence of a sales tax on the sale of medicines. In addition, an advance income tax of 5.5 per cent of import value is

also levied. Import duties on medicines range from 0 per cent to 10 per cent. Medicines for the treatment of cancer, transplants and heart diseases have no custom duty, yet have an advance tax at 5.5 per cent on import value.

7.2.3 Taxation:

Sales Of locally manufactured medicines fall under the Normal Tax Regime (NTR) whereas the Income Tax on sale of imported finished medicines falls under Final Tax Regime (FTR). In the case of exports, the entire export proceeds, whether of locally manufactured medicines or imported medicines also fall under FTR (Institute of Chartered Accountants of Pakistan ICAP, 2018).

7.3 Concessions and Exemptions:

Concession and exemption may be broadly divided into three categories. The first phase of the agreements is intended for foreign exchange by promoting the protection of domestic production in various sectors of the economy. Firms are allowed to import incoming goods at a permit price i.e. below the legal value. This permit / exemption is available in pharmaceuticals. Under various SROs 19 and Schedule 5 of the Taxation Act, 1969. These agreements are usually obtained under certain conditions such confirmation of a particular Department / Agency. The second phase of release is related to the general release under section 99 of the Pakistan Customs Tariff. These exemptions are available to foreign dignitaries and international organizations, imports by charities, scientific institutions, hospitals, export processing centers and special economic centers etc.

This exemption is available on fulfillment of certain conditions such as certificates from the relevant regulatory departments and the Minister to ensure that the goods will be used for the purposes for which they were submitted.

7.4 Relief Measures in CD, ACD and RD:

The Budget 2021-22 offers unprecedented relief measures in Customs Duty (CD), ST and Income Tax (IT) for the industrial sector amid a proposed plan that explains how the government intends to meet the Rs1129 billion hike in the Federal Board of Revenue (FBR) target. As per proposed plan, under the revenue relief changes announced in the Finance Bill, the government aims to give away Rs119bn to industries and individuals. Of these, Rs42bn has been given in CD, 19bn in ST and Federal Excise Duty (FED) while Rs58bn in IT.

The revenue measures under IT will generate Rs116bn, followed by Rs215bn from ST & FED

and Rs53bn from CD measures. The net revenue impact will be Rs264bn after deduction of relief measures. The government has either reduced or exempted completely CD, additional customs duty (ACD) and Regulatory Duty (RD) on imports of 584 tariff lines. To incentivize pharmaceutical products, CD and ACD has been exempted on 358 active pharmaceutical ingredients (APIs), raw material of auto-disable syringes and Remdesivir.

7.5 DISCUSSION:

In addition to the specific demand- and supply-side barriers that pervade the pharmaceutical industry, there are cross-sectoral issues that are responsible for its inefficiency. Most notable are the problems caused by excessive government intervention in the sector, the lack of an all-encompassing policy framework, the weak co-operation of the provincial government, and the weak ability to enforce quality across the value chain. Without major policy, the transformation of the industry is at risk of volatility (Aitken, M 2016).

Overall, government involvement in the pharmaceutical industry is high. Unlike many other countries, Pakistan's pharmaceutical industry remains highly regulated, more priced than quality. The government ends up making concessional policies for those entrepreneurs who have the power to recruit and who do not have access to political networks (such as politically focused drug companies), which often hurt high-value firms (large pharmaceutical firms). Domestic approvals can take time and SROs create uncertainty. Simple steps, such as establishing an FDA-approved lab and performing contract work are far from the government's policy agenda.

This issue stems from the fact that there is no broader goal in this field. DRAP does not have a National Medical Policy (coming from November 2019). In addition, a number of Regulatory Regulations (SROs) have been issued over the years to address urgent issues related to drug policies.

Also, a few provincial policies are in place. This creates uncertainty about government actions at the state and provincial level, leading to liaison issues that create unnecessary delays and create complexity that can easily be avoided. Licensing, manufacturing, registration, pricing, importing, and exporting is handled by the federal government, while distribution and marketing are regulated by the relevant provincial governments. At the provincial level, apart from the signs of improvement, some policies are unnecessarily difficult. A good example of Punjab's policy abolition policy suggesting that providers should negotiate separately with all

regional health departments in order to supply drugs. This is an important reason for the recurring drug shortage in the province. Communication challenges between DRAP and provincial drug control units also exist. Provincial governments are responsible only for controlling drug trafficking. Lack of communication, however, can lead to mistrust between producers. DRAP and provincial inspectors can provide conflicting reviews as these authorities lack communication.

However, a recent positive development is that DRAP adopts a Common Technical Documentation (CTD) system for the registration of pharmaceutical companies, licensing them and making all contact with them. In December 2020, a paperless automated system — Pakistan Integrated Regulatory Information Management System (PIRIMS) — was successfully launched. This program already exists in Europe and the USA (Z,A 2021). The new system can even speed up international marketing, as all processes are defined and their times. The program includes licensing, registration, testing and testing services and provides a platform for the pharmaceutical industry to submit applications, control letters and a response / complaint to deal with applicants' problems. This was done to ensure compliance with the Global Level Measurement Tool WHO Global, an internationally accepted model for assessing the country's regulatory capacity. Once Pakistan clear its compliances, it can proceed with its application to the Pharmaceutical Inspection Convention / Cooperation Scheme (PIC / S), where DRAP has already hired a regulatory specialist. This is an international co-operation program to promote the consistent application of the medical guidelines and their features. It would allow Pakistan to reach at least 50 more countries, from Asia to Europe through standard recognition.

7.6 CONCLUSION:

Global pharmaceutical markets are in flux due to major restructuring, there is an opportunity to strategically enter the global off-patent drugs market that will be worth USD 700 billion in branded generics and USD 381 billion in generics by 2025. In 2020-21 Pakistan’s total exports in these lines were USD 235 million. Pakistan, with a local market of 215 million consumers and more than 700 pharmaceutical companies is poised well to gain from opportunities provided under these shuffling global patterns of supply and demand. However, the current practice of simply importing 95 per cent of the raw material, compounding active ingredients with excipients, coating the pills, and packaging the drugs cannot continue to be the long-term goal of the sector (Ahmas 2021). Overall, COVID-19 has made it clear that the regulatory

environment in the pharmaceutical industry needs to adapt to global industry conditions if the industry is to thrive and live in a highly competitive environment. Over-reliance on imports has exposed the industry's risks to future shocks. The global closure did not even stop the supply of medicines.

To understand Pakistan’s ability to produce drugs, take the example of the pills Paracetamol and Ibuprofen, both basic COVID-19 standard treatment and a number of minor ailments such as the common cold and flu. Pakistan produces these drugs at very low prices, but it does not produce the active ingredients available in these products. Pakistan will not be able to continue producing these drugs if the supply of these active ingredients is interrupted from other countries. At least 80 percent of Pakistan's API requirements for most common medicines such as paracetamol, certain antimicrobials and blood pressure etc., come from overseas first from Germany, Switzerland, China followed by India, Canada and Europe.

The potential can be harnessed through an urgently needed sectoral growth strategy and corresponding action plan, overhauling of the regulatory regime, deregulation of drug prices, strengthening of intellectual property rights and a consistent policy regime. These can address, to a large extent, the unique features of the market that have stunted its transition to maturity.

With MNCs not contributing to new drug registrations at the same rate as in other regional countries, registration of new molecules in Pakistan has fallen. This may be attributed to two reasons. Firstly, delays in the regulatory channel have led to lower registrations, with new molecule registrations pending before Cabinet for nearly 3 years. So even though DRAP and the pricing committee may complete their evaluation and pricing recommendation in a timely manner, as per the Drug Act 1976 pricing has to be approved by the Cabinet, even for generic molecules. This is unique to Pakistan and leads to unnecessary delays. Secondly, this is because compared to the early years of 2000, the number of new applications has also fallen Issues Analysis of the issues is grounded in the value chain. The value chain comprises three major components:

Issues

Analysis of the issues is grounded in the value chain. The value chain comprises three major components: manufacturing, distribution and dispensing to the end user. These have been covered in great detail in the Study.

Potential for growth

With China and India shifting focus to the more value-added innovative pharmaceutical industry, shrinking drug pipelines in developed countries, and a scramble to capture off-patent generic drugs, Pakistan can meet global demand for off-patent original block-bluster drugs in low & middle-income countries. In the short-run, there is an opportunity to strategically enter a market that will be worth USD 700 billion in branded generics and USD 381 billion in generics by 2025.

Products

A total of 9 product lines (at the HS 6-digit level) that Pakistan can focus on have been identified. While Pakistan already exports these lines, its world export shares were less than 0.5 per cent in 2020, with exports of USD 202million.

Markets

The key markets identified are in Africa, East and Central Asia, where Pakistan's main competitors are India, China, and sometimes, Germany, Switzerland.

APIs

Access to low-priced APIs is critical for any pharmaceutical sector based on drug formulation. The sector is weakly developed in Pakistan, with 6-7 local manufacturers producing a little over 30 APIs. Domestic producers are protected by import tariffs ranging from 5 to 25 per cent and supply 12 per cent of the local market.

Vaccines and Antisera

Despite having one of the largest birth cohorts in the world (5.5 million babies in 2019), Pakistan has virtually no domestic vaccine production (abbasi, 2018). The acquisition of vaccine manufacturing capabilities can be a first step towards the production of next-generation, high-value pharmaceuticals in Pakistan. The global market for human vaccines was valued at USD 33 billion in 2019 by the WHO Global Vaccine Market Report 2020.

7.7 RECOMMENDATIONS

These recommendations are in line with action plan aimed at supporting pharmaceutical sector in Pakistan that affected by the COVID-19 crisis. The recommendations aim to help the government and private sector create an enabling environment for private-sector development and improve pharma export competitiveness in Pakistan.

7.7.1 Establish an online reporting mechanism and monitoring committee

An online platform should be developed to monitor and address difficulties faced by exporters and importers. Small and medium-sized enterprises in Pakistan struggle with market regulations and trade procedures when they export or import goods. Yet there is no simple channel to collect and examine their concerns so the relevant institutions can coordinate actions to overcome these obstacles.

7.7.2 Improved price regime

To increase investment and encourage exports, the urgent need of the sector is a sustainable and predictable pricing system for pharmaceutical products.

a. Remove the price ceiling:

Increasing the price of medicines set since 2001 that oppresses profits, hinders growth and limits access to other medicines. The free and transparent pricing law of DRAP will benefit industry performance.

b. Ensure the provision of essential medicines:

The National List of Essential Medicines should be regulated and the prices of all other alternatives should be phased out, as determined by industry integration and inclusion.

7.7.3 Stable Regulatory Regime

a. Redefine DRAP Role:

Instead of focusing on price control, DRAP should improve its technology and capabilities to perform its primary function of quality control and monitoring, similar to regulatory agencies in other countries.

b. WHO-Commissioned Laboratories:

Linked to quality control, Pakistan must obtain WHO accreditation for its major public

laboratories, first through DRAP's National Control Laboratory for Biologics (NCLB), without which, all NCLB testing, registration and extraction of biodiversity is not known worldwide (Abbasi, 2018).

c. Compliance with low production standards:

Set and apply low quality standards for any manufacturer you want to work in Pakistan (e.g., GMP certification compliant with WHO for performance appliances).

d. Credit Services:

There should be improved credit facilities for long-term borrowing to invest in GMPs. This could also be tied to export operations or authorized by WHO / USFDA.

7.7.4 Incentive to invest in FDA-quality plants:

One way to do this would be to allow the prices of herbal products approved by the FDA to be regulated for export. This may also be associated with lower tax rates and lower utility taxes, e.g., electricity.

WHO-Authorized Laboratories:

Laboratories that meet international standards and operate independently are the conditions for export. Importing countries often require studies of bioequivalence and bioavailability.

7.7.5 Improve production & innovation

a. Allow contract production without limit:

Companies should be allowed to improve production configuration (and thus reduce production costs) by undertaking a sub-contract with other companies as required. Reducing restrictions on contract performance is possible if DRAP concerns about quality degradation are also addressed.

b. Create a new eco-system:

In order to compete in global markets and participate effectively in drug discovery using new tools available, the Pakistani industry needs the support of an innovative system. The pharmaceutical industry is virtually non-R&D and has no research culture.

7.7.6 Production of vaccines

1. In order to produce vaccines, DRAP must apply for and obtain a WHO certificate for the National Control Laboratory for Biologics (NCLB), otherwise no vaccine manufacturer in

Pakistan can be considered for WHO approval.

2. Pursue a two-pronged vaccine development policy.

• **Phase I:** DRAP should obtain a WHO certificate for the NCLB. After careful consideration, encourage local firms to develop high-volume vaccines under the auspices of supplementation and detoxification using large-scale imports from overseas WHO certification firms.

• **Phase II:** Provide timely protection to high-quality local firms that produce the goods from the raw material category. The defense includes the government's return on market prices to 100% directly integrated factories. The government is funding the purchase of public hospitals for vaccination under its Sehat Sahulat program. The protection will expire in 5 years when firms reach the scale to break even subsidized prices, depending on what is nearby.

7.7.7 Streamline export regulations and procedures

The SBP should review the import payment requirement. This requirement, designed to control the flow of foreign currency, has made it difficult for retailers to import goods. The general business community has responded well to the SBP's decision in 2020 to allow early payment for imported raw materials, but some companies say its policies for prepayment remain limited.

7.7.8 Promotion of API's park:

Access to low-priced APIs is critical for any pharmaceutical sector based on drug formulation. The sector is weakly developed in Pakistan, with 6-7 local manufacturers producing a little over 30 APIs. Need of hour is to promote API's park in Pakistan. Promotion of API's park will help Pakistan's pharmaceutical industry in following ways;

- The drug manufacturers will get easy access to world-class **common infrastructure facilities (CIF.)**
- The facilities provided under this scheme intends to bring down the manufacturing cost of the API's drugs.
- It will promote self-reliance in pharmaceutical manufacturing.
- The API's drugs parks will also increase the competitiveness of the API drug industry in Pakistan.

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