Non Tariff Measures as a Policy Measure: an Analysis of India-EU Trade in Pharmaceutical Sector

Rakhi Singh [1], Dr. Seema Sharma [2]
[1] Associate Professor, G D Goenka World Institute, Sohna, India.
[2] Associate Professor and HOD, Banasthali University, India

Abstract

The purpose of this paper is to analyse trade in pharmaceutical sector between India and EU with respect to the Non-Tariff Barriers as policy measures. The paper studies about India as a significant player in global generic market and the incentives to use the non tariff barriers. The paper focuses extensively on EU's non tariff barriers with other partners, especially India. The study relies on the secondary data on trade in pharmaceutical sector between India and EU.Pharmaceutical sector is a big enough market for an open warfare among existing and new players looking for growth opportunities. Companies looking to protect their turfs in erstwhile protected markets will look to retain their markets by launching cheaper versions of their patented products. At the same time new players will look for these opportunities of growth.A good indicator of a country's external engagements is whether its foreign and trade policies reinforce each other. The paper shows that in case of very high non tariff barriers, better option for the companies would be to protect their interest by other means.

Keywords: *Non-Tariff Barriers/Measures, Global Pharmaceutical Market, Import Elasticity, Per capita GDP, Exports to EU.*

I. INTRODUCTION

Indian pharmaceutical industry has been playing a very important role in Indian economy. In the course of recent years, the industry has experienced a tremendous growth. Liberalisation in trade and industrial policy in India has led to many structural changes in the domestic industries. Also because of shift in economic and research activities from Europe to India, there was rapid growth in the pharmaceutical sector in India.The sector faces many non tariff trade barriers when it comes to exporting to European union. The papers highlights this aspect of the India's pharmaceutical industry and suggests better options for the companies to protect their interest by other means.

II. NON- TARIFF BARRIERS

With erosion of tariffs as instruments of protection, resulting from multilateral trade negotiations,trading nations have increasingly resorted to the use of Non-Tariff Barriers (NTBs) to insulatedomestic industries from foreign competitions. NTBs satisfy the clamour of certain interests hurtby trade liberalisation and are preferred over tariff barriers to redress balance of paymentproblems, as their impact is immediate and apparent.

NTBs are described as any government measure or practice, other than tariffs, that directlyimpedes the import of goods and discriminates imports, but does not influence local productionand distribution (Hillman, 1991, Linkins, 2002, ASEAN, 2003).These are Quantitativerestrictions, tariff quotas, voluntary export restraints, orderly marketing arrangements, exportsubsidies, export credit subsidies, government procurement, import licensing, anti-dumping/
countervailing duties, technical barriers to trade, to name a few.

III. EU AND NON- TARIFF BARRIERS

The studies show that EU has been very prolific in using Non-Tariff Barriers with its trading partners. But in case of India, the EU seems to be on an overdrive. India is an important trade partner of the EU and a growing global economic power. The growth in the trade of goods between India and the EU has been strong. The country combines a sizable and growing market of more than 1 billion people. The value of EU-India trade grew from €28.6 billion in 2003 to €72.5 billion in 2014. EU investment stock in India is €34.7 billion in 2013. Trade in commercial services quadrupled in the past decade, increasing from €5.2billion in 2002 to €23.7 billion in 2013.

India and European Union (EU) have been engaged in long drawn talks for a bilateral free trade

agreement. Indian side unilaterally cancelled the talks between chief trade negotiators scheduled in the month of August 2015.a few days prior to the talks. The official communication from the Commerce ministry stated that it is "disappointed and concerned by the action of EU in imposing legally binding ban on the sale of around 700 pharmaceutical products clinically tested by GVK Biosciences, Hyderabad" in July of the same year.

In the past too, there have been instances of seizure and detention of Indian generic medicines while in transit at EU ports. These generic drugs were meant for export to Latin American and other countries. India initiated dispute settlement consultations in 2010 at the World Trade Organization regarding this issue. By 2011, a settlement was reached and the EU agreed that generic drugs consignments in transit through its territory would not be seized.

While it may be argued if the latest Indian reaction to the action by the EU was more than proportionate or justified, it does bring into focus the importance of the exports of generics by Indian pharmaceutical companies and in particular to the EU.

IV. GLOBAL GENERICS MARKET – INDIA A SIGNIFICANT PLAYER

India has emerged as a significant player in knowledge and services sectors. Information technology and pharmaceutical products contribute majorly to India's export baskets. India exported USD 15.04 billion of pharmaceutical products in 2013-14. Over last four years, these exports grew at a fast clip of ~14% compounded annually.

Table 1: Indian Exports of Pharmaceutical Products (USD billion)

2009-10	2010-11	2011-12	2012-13	2013-14	~CAGR %
8.95	10.7	13.3	14.6	15.04	14

Source: Pharmexcil

Over 17% of these exports go to EU, making it third biggest market region for India after North America and Africa. The stakes for India are high, as the table attached below shows.

Table 2:India's Pharmaceutical Contribution to Global Healthcare

Region	2013-14 (USD million)	Contribution (%)
North America	4265	28.35
Africa	2867	19.05
EU	2634	17.51
Middle East	979	6.51
LAC	918	6.1
Asean	915	6.08
CIS	846	5.62
South Asia	601	3.99
Asia (Excluding Middle East)	522	3.47
Oceania	253	1.68
Other European Countries	129	0.86
Other America	68	0.45
Others	50	0.33

Source: DGCIS

39% of total generics exports to EU is in the form of APIs while rest is in formulations. (Source: Pharmexcil)

Further analysis reveals that the US is the biggest generics market at USD 67 billion. Countrywise, India contributes significantly to the US, Russian, United Kingdom and Canadian markets.

Table 3: Top 10 global generics market by value (C.Y. 2013)

Region	2013-14 (USD million)	Contribution (%)
United States	67	4.9
China	55	0.02
Japan	12.5	0.5
Germany	12.5	1.6
Brazil	10.5	1.5
Russia	9.25	6.19
United Kingdom	9	4.26
France	7.5	1.66
South Korea	7	1.78
Canada	5.4	2.72

Source: BMS/ IMS, Pharmexcil

V. LICENSING PROCEDURES AS EFFECTIVE NON-TARIFF MEASURES

Like other countries, India too is exposed to non tariff measures in the EU while selling pharmaceutical products (bulk drugs, formulations, generic medicines). These include: company and product registration, product registration only, WHO-GMP certification, packaging and labelling requirements, import bans, anti-dumping measures and pre-shipment inspection. Each of these has a different purpose, regulatory requirement and impact on firm behaviour.Compliance with NTMs has involved significant financial and time costs for the sample pharmaceutical enterprises.

There are different licensing procedures through which the right to sell medicines in specific country or the entire EU can be acquired:

Centralised procedure to market certain types of medicines throughout the EU
Decentralised procedure (DCP) to market the medicine in specific EU countries
National procedure for marketing right in specific EU country
Mutual recognition procedure if one already has a national license in one or more EU countries but wants to market it in others (Source: https://www.gov.uk/apply-for-a-licence-to-market-a-medicine-in-the-uk)

VI. STEPS AND TIMELINES INVOLVED IN OBTAINING AN EU MARKETING AUTHORISATION

The European Medicines Agency is responsible for the scientific evaluation of applications for **centralised marketing authorisations**. Upon submission of a valid application, the evaluation takes up to 210 days, at the end of which the Committee for Medicinal Products for Human Use (CHMP) must issue a scientific opinion on whether the medicine may be authorised or not. This opinion is then transmitted to the European Commission, which has the ultimate authority for granting the marketing authorisation within 67 days after receipt of the CHMP opinion.

Table 4: EU marketing Authorisation timelines

Authorisation steps	Timelines
I - Submission of eligibility request	At the earliest 18 months and at the latest 7 months in advance of submission
II - Notification of intention to submit an application	Approx. 7 months in advance of submission
III - Appointment of rapporteurs	Approx. 7 months in advance of submission
IV - Pre-submission meeting	Approx. 7 months in advance of submission
V - Submission of the application	
VI - Scientific evaluation	210 days of assessment
VII - CHMP scientific opinion	
VIII - European Commission decision on the marketing authorization	Within 67 days after receipt of the CHMP opinion

Source: Applying for EU Marketing Authorisation

Table attached below gives an indication of the costs involved in marketing authorizations for sale in EU territory.

Table 5: Application for a marketing authorization

Application for which a full dossier needs to be presented	Basic Fee	For a single strength associated with one pharmaceutical form and one presentation (Euro 278200)	
	Additional Fee	For each additional strength or pharmaceutical form including one presentation, submitted at the same time as the initial application for authorization (+ Euro 27900)	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial application for authorization (+ Euro 7000)
Application for which a full dossier need not be presented	Basic Fee	For an application for a marketing authorisation pursuant to Article 10(4) of Directive 2001/83/EC. This fee is for a single strength associated with one pharmaceutical form and one presentation (Euro 179800)	For applications for a marketing authorisation pursuant to Article 10(1), Article 10(3) and Article 10c of Directive 2001/83/EC. This fee is for a single strength associated with one pharmaceutical form and one presentation (Euro 108000)
	Additional Fee	For each additional strength or pharmaceutical form including one presentation submitted at the same time	For each additional presentation of the same strength and pharmaceutical form, submitted at the same time as the initial

		as the initial application for authorization (+ Euro 10800)	application for authorization (+ Euro 7000)

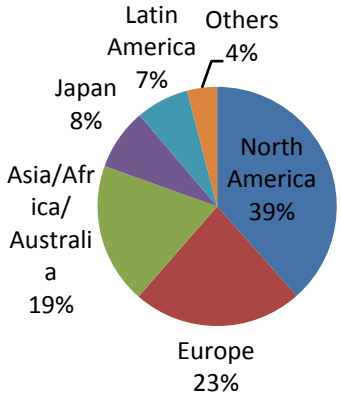
(Source: EU Medicines Agency Fee Schedule.pdf)

Similar schedules are available for extension, grouping, renewal, transfer, inspection, maintenance and variations to authorisations. Each authorisation has significant money and time costs involved.

VII. GLOBAL PHARMACEUTICAL MARKET – INCENTIVE FOR USE OF NON-TARIFF MEASURES

Global pharmaceutical market is worth over USD 1.0 trillion. Top 25 companies' combined portfolios now have over 50% of these sales.

Figure 1



Global Pharmaceutical Sales

Source: Pharma_Global Market Size 2015-2019.pdf

Table 6: Top 10 pharmaceutical players by sales (USD million)

Company	2014	2013
Novartis	51,307	50,444
Pfizer	44,929	44,213
Sanofi	40,037	38,020
Roche	37,607	36,395
Merck & Co	36,550	35,818
Johnson & Johnson	36,422	30,663
AstraZeneca	33,313	32,250
Glaxosmithkline	31,470	32,102
Teva	26,001	24,271
Gilead Sciences	23,673	11,092

Source: IMS Health MIDAS, December 2014

Large global corporations spend as much as 10-20% of their sales towards research and development head. Focus on emerging markets, over the counter (OTC) products, contract manufacturing and generics products in the enormous "off-patent" market, have been part of growth strategy for these companies. It is estimated that USD 20-60 billion of pharmaceutical products will go "off patent" each year, over the next few years. (Pharmaceutical Industry – Opportunities Abound!, The Global Analyst January 2015)

VIII. DISCUSSION AND CONCLUSION

There is a big enough market for an open warfare among existing and new players looking for growth opportunities. Companies looking to protect their turfs in erstwhile protected markets will look to retain their markets by launching cheaper versions of their patented products. At the same time new players will look for these opportunities of growth.

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