

Demystifying the Role of ‘Barriers at and behind the Borders’ in India: A Case Study of Pharmaceutical Products

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Abstract

With the significant reduction of tariff barriers to international trade, other forms of barriers, such as barriers at the border and behind borders are considered as the major challenge to the growth of global trade. These barriers are often high in developing countries as compared to developed ones and arise due to divergent regulatory frameworks, inefficient customs procedures, cumbersome export-import procedures, administrative hassles, hidden taxes, congestion fee and sub-optimal trade infrastructure.

Against this backdrop, this Discussion Paper attempts to understand the role of different types of barriers in the import pharmaceutical products in India. It analyses the effect of three main barriers: tariff barriers; non-tariff barriers; and barriers at the border with a particular focus on understanding the role of procedural and regulatory impediments.

Introduction

With reduction in traditional trade barriers, trade literature has recognised the role of ‘barriers at border and behind the borders’ that arise from inefficient customs clearance, cumbersome trade procedures, regulatory and administrative hassles, hidden taxes, congestion fee and sub-optimal trade infrastructure (Mirza and Bacani, 2013).

The cost associated with these barriers has adverse impacts on the functioning of ‘supply chains’ and affects the participation of firms in global value chain network. ‘Barriers at border and behind the borders’ have been considered one of the major obstacles in facilitating cross-border trade, and they increase the cost of doing trade (Banik and Gilbert, 2008; CUTS, 2015).

The cumulative effects of these barriers increase the imported price of product and this in turn, escalate the final market price. This issue is particularly important in the context of medicines, which are imported in huge volumes, and therefore, has relevance in determining health outcomes for a developing country like India. A marginal increase in price of medicines because of complex regulations, low quality of services at ports and inefficient custom clearance, add up extra cost and hit the patients who are in need for medicines. Moreover, it is squarely opposite to the idea of promoting consumer welfare through free and fair trade.

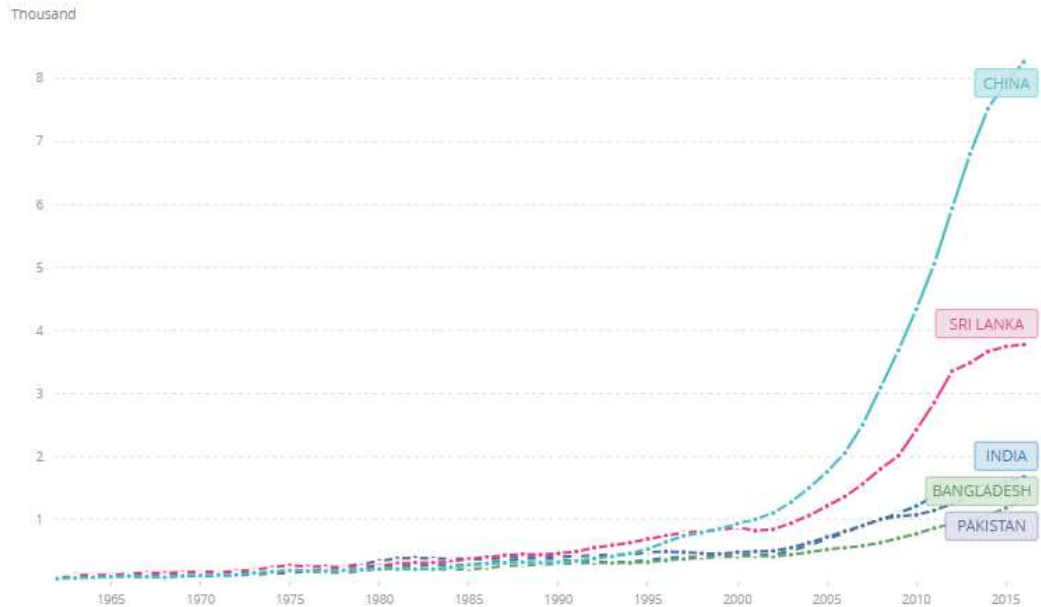
In addition to tariffs, there are other factors, such as non-tariffs and regulatory measures that adversely affect supply of medicines. Kotwani (2013) found that the availability of essential generic medicines is very poor in public sector facilities, which are the primary source of free medicines for a majority of India’s low-income population (ranging from 41.3 percent to 23.2 percent in state government facilities).

In another related study, examining availability of five generic essential medicines in 129 public health facilities across 17 states in India, Gitanjali and Manikandan (2011) found that availability was approaching acceptability at a median of 80 percent but several facilities – particularly in rural areas – had no availability at all.

These tariffs and extra-tariffs factors by affecting accessibility of pharmaceutical products have an important implication on health, and hence, development outcome for India as health is an important component of development. There are studies, which documented positive impact of improved health on labour productivity and economic growth (Bloom and Canning, 2000; Bloom, Canning and Sevilla, 2004).

India, for that matter, is in limelight for being the fastest growing large economy in the world with a population size of more than 1.3 billion. The economy is at a crucial stage of its socio-economic transformation, with majority population being young. Good health of citizens is extremely important to exploit demographic dividends.

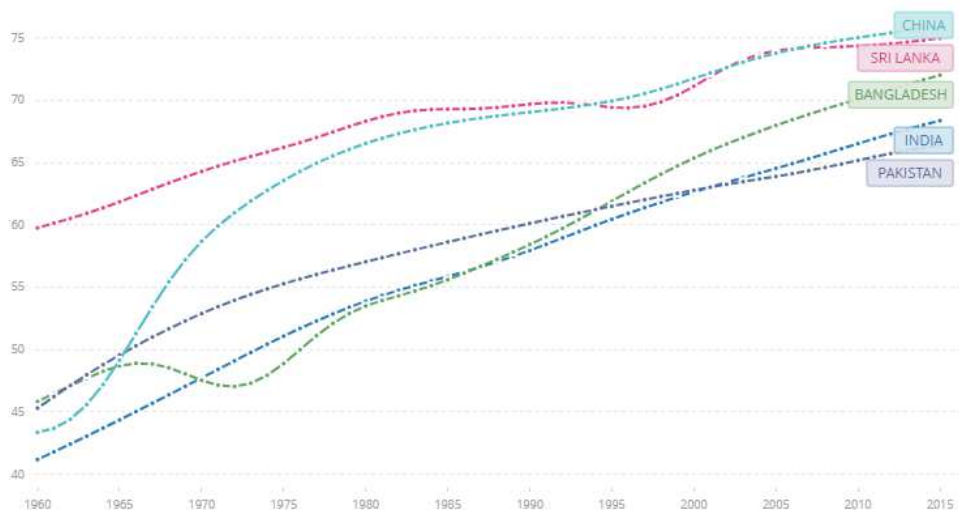
Figure 1: Per Capita Income in Current US\$



Source: World Development Indicators, World Bank (2017)

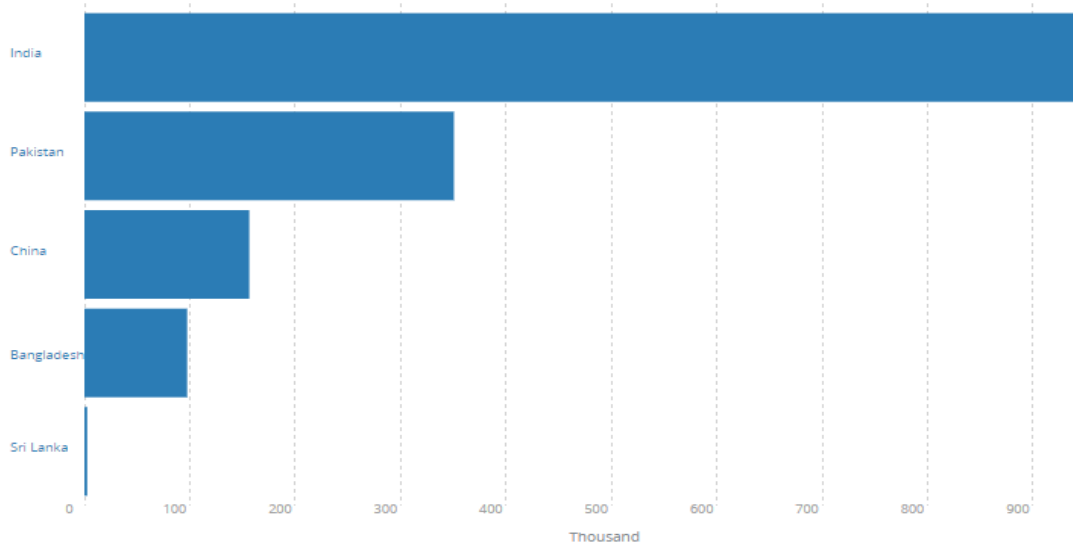
India ranks low in the world in terms of health indicators. Controlling for level of per-capita income, which is to say, comparing India with other similar economies in the region, it is revealed that India is having lower life expectancy and higher infant mortality rate (Figure 2 and Figure 3).

Figure 2: Total Life Expectancy at Birth (in Years)



Source: World Development Indicators, World Bank (2017)

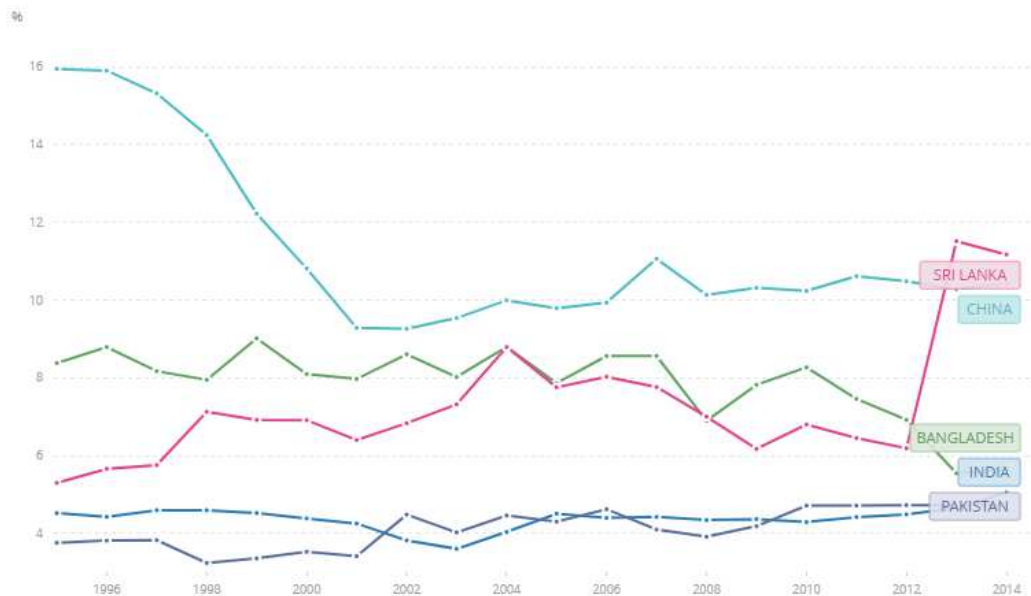
Figure 3: Number of Infants Dying before Reaching One-year of Age in 2015



Source: World Development Indicators, World Bank (2017)

Although, health is a state subject,¹ central government also spends money on health through several centrally sponsored schemes, such as National Health Mission and National Health Insurance Schemes (Rashtriya Swasthya Bima Yojana). However, given India’s large population base, per-capita spending on health is abysmally low.

Figure 4: Health Expenditure, Public (% of Government Expenditure)



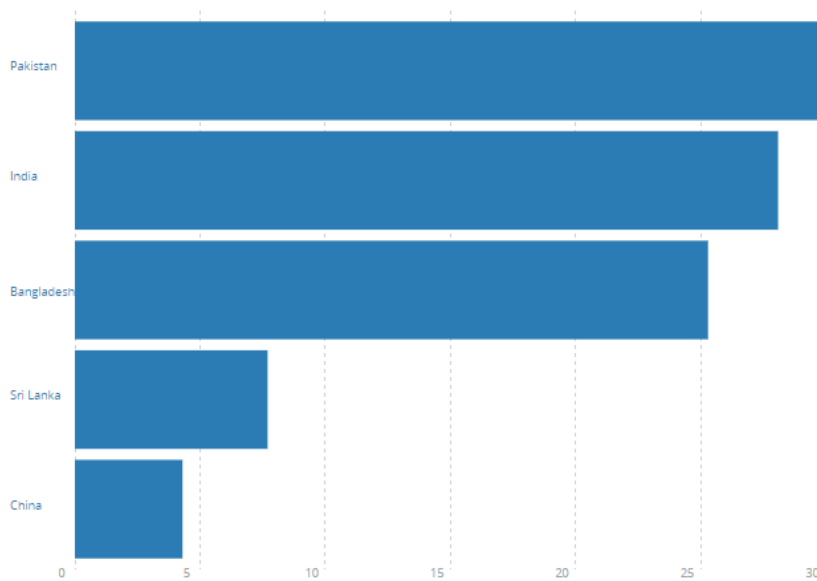
Source: World Development Indicators, World Bank (2017)

¹According to Article 12 of the Constitution of India, the term 'state' can be used to define both the union and the state governments. India has 29 states and 7 union territories.

At around 4 percent of national income, India spends much lesser than China, Sri Lanka and Bangladesh (Figure: 4). When measured in per capita terms, India ranks 154 out of 195 countries in terms of access to healthcare, which is worse than Bangladesh, Nepal, Ghana and Liberia.²

Chronic diseases are the biggest causes of death and disability, in India. They accounted for more than 30percent of deaths, with cardiovascular diseases and diabetes, respiratory conditions and cancers. Exposure to air pollution is a significant problem. The burning of solid fuels in particular is a major risk factor leading to lower respiratory infections and chronic obstructive pulmonary diseases, with side effects, such as cataracts and stroke (Figure: 5).

Figure 5: Cause of Deaths by Communicable Diseases and Maternal, Prenatal and Nutrition Conditions in 2015 (% of total)



Source: World Development Indicators, World Bank (2017)

Given lower level of public expenditure on health, in India, out-of-pocket (OOP) expense are increasingly becoming a large share of household budget – accounting for about one-third of total household expenditure. In rural India, almost 80 percent of the OOP expenditure is on medicines, whereas in urban areas, it is around 75 percent.³ India is also poorly insured, explaining why people have to rely on OOP.

Every year, more than one-third of the patients admitted to hospital are pushed into poverty. As rural incomes are lower than urban incomes, on an average, a rural household pays 140 percent of their annual income in OOPs for a hospital stay compared to 90 percent for those in urban areas.

People meet their OOP – some 47 percent of the cost of hospital admissions in rural areas and 31 percent in urban areas – by borrowing and the sale of personal goods and assets. This affects their

²For more on this see, the Lancet World Report (2015).

³For more on this see: <http://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/prices-of-essential-medicines-cut-by-30-50/articleshow/56791757.cms>. Accessed on 29.08.2017.

livelihoods and education of their children (with an impact on inter-generational income flow). Therefore, it is an absolute necessity that government ensure better healthcare services, and given chronic nature of disease make sure it ensure cheaper availability of medicines.

How to Ensure Availability of Cheaper Medicines?

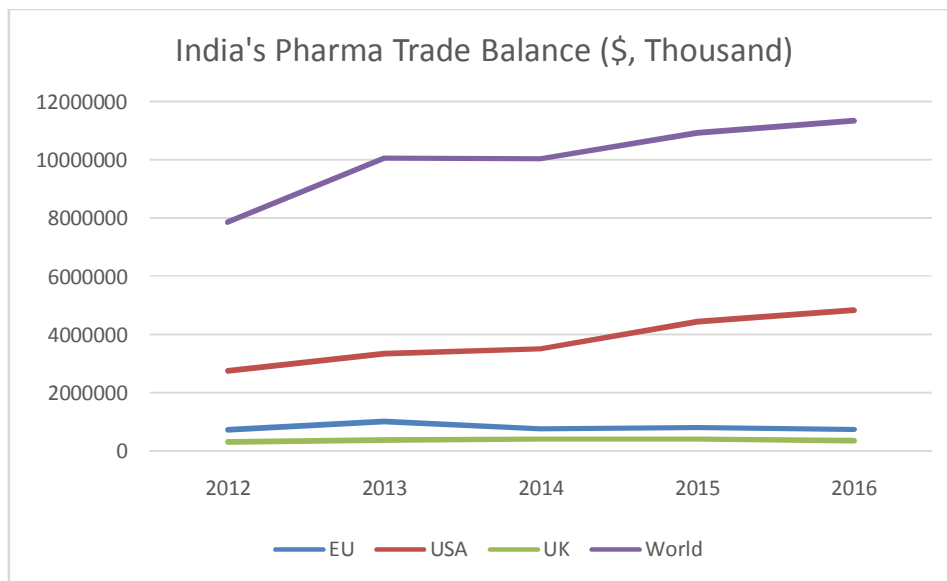
If domestic firms are not competitive and capable enough to manufacture medicines, cheaper availability of medicines can be ensured through imports. Examining India’s pharmaceutical trade data, an important trend is emerging. India’s pharmaceutical trade balance with respect to developed countries is positive (see Figure 6 and 7). This is contrary to popular perception that India is still dependent upon developed countries for medicines.

In recent times, India is exporting more to developed countries and other emerging economies in comparison to what it is importing from them. The major export destinations include countries like USA, UK, Brazil, and Russia. India has emerged as a major exporter of generic drugs of diseases, such as diabetes, antidepressants, high blood pressure, epilepsy and even cancer, in part because the Indian government allows foreign multinationals to invest in India.

Tie-ups between Indian domestic drug manufacturers and foreign multinationals – Piramal Healthcare with Abbott Laboratories, Ranbaxy Laboratories with Daiichi Sankyo; Dr. Reddy’s Laboratories with GlaxoSmithKline; Shantha Bio-technics with Sanofi Aventis; and Biocon with Bristol Myers Squibb – have allowed India to move up the value chain, with formulations and packaging moving in here. This in a way explains India’s positive trade balance.

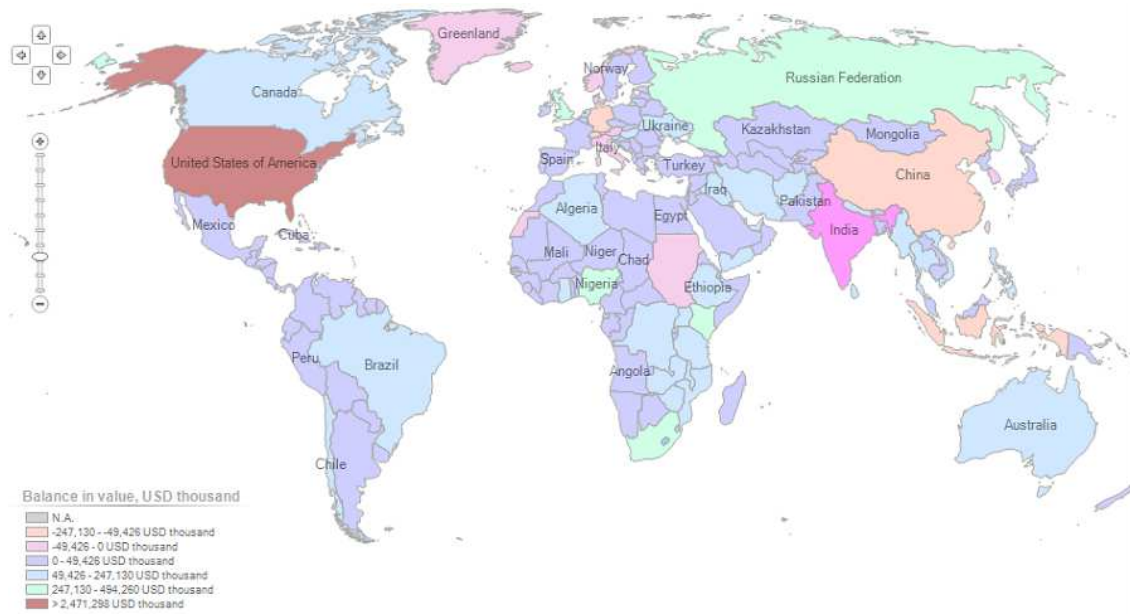
In terms of imports, India imports mainly from US, EU, Switzerland and China. Within Europe, India import mainly from Germany, Belgium, and Switzerland. Volume of imports from the EU region have increased more rapidly than those from US and China. Although, imports from EU and Switzerland have outpaced those from China, but in recent years in terms of growth rate India is increasingly importing active pharmaceutical ingredients from China (Figure 8).

Figure 6: India's Trade Balance



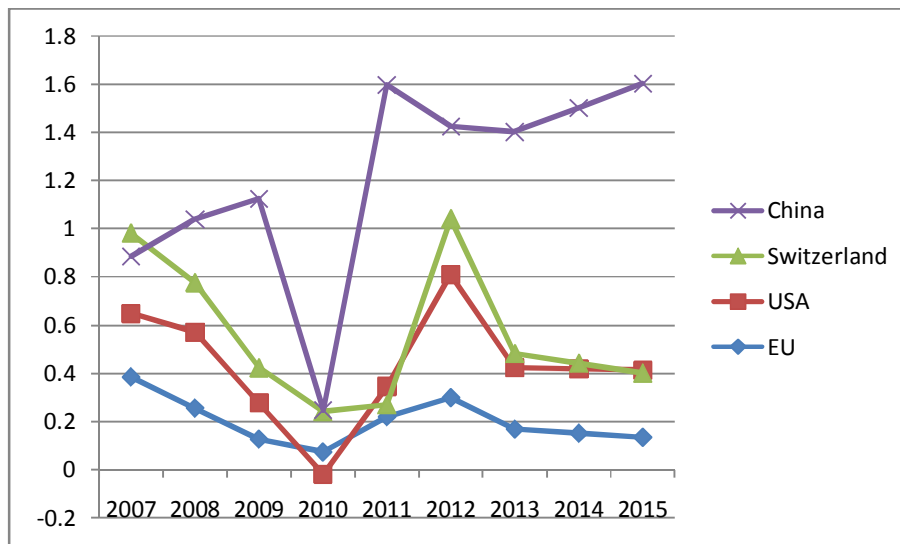
Source: International Trade Centre (2017)

Figure 7: Direction of India's Pharmaceutical Trade



Source: International Trade Centre (2017)

Figure 8: Growth of India's Imports of Medicines



Source: International Trade Centre (2017)

However, in spite of India emerging as a major exporter in pharmaceutical items, India still has one of the highest tariff rates when it comes to importing the same.

Tariffs

A large body of literature shows that tariffs increase the prices of imported products directly, by imposing a tax on them. Tariffs are essentially regressive taxes as they take a higher proportion of income from the poor than they do for those higher up the income scale.

Stevens and Linfield (2010) examined the impact of weighted average tariffs and domestic taxes on finished pharmaceutical products in case of low and middle-income countries. The study concluded that overall tariff on medicines had reduced drastically between 2005 and 2009. But, a number of middle-income countries still impose high levels of duties, thus amplifying the price of medicines.

A study by Banik and Stevens (2015) analysed the impact of tariffs on pharmaceutical products in emerging economies. One of the major findings of their work is that the total volume of trade in pharmaceutical products has increased during the period of 2006 to 2013 for countries outside the World Trade Organisation's (WTO's) 'Zero-for-zero initiative'. Under 'Zero-for zero initiative' US and 21 of its trading partners, agreed in 1995 to the reciprocal elimination of import duties on approximately 7,000 pharmaceutical products under the WTO Pharmaceutical Agreement.

The growth of trade in pharmaceutical products was remarkable and grew at a compounded annual growth rate (CAGR) of 20.7 percent. This implies that tariffs remained a major factor for a large proportion of marketed pharmaceuticals and impede access to medicines.

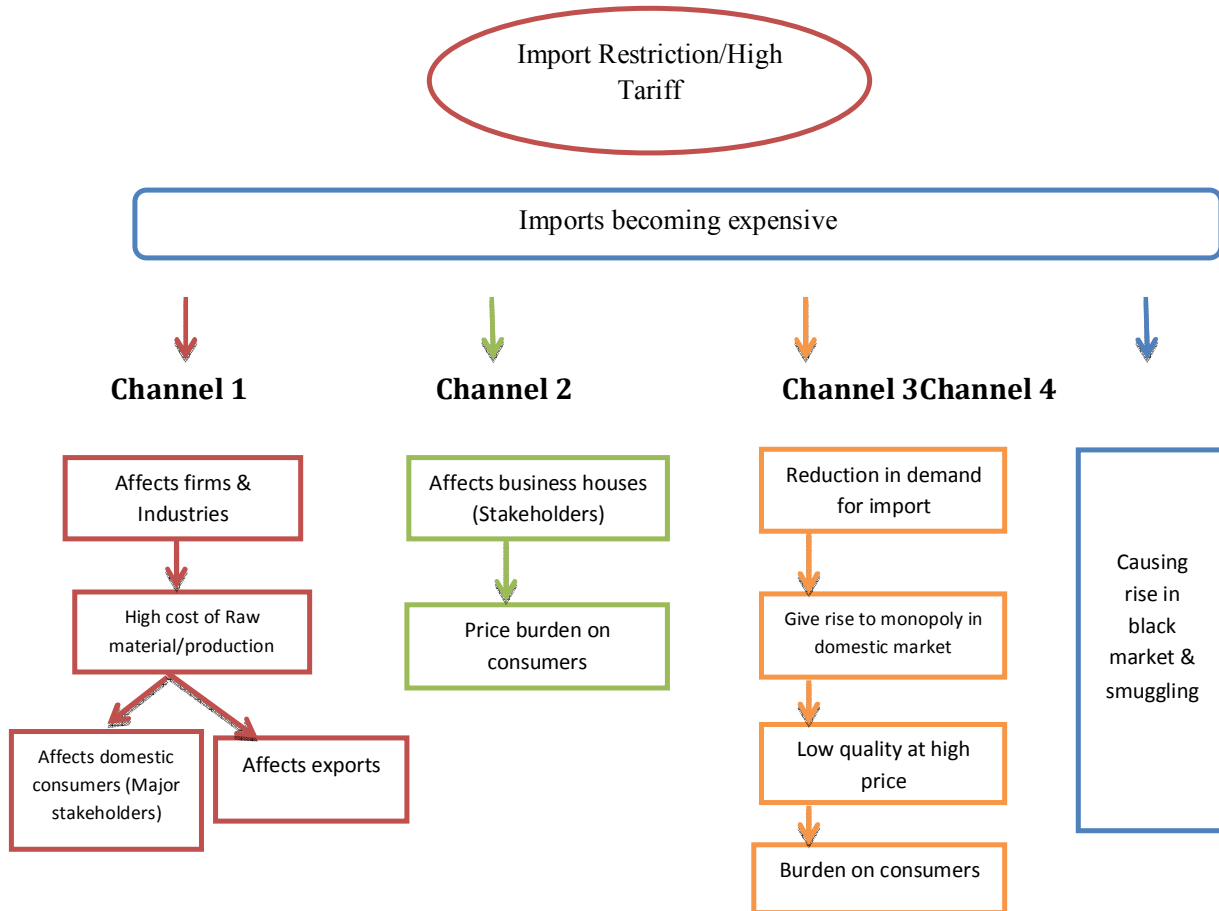
India is at the top (or more properly, bottom) five offenders on drug tariffs, with a levy of 10 percent across the board on all categories of imported medicines and vaccines. Only the governments of Nepal, Pakistan, DR Congo (11 percent) and Russia (10.2 percent) charge their ill citizens more. Globally, the other highest drug tariffs can be found in Uruguay (9.9 percent), Argentina (9.8 percent), Brazil (9.8 percent) and Thailand (9.3%). All these countries outside the WTO Pharmaceutical Agreement are increasing their consumption of medicines as they grow wealthier. The value of global export in pharmaceutical items has grown from US\$228bn in 2006 to US\$ 506bn in 2016. In simple terms, this means more people in countries, such as India, Brazil, and Russia have to pay more for medicines, as a result of government import duties.

As per the WTO Tariff Database, it is being noted that a number of pharmaceutical products falling under tariffs coverage have not fallen between 2006 and 2016. During 2016, under HS-3004 category, India has imposed tariffs on 137 products. It was found that the product category with the highest number of tariff lines is HS-300490 (other medicaments, in packaging for retail sale). HS category 300490 contains, among others, anaesthetics, anti-retrovirals, antimalarials, and a number of antiseptic product categories. Import duties (tariffs) can also be major determinant of final price, as they can significantly increase the price of imported goods before they embark on the journey down the distribution chain.

Tariffs have far reaching economic implications to stakeholders such as domestic consumers, business groups and industries. The analytical framework (Graph-1) explains the multi-dimensional effects of tariffs on the economy as a whole (Sarkar and Patrick, 2015). Using this framework, the European Commission (2003) analysed the role of taxes and tariffs on pharmaceutical products used in treatment of communicable diseases in 57 countries. The study found that many of the countries (Pakistan, Nigeria, China and India) that impose high duties and taxes have inadequate access to

medicines. Overall, there is evidence that tariffs being punitive, escalate retail price of pharmaceutical products.

Graph1: Analytical Framework



Source: Pinak Sarkar and Martin Patrick, "India's trade barriers: an analysis with reference to tariffs and customs procedures, pp. 201

The good news is India has ushered in domestic tax reforms that is likely to reduce domestic tax rates on medicines. India has recently introduced Goods and Services Tax (GST) which creates a common and integrated market (across various states in India) by subsuming various indirect taxes, such as excise duty, service tax, countervailing duty, valued added tax and also state levies, octroi, entry tax, local taxes and luxury tax.

The GST is an indirect tax on the supply of goods and services from the manufacture to the end consumer. It is a tax which is levied on the basis value addition in the supply chain and credit of inputs taxes will be refunded at each stage and subsequent stages of value addition. The final consumer will pay the GST levied by the last supplier in the supply chain, and will not have to pay any other indirect tax. GST in effect has brought down domestic tax rates on medicines (see Table 1)

Table 1: Disaggregated Calculation of Import Duty on Pharmaceutical Products in India

Import Duty (Previous Regime)				Import Duty under GST			
A	Assessed Value		100	A	Assessed Value		100
B	Basic Custom Duty	@10 %	10	B	Basic Custom Duty	@10 %	10
C	Countervailing Duty on (A+B)	@6	6.6	C	Inter State GST (on A+B)	A majority of pharmaceutical products fall under the slab @ 12%	13.2
D	Cess (Education Cess 2 % + Sec. & higher Education Cess 1% (on B+C))	@3 %	0.6				
E	Special Additional Duty (on A+B+C+D)	@4	4.7				
F	Total Custom Duty (B+C+D+E)		22	D	Total Custom Duty (B+C+D)		23.2
E	Custom Duty Net off CENVAT (F-(C+E))		12.0	E	Custom Duty Net off Credit (D-C)		10.0

Source: Author's Calculation

Under the current GST regime, the total duty paid on imported pharmaceutical products stands around 10 percent. Although, implementation of GST has simplified the tax structure in India and brought a greater degree of transparency, yet this tax rate of 10 percent is relatively high when compared with other OECD countries. Indian consumers, especially the poor, still have to pay higher price because of taxes.

In addition to tariffs, price of medicines can increase because of non-tariffs barriers and regulatory measures. Olcay and Laing (2005) noted that extra-tariffs factors, such as sales taxes including value-added tax (VAT), mark-ups and other charges have higher impact on price of medicines than tariffs do. As an imported pharmaceutical product moves along the distribution chain, it undergoes many mark-ups: port charges, warehouse costs, local government levies, distribution costs and retailer mark-ups, to name a few.

To understand how these extra-tariffs regulatory measures add up to cost, IMS Institute for Healthcare Informatics undertook a study covering five different genres of drugs in India (IMS, 2014). These medicines fall under five therapeutic areas, namely, antibiotics, anti-diabetics, anti-epileptics, anti-hypertensives, and respiratory agents. This study revealed that in India, the maximum margin for distributors can vary between 8 percent and 10 percent. The retail drug sellers keep a margin of around 15 percent. And all these have implications in raising final price of medicines.

Non-tariff Barriers and Regulations

Non-tariff barriers (NTBs) are also important factors, which can affect free flow of imported medicines. There are many types of NTBs that can hinder exports. As tariff increase is not permissible, many countries are now imposing NTBs (permissible under the WTO framework) to protect their domestic economy. NTBs mostly come under the Rules part of General Agreement on Tariffs and Trade (GATT). Each one of these NTBs were codified as agreements during various rounds of GATT negotiations for a purpose. These agreements are referred to as NTBs if they are used for restricting market access and not for the purpose with which they were codified.

For instance, antidumping Agreement was codified during Tokyo Round of GATT negotiation, to stop predatory pricing activity of foreign firms.⁴ Under globalised regime, following predatory pricing strategy is not possible. If foreign firm raises its price there are other competitors who will be willing to sell produce at a lower cost.

Therefore, there is no rationale for using antidumping measures, and yet it is most prominent type of NTB. Most nations use antidumping measures as a tool merely to protect their domestic industries, and not to stop predatory pricing. Likewise, Sanitary and Phytosanitary are standards set by any nation to safeguard the health of its consumers.

Interestingly, many countries are setting their health standards at a level higher than that prescribed internationally. For example, in case of tobacco exports, the internationally permissible level of DDT residue is four parts per million (ppm), while Japan and US had set their permissible level at less than 1 ppm. They have done this to block tobacco exports from other countries. Similarly, soon after the US financial crisis, India has imposed ban on imports of a number of live animal products, including processed meat, eggs, pigs, etc., from the rest of the world in the pretext of avian influenza (swine flu) virus although these items cleared international health standard norms (Banik, 2009).

Moreover, Sanitary and Phytosanitary measures used for restricting market access, and not to safeguard health of consumers becomes a NTB. The prevalence of NTBs can create severe shortage of essential medicines. The reduction in NTBs will facilitate trade, thereby enhancing accessibility and affordability of medicines to the poor.

United Nations Conference on Trade and Development (UNCTAD) report (2016) has classified major types of Non-Tariff Measures (NTMs). These are listed in Box 1. NTMs have a much broader concept and are defined as policy measures, other than custom tariffs, that can potentially have an economic effect of international trade in goods. NTBs are a subset of NTMs, implying a negative impact on trade.

⁴ Predatory pricing refers to the practice of selling a product far below its cost of production, with the intention of driving the competitors out of the market. However, once the low price charged by incumbents starts to serve as an entry barrier, in the long run foreign producers raise the prices to make up some of their early losses.

Box 1: Different Types of NTMs

Chapter A on SPS measures, refers to measures affecting areas such as restrictions for substances, hygienic requirements, or other measures for preventing dissemination of diseases. It also includes all conformity assessment measures related to food safety, such as certification, testing and inspection, and quarantine.

Chapter B on technical measures, refers to measures such as labelling and other measures to protect the environment. It also includes conformity assessment that relates to technical requirements such as certification, testing and inspection.

Chapter C classifies the measures related to pre-shipment inspection and other formalities performed in the exporting country prior to shipment.

Chapter D refers to contingent measures, which are measures implemented to counteract particular adverse effects of imports in the market of the importing country, including measures aimed at unfair foreign trade practices. They include antidumping, countervailing, and safeguards measures.

Chapter E includes licensing, quotas, and other quantity control measures, group measures that have the intention of limiting the quantity traded, such as quotas. It also covers those licences and import prohibitions which are not SPS or TBT related.

Chapter F includes price control measures, which are those implemented to control or affect the prices of imported goods in order to, inter alia, support the domestic price of certain products when the import prices of these goods are lower; establish the domestic price of certain products because of price fluctuation in domestic markets, or price instability in a foreign market; or to increase or preserve tax revenue. This category also includes measures, other than tariff measures, that increase the cost of imports in a similar manner (para-tariff measures).

Chapter G concerns finance measures, referring to measures restricting the payments of imports, for example when the access and cost of foreign exchange is regulated. This chapter also includes restrictions on the terms of payment.

Chapter H concerns measures affecting competition. These measures grant exclusive or special preferences or privileges to one or more limited group of economic operators. They refer mainly to monopolistic measures, such as state trading, or sole importing agencies, or compulsory use of national services or transport.

Chapter I concerns trade-related investment measures, group measures that restrict investment by requiring local content or requesting that investment should be related to export to balance imports.

Chapter J includes distribution restrictions, referring to restrictive measures related to internal distribution of imported products.

Chapter K concerns restriction on post-sales services, for example, restrictions in the provision of accessory services.

Chapter L contains measures that relate to subsidies that affect trade.

Source: UNCTAD (2016)

As per the *Macmap database*, India imposes a large number of NTMs on the import pharmaceutical products. The total number of NTMs used for the import of pharmaceutical products was 3958 in 2016. The most frequent NTM used in India is labelling requirement (21.4 percent); packaging requirement (12.99 percent); authorisation requirement (9.83 percent); registration requirement (8.34 percent); and traceability requirement (6.39 percent) respectively.

Besides, there are other forms of NTMs which are most frequently used by India on pharmaceutical products. Furthermore, it is important to note that the most of NTMs in India on pharmaceutical products are related to inefficient customs procedures, followed by process and products.

Table2 Different Types and Number of NTMs Imposed by India onPharmaceutuical Products

NTM Code	Number of NTMs	% Share	NTM Description	Classification	Chapter Description
B110	201	5.1	Prohibition for TBT reasons	Product	TBT
B140	389	9.8	Authorisation requirement for TBT reasons	Customs	TBT
B150	330	8.3	Registration requirement for importer TBT reasons	Customs	TBT
B310	847	21.4	Labelling requirement	Process	TBT
B330	514	13.0	Packaging requirement	Process	TBT
B420	125	3.2	TBT regulations on transport and storage	Process	TBT
B700	213	5.4	Product quality or performance requirement	Product	TBT
B853	199	5.0	Distribution and location of products after delivery	Customs	TBT
B859	253	6.4	Traceability requirement, n.e.s	Customs	TBT
C300	209	5.3	Requirement to pass through specified ports and customs	Customs	Pre-shipment inspection and other formalities
F190	192	4.9	Other administrative measures affecting customs value	Customs	Price control measures including additional taxes and charges
F610	199	5.0	Customs inspection, processing and servicing fees	Customs	Price control measures including additional taxes and charges
F650	224	5.7	Import license fee	Customs	Price control measures including additional taxes and charges

Source: UNCTAD (2016) and Macmap, ITC

The increase usage of NTMs onpharmaceutical products in India is due to the multiplicity of drug approval agencies. There are multiple regulators for labelling requirement ofpharmaceutical products in India. For instance, Drug and Cosmetics Rules, 1945 set labelling standards for pharmaceutical products in India. At the same time, the Standards of Weights and Measures Act, 1976 and the

Packaged Commodities Rules, 1977, Legal Metrology (Packaged Commodities) Rules, 2011 have additional labelling requirements for the import of any products in India. The multiplicity of regulations not only adds complexities but add significant costs. Complying with divergent labelling standards is always time consuming, expensive and escalates the final price of imported pharmaceutical products.

India has plenty of regulations for the import of pharmaceutical products. The Central Drugs Standard Control Organisation (CDSCO) is an apex body that governs the import and export of the drugs in India through 11 port offices located in different parts of the country. Other than this, there are several other factors, which also apply on export, import and sale of pharmaceutical products in India.

Barriers at Border: The Role of Procedural and Regulatory Impediments

Globally, there is strong consensus that barriers at border negatively impact cross-border trade and these barriers are often higher on import than export. Barriers at border are: inefficient customs clearance procedures, lacking harmonised documents, have cumbersome trade procedures, absence of harmonised procedures and key agencies (testing and laboratories), sub-optimal trade infrastructure and lack of coordination among operating agencies (CUTS, 2015)

According to a recent study of Organisation for Economic Co-operation and Development (OECD), the cost of poor border procedures could range between 2 to 15 percent of the total transaction value of global trade. This is primarily due to deep rooted inefficiencies in export-import clearance procedures and customs clearance at border.

The cost emanating from regulatory requirement is higher than tariff and affects the participation of firms in global trade, shaped by value chains. A diverse range of policies and procedures apply at different stages of supply chain and any cost associated with these procedures escalate trade costs along the supply stage at each stage and produces erratic effects of function of global supply chains (Ferrantino, 2012).

India has several problems areas in trade facilitation and there is substantive transaction costs involved in trading with India (Roy, 2014). The sub-optimal performance on various trade facilitation indicators can be noted from the World Bank's report on Trading Across Borders. The report has ranked India at 143 position out of 189 countries in 2016. India's performance on various indicators – time and cost (excluding tariffs) associated with three sets of procedures – documentary compliance, border compliance and domestic transport – within the overall process of exporting or importing a shipment of goods is sub-optimal and reflects huge asymmetries in trade infrastructure.

In this regard, it is pertinent to note that there is huge variation in the cost of import and export in India. The cost and time involved in export is significantly lower than the cost of import in India. The average time spent on export and import of a consignment is 3.5 and 12.5 days respectively. In the same vein, cost associated with border compliance in India is lower on export while compared with import.

The cost for border compliance for export and import are US\$85 and US\$556 respectively. A recent study by Sarkar and Patrick (2015) analysed the role of eight factors (burdensome import procedures, tariffs, corruption at border, high cost, domestic technical requirement, crime and theft and inadequate infrastructure) that create obstacles in importing goods in India. Among all factors, the burdensome import procedures were noted as major factors that create difficulties for importers.

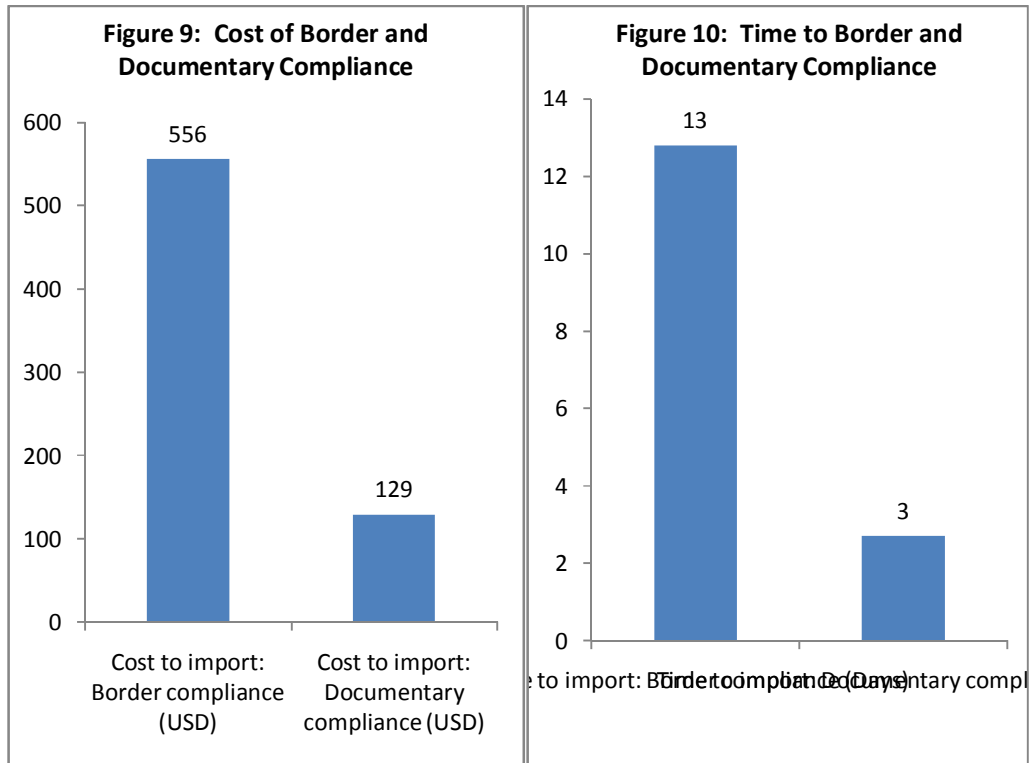
Case Study⁵

To understand the regulatory burden, we conducted a primary survey talking with a custom house agent (CHA) and two importers involved with importing chemicals used for manufacturing pharmaceutical products in India. The import procedures trying to import through Jawaharlal Nehru Port Trust (JNPT) – India's leading port operating out of Mumbai – is quite intricate. Importers and CHA reported they encounter multi-dimensional challenges relating to both soft and hard infrastructure,⁶ with a direct impact on the clearance of imported pharmaceutical products.

This magnitude of the problem can be well analysed from the World Bank database on Trading across Border report, which calculated the cost of import and time to import at JNPT. This highlights the complexities involved in various procedures of importing goods through JNPT port which escalate the final price of any imported goods including raw materials of pharmaceuticals.

⁵This section captures the information from secondary sources as well as perspectives of a custom house agent and importers

⁶Hard infrastructure are physical assets such as ports, building, etc. which provide services. Whereas, soft infrastructure refers to delivery of specialized services to people such as communication, and the body of rules and regulations governing the various systems.



Source: World Bank

Currently, the JNPT port is overburden. It is working at 85 percent of its capacity whereas 70 percent is considered as ideal capacity in most of advanced countries, such as Singapore, Japan and South Korea (Indian Brand Equity Foundation, 2017). The inadequate capacity of ports is further exacerbated by India's 30 percent containerisation, which is far below the global average of 60-70 percent.⁷

The highest draft at JNPT port is 14 meter, which is inadequate for mother vessels, and the unavailability of such drafts has diverted mother vessels to Gujarat. Diversion in traffic from JNPT to Gujarat port also causes loss to private terminal operators, who have invest substantial amount of money at the JNPT port. This in turn undermines the interest of private players to make investments in port development.

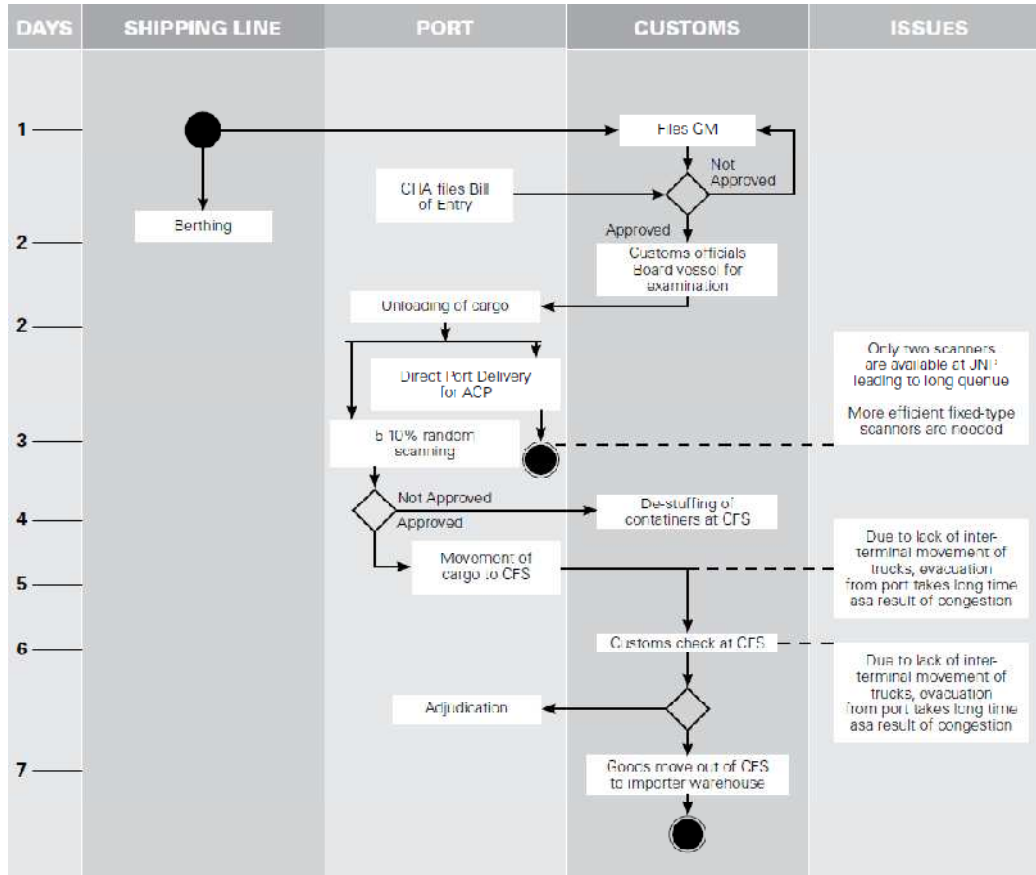
The procedures of completing various customs clearance and other formalities are consuming a considerable amount of time at the JNPT, which in turn is creating hindrance while import clearance. The imported consignment of pharmaceutical products is subject to get the clearance as per the rules drafted in Custom Act 1962 and Foreign Trade (Development and Regulations) 1992.

Other than this, imported pharmaceuticals products are also subject to various rules and regulations under the Drugs and Cosmetics act, 1940, Pharmacy act, 1948, Drugs and Magic Remedies act, 1954, Medicinal and Toilet Preparation act, 1956, Narcotic and Psychotropic Substances act, 1985, The Drugs (Prices Control) order, 1995. Import clearance at JNPT involves complex and time consuming

⁷SME World, 'It is Right Time to Corporatise Ports' http://www.smpworld.com/n_n_kumar_interview.html

procedures. The below mentioned Figure explains the standard procedure of import clearance at JNPT port.

Figure 11: Non-containerised and Containerised Movement at JNPT Mumbai



Source: Bridging Infrastructural Deficit at Selected Ports in India, BRIEF, 2016, pp. 36-37

Importer or CHA need to prepare a number of documents for the clearance of imported pharmaceutical consignment. The mandatory documents include bill of lading, commercial invoice, packing list, purchase order, copy of letter of credit, insurance certificate, certificate of origin, valuation and declaration forms, IEC number, permanent account number, mod vat declaration, freight certificate and freight bill (if freight is payable) in India. Other than these documents, an importer of pharmaceutical products has to fulfill the obligation laid under the Drugs and Cosmetics act, 1940 and other acts.

Besides, importers have also suggested that charges paid for storage of imported consignment are relatively higher than export consignment. The Central Warehousing Corporation (CWC) levy different charges for the storages of exported and imported products. Importers consider that that the discriminatory treatment between export and import is not a right policy. An increase in cost due to this, escalate the cost of imported products, which in turn, is increasing the market price of final product.

Finally, importers and CHAs are deeply concerned over the existing nexus between Container Freight Station (CFS) and shipping liners, which has curtailed their flexibility to choose CFS for the clearance for their imported consignments. The shipping lines nominate CFS for importers based on their preference and links. The CFS nominated by shipping lines usually charges exorbitant rates, which put additional burden on importers and increase the cost of imported consignment. In addition, the vehicle picking up an import container from the JNPT port is also suggested by the CFS at fixed transportation cost. This restricts the ability of importers to bargain with the transporters. All these regulatory issues add up to the cost, which finally affect price of imported medicines.

Conclusion

Health is an important component of development. Although growing fast, India ranks lowly among other similar economies in the world when evaluated in terms of health indicators. Penetration of health insurance products is low and so is public expenditure on health. As a result, a majority population has to depend upon OOP expense to meet their health need. Every year many are driven to poverty because of high cost of healthcare. Under such circumstances, cost of medicines has an important role to play in determining health outcome. India import bulk of medicines and vaccines, mainly from Europe and US. There is evidence of both tariffs and NTBs having an impact on increasing the price of medicines. While it is recognised there is a need for reforms to make India a better place to do business, but this paper points out regulatory issues still remain a cause of concern, especially when it comes to importing pharmaceutical products.

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