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## EXPORT POTENTIAL FOR OTC DRUGS IN CENTRAL ASIAN COUNTRIES

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## **List of abbreviations**

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



## **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. Pharmaceutical sector contribution in GDP is 1.17%. Nonprescription medicine, commonly known as OTC medicine, is medication that can be acquired without a prescription. Pakistan is a large market for importing over-the-counter drugs in the world, as Pakistan exports over-the-counter medicines worth USD 8.5 million, while the import bill is about 2 times greater, at USD 17.3 million. The national pharmaceutical industry has grown over the years, particularly in the recent decade. Central Asian countries are major importers of over-the-counter medications. Pakistan has an excellent chance to expand its OTC exports to Central Asian countries such as Uzbekistan, Kazakhstan, and Kyrgyzstan. These countries are prospective Central Asian markets for Pakistan's medicines. The majority of these countries' pharmaceutical imports are based on OTC pharmaceuticals such as Unani medicine, Homeopathy, Paracetamol, cough syrups, and so on, while Pakistan exports very few OTC drugs to them. Pakistan's contribution of OTC medicine exports to Central Asian countries is less than 1 percent, despite the fact that these countries purchase a large amount from the rest of the world. While, Pakistan has an advantage in terms of distance, and it is simple to approach these countries.

Major issues that Pakistani pharmaceutical exporters face in central Asian countries are high product registration fee, visa issues, distribution facilities etc. The potential can be harnessed through an urgently needed sectorial 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.





## **Chapter 1**

### **Introduction**

Nonprescription medicine, commonly known as OTC medicine, is medication that can be acquired without a prescription. They are safe and effective when used in accordance with the label's directions and as directed by a health care practitioner.

Pakistan is a large market for importing over-the-counter drugs in the world, as Pakistan exports over-the-counter medicines worth USD 8.5 million, while the import bill is about 2 times greater, at USD 17.3 million. The national pharmaceutical industry has grown over the years, particularly in the recent decade. The industry is attempting to modernize itself, and today the bulk of the business adheres to local Good Manufacturing Practices (GMP) rules, with a few adhering to international guidelines. Currently, the industry can produce a wide range of conventional items, from simple tablets to capsules, ointments, and syrups.

Central Asian countries are major importers of over-the-counter medications. Pakistan has an excellent chance to expand its OTC exports to Central Asian countries such as Uzbekistan, Kazakhstan, and Kyrgyzstan, among others. Pakistan's contribution of OTC medicine exports to Central Asian countries is less than 1 percent, despite the fact that these countries purchase a large amount from the rest of the world. Pakistan has the advantage in terms of distance, and it is simple to approach these countries.

Uzbekistan, Kazakhstan, and Kyrgyzstan are prospective Central Asian markets for Pakistan's medicines. The majority of these countries' pharmaceutical imports are based on OTC pharmaceuticals such as Unani medicine, Homeopathy, Paracetamol, cough syrups, and so on, while Pakistan exports very few OTC drugs to them. These countries require high-quality goods, and the majority of them have low NTBs, which work to Pakistan's benefit (Ahmas 2021). The growth of pharmaceutical exports is mostly based on population, and these countries are appealing primarily owing to their geographical proximity to Pakistan and the inexpensive requirements that may be provided by Pakistani enterprises.



## Pakistan Exports OTC Drugs to Uzbekistan, Kazakhstan and Kyrgyzstan

**Table 1 Pakistan Exports OTC Drugs to Uzbekistan, Kazakhstan and Kyrgyzstan**

Year	Country	Pakistan Exports of OTC Drugs	Imports of that Country	Pakistan's Share	Average Tariff faced by Pak	Pak Export to world
		USD Million		Percentage		USD M
2021	Uzbekistan	2.4 m	562m	0.3%	5%	8.5m
2021	Kazakhstan	1.5m	810m	0.1%	2%	8.5m
2021	Kyrgyzstan	2.3 m	150m	1.5%	0.7%	8.5m

has been no considerable research on the export potential of OTC medications in Central Asian countries. This sector requires research so that manufacturers can learn about new export potential in this field. This industry is expected to earn USD 100 million each year.

### 1.1 Objective of Study

The main aim of this study is to investigate the export potential for OTC medications in Pakistan. The following are the broad objectives:

- 1- To examine the market potential for over-the-counter (OTC) products in Central Asian countries.
- 2- To investigate API production and use of APIs in certain over-the-counter OTC products.
- 3- To explore the prospects for over-the-counter (OTC) medications in Central Asian countries in the presence of FTA and PTA.

### 1.2 API's used in OTC Drugs

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.

**Table 2 API's Used in Manufacturing of OTC Drugs.**

HS Code	OTC Drug	API Used	Description of API	Pak Top Export Markets
30049070	Aspirin	<u>Acetylsalicylic Acid</u>	Its analgesic, antipyretic, and anti-inflammatory properties make it a powerful and effective drug to relive symptoms of pain, fever, and inflammation.	-----
30049091	Cough Syrup	Dextromethorphan, and Guaifenesin	DEXTROMETHORPHAN; GUAIFENESIN is a combination of a cough suppressant and expectorant. It is used for the relief of cough, stuffy nose.	-----
30049092	Paracetamol	Paracetamol	Paracetamol, also known as acetaminophen or APAP (which is the active ingredient), is a commonly used medication for the treatment of mild to moderate pain and fever.	Djibouti Oman United Arab Emirates
30049050	Eye Drops	Polyethylene glycol, Polyvinyl alcohol, Tetrahydrozoline HCl Propylene glycol, Povidone, Glycerin	Redness reliever, Relief of burning & irritations. Relieve dryness of the eye	Kenya Nigeria Tanzania Uganda
30049060	Ointments	petrolatum, mineral oil, paraffins, synthetic hydrocarbons	Used in cosmetics, When used for medical purposes, they are used for Cuts and scrapes, Burns, Bites etc.	Kenya Sri Lanka
30049010	Unani Medicine, Ayurvedic medicine	Herbs, shrubs, leaves, barks, heartwood, flowers, seeds, fruits, fruit kernel, oils, gums, resins etc.: Animal byproducts like ghee, milk, honey	Offers treatment of diseases related to all the systems and organs of the human body. The treatments for chronic ailments and diseases of skin, liver, musculo-skeletal and reproductive systems etc.	Uzbekistan Afghanistan Kazakhstan Lithuania United states
30049020	Homeopathic medicine	Natural substance derived from plants, animals	The active ingredients of homeopathic medicines are generally identified by the Latin name of their source. For example, apis mellifica (commonly known as honeybee).	Bangladesh Malaysia United States Yemen

Source: ITC Trade Map

### 1.3 How and where are APIs made?

The API market alone is already a multi-billion-dollar market. APIs are mainly produced in large production plants. It's a complex chemical process of several steps. It's made from starting materials which can be a raw material or intermediate. Back in the days, pharma companies made and formulated the API and medicine in their home countries.

Today, India and China are the largest API producing countries. Some of the largest suppliers and manufacturers of API's are also present in Pakistan and they are Pharmagens limited, Zafa pharmaceuticals, City pharma etc. They are all founded, or based in Lahore, Punjab Pakistan. All these API manufacturers are manufacturing basic API's which are used in OTC Drugs such as Paracetamol, cough syrups, Aspirin etc. This API manufacturer has big manufacturing units and can meet country's demand for API if supported by Government.

Figure 1 API Manufacturing Plant



Source: TDAP Research Wing

Around 300-350 pharma companies in Pakistan are purchasing API's from these API manufacturing local companies while remaining import from China, India, Switzerland, Germany etc. Due to this import bill increases.

Figure 2 API Production Unit





## **CHAPTER 2**

### **Pakistan's trade analysis with different central Asian Countries:**

#### **2.1 Analysis of Pakistan and Uzbekistan**

The Republic of Uzbekistan (Uzbekistan) is a country in Central Asia with an area of 447,400 square kilometers. It stretches 1,425 kilometers from west to east and 930 kilometers from north to south. It shares a border with the other four Central Asian States and is only one of two countries in the world completely surrounded by other landlocked countries. With the Central Asian States, Uzbekistan shares a border with Turkmenistan to the southwest, Kazakhstan to the north, and with Tajikistan and Kyrgyzstan to the south and the east. It also shares a short border with Afghanistan to the south.

Relations between Uzbekistan and Pakistan were established when Uzbekistan became independent in 1992. The relations became stronger when both the countries worked together to counter terrorism in Afghanistan. Pakistan and Uzbekistan enjoy pleasant and friendly political ties and have signed bilateral agreements with each other. The two countries have signed about 56 bilateral agreements and MOU's since 1991, to expand good relations.

Pak-Uzbekistan Business Forum was held in Tashkent in July 2021 to promote bilateral trade. Over 2,000 business meetings were held during the forum, which resulted in the signing of nearly \$50 million in agreements and deals, as well as 14 other Memorandums of Understanding.

Two countries inked the Uzbekistan-Pakistan Transit Trade Agreement (AUPTT) on July 15 in 2021. The key aspects of AUPTT as follows: transit trade between Uzbekistan and Pakistan will take place via pre-determined routes, with only specific ports and border crossings being used. Uzbekistan and Pakistan, are expected to provide appropriate infrastructure and people at border crossings, as well as separate sites for off-dock terminals and warehousing at entry/exit ports and other customs-notified locations on a reciprocal basis (Ministry of Investments and Foreign Trade of the Republic of Uzbekistan).



While each country was responsible for regulating transport operators such as trucking companies registered on its soil, Uzbekistan and Pakistan would issue Road Transport Permits that would allow convey operators to transport products via the territory of the other country. Uzbek vehicles could transport products to sea ports via Pakistan rather than needing to reload them onto Pakistani trucks at the Afghanistan-Pakistan border.

Uzbek government would recognize Pakistani driver’s licenses and vehicle registration paperwork, and that the Uzbek and Pakistani governments would speed up and simplify the procedure of issuing multiple-entry visas to truck drivers from both nations.

**2.1.1 Trade Overview:**

Uzbekistan is one of the biggest importers of pharmaceutical and import about USD 1.1 billion of pharma products from the world in 2020-21. About USD562 million of pharmaceutical imports of Uzbekistan based on OTC drugs such as Unani medicine, Homeopathic, Aspirin, Paracetamol, cough syrups etc. while Pakistan export them a very little quantity of OTC drugs worth of USD 2.4 million.

**Table 3 Pakistan’s Exports of OTC Drugs to Uzbekistan**

HS Code	HS Code	Product Description	Pakistan Export to Uzbekistan	Uzbekistan Imports from world	Pakistan’s share	Average Tariff faced by Pak	Indicative trade potential
<b>Pakistan</b>	<b>Uzbekistan</b>		<b>USD Million</b>	<b>USD Million</b>			<b>USD Million</b>
30049060	3004900000	Ointments	-	9.7m	0%	5%	9.7m
30049010 30049070 (Aspirin)	3004900002	Unani medicine, Ayurvedic, Aspirin and oriental type medicine	2.4m	519m	0.4%	5%	516.6m
30049092	3004900006	Paracetamol	-	0.7m	0%	5%	0.7m
30049091	3004900009	Oral suspension, cough syrup	-	33m	0%	5%	33m

Source: ITC

Uzbekistan is importing OTC drugs worth of USD 562 million from world while Pakistan is exporting OTC drugs to Uzbekistan of just USD 2.4 million and this share of Pakistan is below than 1%. Pakistan has huge trade potential in exporting OTC drugs to Uzbekistan.

Trade with Pakistan has been very erratic. Although all imports from Pakistan have stayed fairly constant, exports show unpredictability as these have ranged from USD 2.4 million. The



huge drop in exports came largely because of political instability in Afghanistan, since the trade route from Pakistan to Uzbekistan is through Afghanistan.

Transportation of pharma products is a major issue, but now Pakistan can send its products on trucks via Afghanistan. As Pakistan and Uzbekistan have exchanged goods through war-torn Afghanistan for the first time, in a move hailed as a milestone for regional economic integration.

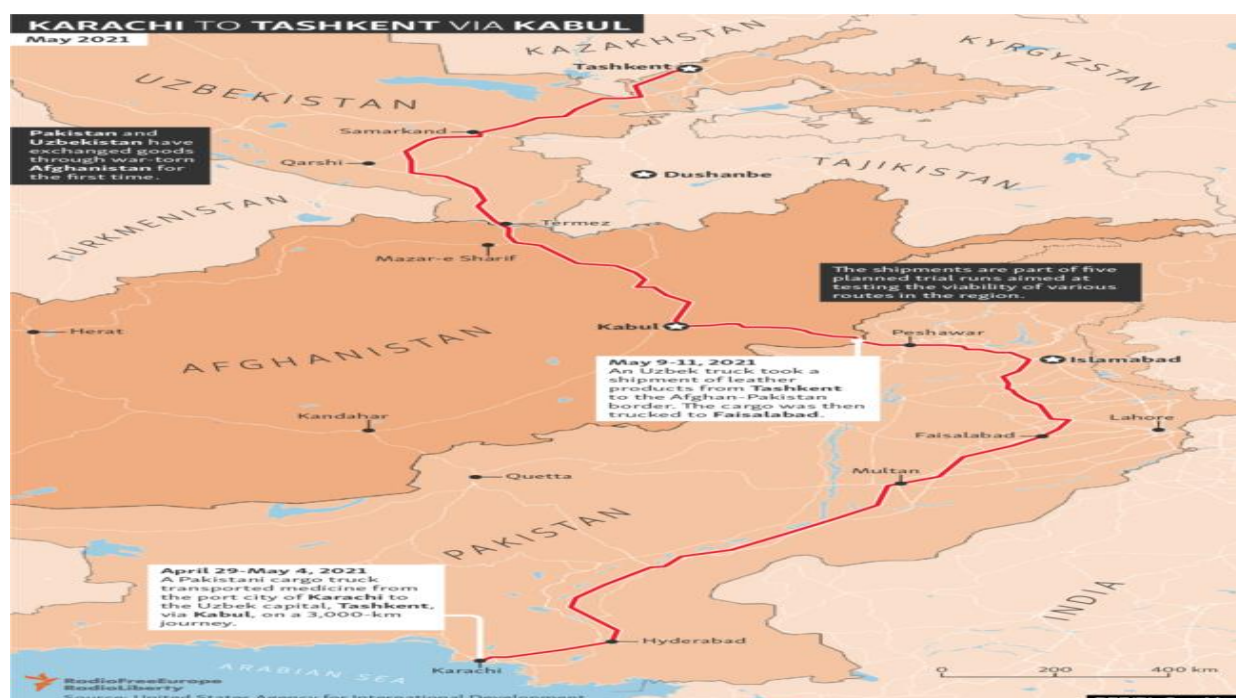
A Pakistani cargo truck transported medicine from the port city of Karachi on April 9, 2021 to the Uzbek capital, Tashkent, via Kabul. It arrived on May 4, 2021. An Uzbek cargo truck then took a shipment of leather products from Tashkent on May 9 and arrived at the Afghan-Pakistani border (Torkham crossing) on May 11, 2021. It then was trucked to Faisalabad on May 13.

The shipments are part of five planned trial runs aimed at testing the viability of various routes in the region, where trade has been hampered by the decades-old conflict in Afghanistan and longstanding diplomatic tensions between Kabul and Islamabad.

The project has received technical and financial support from the United States Agency for International Development (USAID). The agency said the initiative is intended to “boost regional trade integration and connectivity.”

The shipments were made under the Transports Internationaux Routiers (TIR) Convention, a customs agreement that facilitates the international transport of goods. The multilateral treaty eliminates the need to pay customs duties and taxes. Afghanistan rejoined the TIR after a 30-year suspension in 2013, while Pakistan joined in 2017.

Figure 3 Road Transportation of Pharmaceutical Products from Karachi to Tashkent



Source: United States Agency for International Development

### 2.1.2 Pakistan’s Competitors in Uzbekistan:

India and China are Pakistan’s major competitors in exports OTC Drugs to Uzbekistan.

**Table 4 Pakistan’s Competitors of OTC Drugs in Uzbekistan**

Product Description	Pakistan’s Competitors	Exports Value	Share in Imports	Average Tariff
		USD Million		
Ointments	India China	1.6	16.4%	5.3%
		-	-	5.1%
Unani medicine, Ayurvedic and other oriental type medicine	India China	78	15%	5.3%
		28	5.3%	5.1%
Paracetamol	India China	0.4	57%	5.3%
		0.1	14%	5.1%
Oral suspension, cough syrup	India China	1.1	3.3%	5.3%
		0.2	0.3%	5.1%

India and china capture most part of Uzbekistan market. India have its pharmaceutical manufacturing units and distributions in Uzbekistan, due to this India hold Uzbekistan’s pharma imports. While Pakistan has no manufacturing units and distribution of pharmaceuticals in Uzbekistan. No doubt Pakistan has huge OTC Drugs export potential in Uzbekistan.



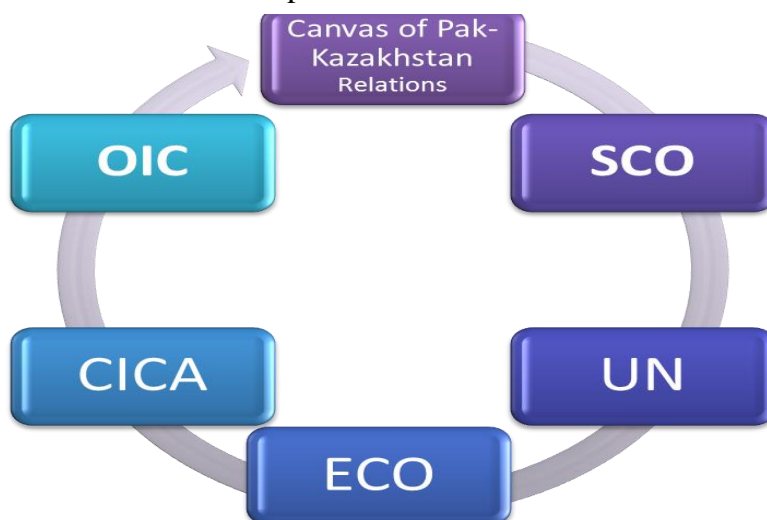
## 2.2 Analysis of Pakistan and Kazakhstan

In modern times, Pakistan was among the first countries to recognize Kazakhstan when it emerged as an independent state on December 16, 1991. This year both brotherly countries are celebrating 30 years of diplomatic ties that were established in 1992 when the First President of Kazakhstan visited Pakistan.

Current years are witnessing the beginning of a new era in the relations of Pakistan and Kazakhstan with prime focus on commerce, and trade. The prospects of stability in Afghanistan, the emerging multipolar world order, the progress of Belt and Road Initiative (BRI) in Central Asia and South Asia are opening new vistas of opportunities for bilateral trade and investment. China Pakistan Economic Corridor (CPEC) is the flagship project of BRI that offers the Central Asian countries access to the warm waters of Gawadar sea port. Then, over 120 projects of BRI are operating Kazakhstan for its significance as global transit hub.

### Pak-Kazakh Horizon of Diplomatic Relations

Figure 4 Pak-Kazakh Horizon of Diplomatic Relations



Source: TDAP Research Wing

The scope and horizon of diplomatic relations between the two countries are diversified and dynamic due to which right from the beginning both the countries have been sharing better political understandings include various official mutual visits of their leadership and cooperation and meaningful coordination within various international organizations i.e. the United Nations (UN), the Organization of Islamic Cooperation (OIC), Economic Cooperation Organization (ECO), Shanghai Cooperation Organization (SCO) and Conference on



Interaction and Confidence-Building Measures in Asia (CICA). Moreover, Pakistan provides natural link to connect the Eurasian region with the Arabian Sea and South Asia

Kazakhstan is one of the biggest importer of pharmaceutical products and import about USD 1.5 billion. Out of this total pharma imports, Kazakhstan import OTC Drugs worth USD 781 million.

**Table 5 Pakistan Exports of OTC Drugs to Kazakhstan**

HS Code	HS Code	Product Description	Pak Export to Kazakhstan	Kazakhstan Imports from world	Pak's share	Average Tariff faced by Pak	Indicative trade potential
Pakistan	Kazakhstan		USD Million	USD Million			USD Million
30049010 30049070 (Aspirin)	3004900002	Unani medicine, Ayurvedic, Aspirin and oriental type medicine	1.3m	757m	0.1%	2%	755.7m
30049092	3004900006	Paracetamol	-	4m	0%	2%	4m
30049091	3004900009	Oral suspension, cough syrup	0.2	20m	1%	2%	19.8m

Source: ITC TradeMap

Pakistan has huge export potential for OTC Drugs in Kazakhstan, while Pakistan just export OTC Drugs of worth USD 1.5 million which is just 0.1% of total imports of OTC Drugs of Kazakhstan.

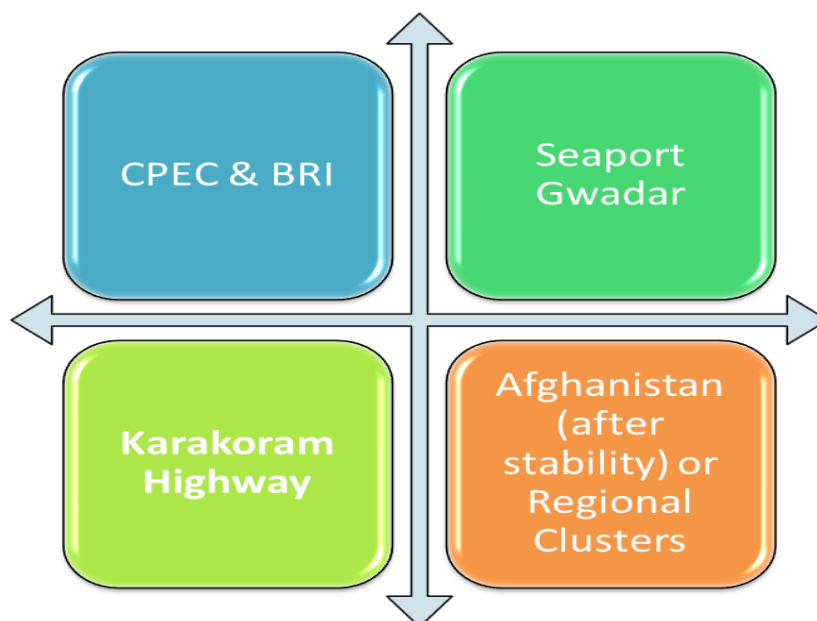
### Difficulty in Trade

Being a land-locked country with restricted access to the open seas, Kazakhstan's pharmaceutical trade with Pakistan is very limited. The bilateral trade between the two countries has potential, which unfortunately is not being achieved due to the lack of a logistics network. The trade route between Pakistan and Kazakhstan relies on the Regional Cooperation for Development Highway which goes through Afghanistan to Almaty Kapshagay Highway in Kazakhstan. The law and order in Afghanistan has been unstable for many years which makes trade between Kazakhstan and Pakistan unsafe and time-consuming (Alam, Shaista, 2015).

### Bilateral Trade & Possible Means:

Since Kazakhstan is the biggest land-lock country of the world having no direct road, rail, sea and air links with Pakistan so it is strongly recommended that both countries should focus on some “innovative plans” to enhance their levels of connectivity in the future. Strong political commitments and inclusion of private sectors may be useful to achieve the desired goals of socio-economic integration and greater regional connectivity.

Figure 5 Future Possible Opportunities of Transportation between Pakistan and Kazakhstan



Source: TDAP Research Wing

Lack of direct geographical communications seriously hamper bilateral economic and trade cooperation and coordination. But through serious initiatives the volumes of bilateral trade may be increased. Pakistan’s access to western China and Central Asia has been greatly expanded by the reconstruction and renovation of the strategically Karakoram Highway in the 2000s which may be utilized to enhance regional connectivity.



### 2.2.1 Pakistan’s Competitors in Kazakhstan

India and China are Pakistan’s major competitors in exports OTC Drugs to Kazakhstan

**Table 6 Pakistan’s Competitors of OTC Drugs in Kazakhstan**

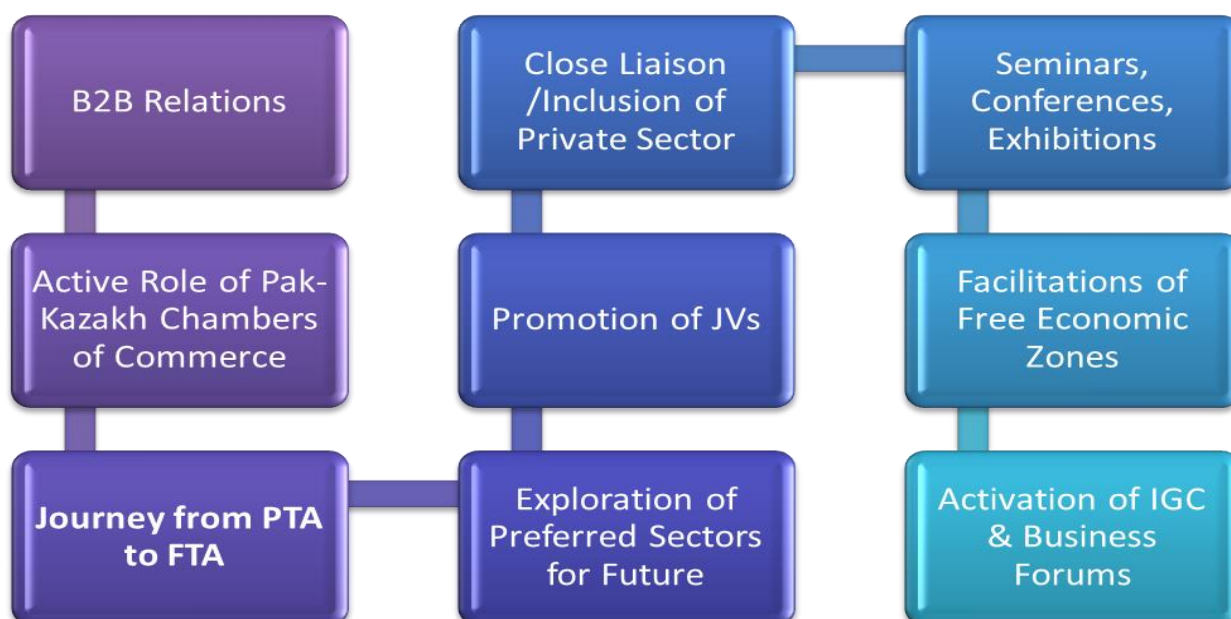
Product Description	Pakistan’s Competitors	Exports Value	Share in Imports	Average Tariff
		USD Million		
Unani medicine, Ayurvedic and other oriental type medicine	India	80	10%	2.5%
	China	2.3	0.2%	2.5%
Paracetamol	India	0.6	15%	2.5%
	China	-	-	2.5%
Oral suspension, cough syrup	India	4	20%	2.5%
	China	0.6	3%	2.5%

Source: ITC TradeMap

India and china are Pakistan’s competitors in Kazakhstan in exporting OTC drugs, and these countries are exporting those products which Pakistan can also export and have potential to export. Need of hour is to make some serious steps to capture Kazakhstan pharmaceutical market.

### 2.2.2 Diversified & Integrated Operationalization & Channelization

Figure 6 Diversified & Integrated Operationalization & Channelization



Source: TDAP Research Wing

Since we are living in an era of commercial diplomacy there is an urgent need to improve trade relationship through systematic awareness among the business circles of both the countries.2.3



### **2.3 Analysis of Pakistan and Kyrgyzstan**

Relations between Kyrgyzstan and Pakistan were established on 20 December 1991 shortly after Kyrgyzstan became independent from the Soviet Union. Diplomatic relations were formally established on 10 May 1992.

The geo-strategic position of Pakistan and Kyrgyzstan also highlights their geo-economic importance, which could play a significant role in promoting trade connectivity amongst different regions and potential markets of the world.

Due to its geostrategic importance, Pakistan is currently a major player in global and regional trade, bordering the Middle East and South Asian states on the one hand and the global economic power China on the other.

Similarly, Kyrgyzstan, due to its very important geographical location, has a distinctive place among the Central Asian states (CARs). Geographical location of Kyrgyzstan offers many opportunities for trade with Pakistan as it is the shortest entry point of Pakistani products to the 'Eurasian Economic Markets' of 182 million people comprising Russia, Kyrgyzstan, Kazakhstan, Belarus and Armenia.

Pakistan and Kyrgyzstan collaborate and cooperate with each other in several ways to strengthen economic and trade ties. One such example is the establishment of the State Bank of Pakistan branch in Kyrgyzstan's capital, Bishkek.

In order to develop commercial and trade links, Pakistan and Kyrgyzstan work and cooperate in a variety of ways. Twenty-two Pakistani banks are already operating there.

Furthermore, bilateral ties have strengthened greatly as both countries support and interact with each other at many international forums such as the Organization of Islamic Cooperation (OIC), United Nations (UN), Economic Cooperation Organization (ECO), Shanghai Cooperation Organization (SCO) and others.

“Kyrgyzstan is not developed in pharmaceutical sector and offers great opportunities to Pakistani pharma companies.” Kyrgyzstan imports pharmaceutical products of USD 204 million, and from this imports OTC Drugs imports is about USD 150 million.

**Table 7 Pakistan's Exports of OTC Drugs to Kyrgyzstan**

HS Code	HS Code	Product Description	Pakistan Export to Kyrgyzstan	Kyrgyzstan Imports from world	Pak's share	Average Tariff faced by Pak	Indicative trade potential
Pakistan	Kyrgyzstan		USD Million	USD Million			USD Million
30049010 30049070 (Aspirin)	3004900002	Unani medicine, Ayurvedic, Aspirin and oriental type medicine	2m	99m	2%	0.7%	97m
30049092	3004900006	Paracetamol	-	0.4m	-	0.7%	0.4m
30049091	3004900009	Oral suspension, cough syrup	0.3	51m	0.5%	0.7%	50.7m

Pakistan export very little quantity of OTC Drugs to Kyrgyzstan, while Pakistan has huge export potential for OTC Drugs. The main reason for such a low level of two-way trade is little knowledge about each other's markets.

Pakistani pharmaceutical businessmen could invest individually or through joint ventures in Kyrgyzstan. Pakistan could use Kyrgyzstan as a gateway to enter into the European Union market and could avail benefits from GSP Plus status (Anum, 2018).

Goods once exported to Kyrgyzstan can be further transported to the Eurasian markets without payment of customs duties. Given the strategic location of Kyrgyzstan and its membership of Eurasian Economic Union, a trade delegation may visit Kyrgyzstan to look for new markets for Pharmaceutical products. Direct flights between the two countries on a regular basis would help improve trade and cooperation.

Kyrgyzstan was interested in development of short transportation links through its territory between Central Asia and China and Pakistan with access to the Gwadar and Karachi ports, using railway and automobile roads, which were being constructed in the framework of the China-Pakistan Economic Corridor (CPEC).

### 2.3.1 Pakistan's Competitors in Kyrgyzstan

India and China are Pakistan's major competitors in exports OTC Drugs to Kyrgyzstan

**Table 8 Pakistan's Competitors of OTC Drugs in Kyrgyzstan**

Product Description	Pakistan's Competitors	Exports Value	Share in Imports	Average Tariff
		USD Million		
Unani medicine, Ayurvedic and other oriental type medicine	India	16	16%	1.2%
	China	2	2 %	1.2%
Paracetamol	India	-	-	1.2%
	China	-	-	1.2%
Oral suspension, cough syrup	India	2.4	4.7%	1.2%
	China	0.8	1.5%	1.2%

India and china are Pakistan's competitors in exports of OTC Drugs. Today, shortest automobile roads connect China to Kyrgyzstan through two border mountain passes in Kyrgyzstan - Torugart in the north and - Erkeshtam in the south, located only about 200-km from the Chinese city of Kashgar.

Kyrgyzstan and China shared a long border, therefore, Pakistan and Kyrgyzstan should make good use of the China-Pakistan Economic Corridor (CPEC) for attaining better connectivity to deeply explore each other's markets.

The Quadrilateral Traffic and Transit Agreement (QTTA) between Pakistan, China, Kyrgyzstan and Kazakhstan, which is part of CPEC, offers an excellent communication network between Central Asia and Pakistan's Gawadar Port in the Arabian Sea.

Pakistan and Kyrgyzstan, two CAREC (Central Asia Regional Economic Cooperation) nations that are close neighbors, may considerably benefit from enhanced regional connectivity and trade. Both nations are growing economies with substantial agricultural bases and significant strategic benefits to offer the alliance.

Despite regular high-level active engagements with each other, trading volume is quite modest. The current trade volume does not match the actual potential that exists between the two nations.



## **Chapter 3**

### **Major Barriers/ Issues in Trade with Central Asian Countries**

In order to sign trade agreement with any country, major parameters of ease of doing business must be accomplished. With Uzbekistan, Kazakhstan and Kyrgyzstan Pakistan has to face;

#### **Currency Exchange**

US dollars are very limited in Uzbekistan, Kazakhstan and Kyrgyzstan and they trade in their local currency. In these countries, Pakistani exporters receive payments in Som and tenge, which has three different exchange rates. Moreover, informal currency exchange is almost double the actual exchange rates. Because of strict government regulations, Pakistani exporters are not allowed to carry US dollars along.

#### **Registration Process**

Registration process in central Asian countries is too hard and complicated. As in order to register a medicinal product within the frame of the procedure according to the Decree of the Cabinet of these countries, it is necessary to provide the following documents to the State Centre of Expertise and Standardization of Medicinal Products, Medical Devices and Medical Equipment of the Ministry of Health:

Application form with the attached documents:

- i. Legalized Power of Attorney from the applicant to the representative;
- ii. Legalized copy of Business license of the applicant;
- iii. Legalized copies of the Manufacturer's Authorizations for all manufacturing sites involved in manufacturing process issued by the competent authorities of countries-manufacturers;
- iv. Legalized copies of GMP Certificates for all manufacturing sites involved in manufacturing process issued by the competent authorities of countries-manufacturers;
- v. Legalized copy of the Agreement or the Letter of relationships between the applicant and manufacturer of medicinal product if different;





- vi. Legalized copy of certificate of a pharmaceutical product (CPP) or legalized copy of registration certificate issued by the competent authority of country of manufacturer or justification of its absence;
- vii. Legalized copies of registration certificates issued by the competent authorities of countries, where said medicinal product is registered, or justification of their absence.

Registration dossier in the format of 4 parts (including administrative, chemical, pharmaceutical, biological, pharmacological and clinical documentation).

Samples of medicinal product and standard samples in an amount required for the triple test.

### **Duration of Registration Process**

According to the procedure of state registration of a medicinal product should be conducted within 155 days without considering the time for preparation of responses to the remarks. However, in accordance with the usual practice depending upon the completion of the provided materials and scope of documentation, number of requests of the competent authority and other factors the procedure of state registration of medicinal product may constitute about 6-8 months without considering the time for preparation of responses to the remarks.

### **Product Registration fee**

Product registration fee in central Asian countries is too high. As registration fee for one pharmaceutical product cost USD 10,000 to USD 15,000. This high cost of product registration is a big hurdle in export promotion of OTC Drugs. For example, the government of Kazakhstan requires bioequivalence or bio-similar compliance from exporters of pharmaceutical products which costs approximately US\$ 250,000 to US\$ 500,000. Exporters are unable to afford such exorbitant prices.

### **Validity Term and Renewal**

The Certificate about the state registration of a medicinal product in central Asian countries are valid for **5 years** and after that it is necessary to renew it each time for the next 5 years. The procedure of the renewal of the registration must be initiated within 3 months before expiration of previous registration.



### **Language Barrier:**

Pakistani exporters face language barrier as even English is not spoken in Uzbekistan, Kazakhstan and Kyrgyzstan commonly. Services of professional translators are required for most communication.

In Uzbekistan Uzbeks is the primary language while Russian is secondary language spoken by most of the urban population. Uzbeks make up more than four-fifths of the population, followed by Tajiks, Kazakhs, Tatars, Russians, and Karakalpaks. (Ahmad, M 2020).

Kazakhstan is quite diverse: 67.5% of the population is ethnic Kazakhs and 19.8% ethnic Russians. Other groups include Tatars (1.3%), Ukrainians (2.1%), Uzbeks (2.8%), Uyghurs (1.4%), Belarusians, Azerbaijanis, Dungans, Kalmyks, Chuvashes, Poles and Lithuanians.

In kyrgyzstan, primary language is Kyrgyz and Russian and other languages are Tatars, karakalpaks.

In all these states use of English language is very low. This is major issue that Pakistani exporters faced.

### **Visa Issue**

Almost all manufacturers of pharmaceuticals face problem of visa issuance in central Asian countries. Going to Uzbekistan requires a visa for most nationalities in the world. Only 17 nationalities enjoy visa exemption, which means that the rest of them need to go through some kind of process to obtain a visa. While some nationalities are eligible for an Uzbekistan e-Visa, Pakistan nationals do not enjoy this privilege. Not yet, at least. Unfortunately, Pakistan is not currently on the list of countries whose citizens can enter Uzbekistan using an electronic visa. Similarly, there are issues regarding visa in Kazakhstan and Kyrgyzstan.

### **Banking Issues**

There are no international banks in Uzbekistan, Kazakhstan and Kyrgyzstan.

**Bureaucratic Hurdles:**

Government of Kazakhstan and Uzbekistan are known for delaying the process and red tapism. Pakistani exporters face huge difficulties for even simple documentations or registrations.



## **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.

## **Transit/ Supply Lines:**

There is currently no transit agreement signed by either of the governments. APTTTA is yet to be formalized which will open corridor for Pakistan in Uzbekistan, Kazakhstan and Kyrgyzstan and other CIS countries.

## **Distribution and sales challenge**

As distribution networks in Uzbekistan, Kazakhstan and Kyrgyzstan have been diversified and upgraded over the years. The major sales and distribution challenges for businesses have shifted from simply getting goods to market to more concern about legislative and regulatory issues. Finding distributions and start marketing on their own is too much difficult for Pakistani pharma companies.

## **Insecurity a 'Severe Hurdle'**

Travelling towards Uzbekistan, Kazakhstan, and Kyrgyzstan via Afghanistan always have security issues. Observers say the biggest hurdle for regional economic connectivity is the war in Afghanistan. There always remain widespread fears of an intensified civil war in Afghanistan.

It is unclear if the Taliban gave its backing to the Pakistan and Uzbekistan cargo route, which passes through territory controlled by the militant group. The Taliban commands or contests around half of Afghanistan.

## **Data Sources**

The data taken from ITC-Trade Map, ComTrade, PRAL, Pakistan Business council, World Bank, TDAP Reports, and Product Officers, Manufacturers and Exporters



## **Chapter 4**

### **Conclusion and Recommendation:**

#### **4.1 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.

Nonprescription medicine, commonly known as OTC medicine, is medication that can be acquired without a prescription.

Pakistan is a large market for importing over-the-counter drugs in the world, as Pakistan exports over-the-counter medicines worth USD 8.5 million, while the import bill is about 2 times greater, at USD 17.3 million. 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.

Central Asian countries are major importers of over-the-counter medications. Pakistan has an excellent chance to expand its OTC exports to Central Asian countries such as Uzbekistan, Kazakhstan, and Kyrgyzstan, among others. Uzbekistan, Kazakhstan, and Kyrgyzstan are prospective Central Asian markets for Pakistan's medicines. The majority of these countries' pharmaceutical imports are based on OTC pharmaceuticals such as Unani medicine, Homeopathy, Paracetamol, cough syrups, and so on, while Pakistan exports very few OTC drugs to them. Pakistan's contribution of OTC medicine exports to Central Asian countries is less than 1 percent, despite the fact that these countries purchase a large amount from the rest of the world. While, Pakistan has an advantage in terms of distance, and it is simple to approach these countries.



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.

Pakistan has a large installed capacity for OTC products. As a result, Pakistan's industry may export its goods and earn foreign currency. This may be achieved if the government provides them with financial aid and tax benefits.

## **4.2 Recommendations**

The following policy guidelines are proposed to increase exports of OTC Drugs in Uzbekistan, Kazakhstan and Kyrgyzstan.

- 1- Chambers of Commerce in these countries must institutionalize their coordination to bring together the business communities by seminars, visits and exhibitions.
- 2- Government of Pakistan should sign some MOU's regarding product registration fee in these countries, because registration fee is too high.
- 3- Institutional research should be carried out to explore the preferred sectors for future.
- 4- All countries could promote joint ventures under sovereign guarantees.
- 5- The shortest route from Chinese city of Kashgar to Kyrgyzstan is about 200 km, through two Kyrgyz passes of Torugart and Erkeshtam. It should be utilized for linking to the warm waters of Gowadar port.
- 6- Transit agreement with Uzbekistan must be finalized sooner than later. Signing of APTTTA is need of the hour.
- 7- Pakistan Single Window Operation must be established to assist exporters for documentations and expediting bureaucratic processes.
- 8- under the governance of State Bank of Pakistan, banking channels must be established to sort exchange and transaction issues
- 9- Government agencies can help exporters by providing testing facilities at customs department to fulfill requirements related to Technical Barriers to Trade (TBT) measures at subsidized rates.



- 10- Marketing Activities especially exhibitions in Kyrgyzstan will provide an edge to Pakistani exporters as none of the competitors are doing exhibitions in Kyrgyzstan currently. Similarly, in Uzbekistan exhibitions will give a boost to introduce Pakistani products.
- 11- Being a prime Think Tank on Euro-Asia in Pakistan and region as well, the CGSS Pakistan may also be useful and effective to form befitting policies to gear-up bilateral trade volumes in the days to come. Furthermore, the CGSS Pakistan is ready to arrange a number of seminars, conferences, round-tables collaborations by including all the main stakeholders and road-shows to be held in the major cities of Pakistan and Kazakhstan with the aim of increasing awareness of local business circles about mutual potential of both the countries in terms of trade and investment opportunities, as well as tourist potential.
- 12- For further strengthening of cooperation in the fields of tourism, air-links/communications and hospitality both countries must consider positively to have trilateral agreement (Kazakhstan-Uzbekistan-Pakistan) because both the Central Asian Countries (CACs) have already signed a “joint Visa mechanism” for the promotion of tourism and hospitality sectors. Although, Islamabad and Astana (PIA & Astana Air) have already started research work to look into possibility of direct air link between the two countries however, the plan could not materialize because of want of passengers, on this route. To overcome this shortcoming, a trilateral agreement may be signed among (Kazakhstan-Uzbekistan-Pakistan) to start-up the direct flights through interconnected possibilities with Turkey & EU.
- 13- A facility may be negotiated with the government of Kazakhstan to allow Pakistani exporters to re-export their goods to other Eurasian countries including Russia.
- 14- Establishment of Pakistan Trade Center at eminent locations of Almaty, Khorgos, Shimkin and Nursultan would boost bilateral trade.
- 15- Trade Development Authority of Pakistan (TDAP) should provide facilities of distributors in these countries.
- 16- Along with BRI, the Central Asia Regional Economic Cooperation (CAREC) Program of Asian Development Bank should be materialized early whose Corridor No.5 also connects Central Asia to Gowadar and Karachi ports of Pakistan.
- 17- Already signed MOU between National Export and Investment Agency “KAZNEX INVEST” JSC and Trade Development Authority of Pakistan (TDAP) to arrange exhibitions, exchange business delegations and hold seminars on trade must be utilized.



- 18-** Two railway links of Kazakhstan-Turkmenistan-Iran and Pakistan-Iran-Turkey must be joined to establish rail connectivity between Islamabad and Nursultan.



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