Non-Tariff Measures, Technological Capability Building and Exports in India’s Pharmaceutical Firms

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Frederick Nixson* and Ganeshan Wignaraja**

Abstract

As tariffs fall over time, attention inevitably focuses on non-tariff measures (NTMs). Governments are increasingly imposing mandatory technical regulations on products for reasons of security, health or the environment and have facilitated the introduction of non-mandatory (voluntary) standards for products in order to facilitate their utilisation. The WTO administers the implementation of the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS), which together constitute the core of modern NTMs.

This paper presents a case study of the effects of NTMs on Indian pharmaceutical exports (bulk drugs and formulations). Within the broad context of India’s recent export performance, market access, competitiveness and technological capability building, the study utilises enterprise-level data to identify the type and nature of NTMs faced in export markets, the compliance with NTMs (including preliminary estimates of the costs of compliance), technology strategies of enterprises in response to NTMs and institutional support. The study highlights differing perceptions as to the significance of NTMs, the importance of firm-level research, lessons for other low-income economies and the need for enterprises to adopt offensive technological strategies. The study concludes by identifying a number of domestic constraints and market failures that are at least as important as NTMs in explaining India’s relatively poor export performance.

Keywords: Non-tariff measures, WTO agreements, technological capability, exports, pharmaceuticals, India.
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1. INTRODUCTION

The reduction in barriers to trade has been a particular objective of various rounds of trade negotiations, and one of the most important outcomes of the Fourth Ministerial Meeting of the World Trade Organisation (WTO) in Doha in November 2001 was to give greater prominence to the issue of market access to exports of particular interest to developing countries. Although significant progress has been made in this respect, there nevertheless remains the concern that not all commitments made by the developed economies have been implemented and that expected benefits have not materialised.\(^1\)

As tariff barriers have fallen over time, and as Non-Tariff Barriers (NTBs) are phased out, attention has inevitably focused on Non-Tariff Measures (NTMs). Governments have increasingly imposed mandatory technical regulations on products for reasons of security, health or the environment, and have formulated or encouraged the design and introduction of non-mandatory (voluntary) standards for products in order to facilitate their utilisation. In addition, member countries of the WTO may apply trade-restrictive measures for the protection of human life or health and of plant and animal life or health (Das, 1999, Chapters III.4 and III.5). The WTO administers the implementation of a set of agreements that include the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS). These two Agreements constitute the core of what have become known as Non-Tariff Measures (NTMs).

There has been a steady growth in the regulations that relate to health, safety, consumer protection and the environment over the past thirty years. NTMs may be formal in that they are stated explicitly in official legislation or government mandates, or they may be informal, arising from administrative procedures for example, which makes them difficult to identify and measure. Both regulations and standards can play a positive role in encouraging international trade, through the provision of consistent and understandable information. But equally obviously, NTMs may be used to protect domestic producers, distort markets and impose costs on exporters, which, in the case of low-income economies, may make exports uncompetitive and block access to important markets. Given that the developing countries themselves are undergoing often quite rapid trade liberalisation, the continued existence of a variety of barriers to developed economy markets remains a key issues for policy makers and trade negotiators.

NTMs raise both important theoretical issues and problems relating to the estimation of their quantitative significance. It is difficult in the literature to differentiate NTMs from NTBs, and there is a common misconception that they are identical. Furthermore, there are important
differences between perceptions and reality, both with respect to the views of governments and those of individual enterprises.

The purpose of this paper is to identify and discuss the significance of NTMs to Indian exports of pharmaceutical products. In the wake of the 1991 economic reforms, pharmaceuticals have emerged as one of India’s most important exports. The industry’s prospects, however, may be affected by NTMs in export markets. There is a dearth of information on NTMs on pharmaceutical exports and a novel aspect of the research reported in this paper was the collection of firm–level evidence. Ten pharmaceutical companies, located in and around New Delhi, were interviewed in March-April, 2001. The companies were selected on a non-random basis, with a focus on those companies, whether large or small, which exported a substantial proportion of their total output. This is not therefore a representative sample and care must be exercised in the interpretation of the information collected and the generalisation of the conclusions reached. Nevertheless, the use of a structured questionnaire during interviews permitted wide ranging discussions on factors, both external and domestic, that determine export performance of individual enterprises and enterprise responses to the problems identified. The discussion of NTMs is placed within the wider context of market access, technological capability building at the enterprise level to improve global competitiveness and the roles that both the public and private sectors can play in helping enterprises develop those capabilities.

Section Two presents a brief overview of the Agreements on TBTs and SPSs, which constitute, in our opinion, the core of NTMs. It also identifies how different firms may develop alternative strategies to deal with the imposition of NTMs. Section Three places the study within the broader context of recent Indian export performance and Indian perceptions of the vulnerability of their exports to NTMs.

In Section Four, we attempt to identify the nature and incidence of the major NTMs at both the sector and enterprise level, to list the number and incidence of NTMs by market, to identify the competitive strategies of the affected enterprises, to estimate compliance costs (where data permit) and to identify the sources of assistance that companies had access to and could draw upon. Section Five concludes, highlighting the importance of firm-level research, the problems encountered in identifying NTMs, differing perceptions both between individual firms, and the sector as a whole and the Indian Government as to the extent and significance of NTMs, and the wider lessons that can be drawn from the case study, which can improve policy in both India and other low-income economies.

The analysis of the data, and the views expressed, are those of the authors and should not be ascribed to the sample companies.
2. THE ANALYTICAL FRAMEWORK

As noted above, the Agreement on Technical Barriers to Trade (TBT) and the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) constitute the core of what have become known as Non-Tariff Measures (NTMs).

There has been increasing use of technical regulations as instruments of commercial policy over the past decade and it has become clear that domestic regulation affecting imports through technical requirements, testing, certification and labelling represents “…one of the most important new areas for focus in continuing liberalization efforts” (Maskus and Wilson, 2000, p.2; see also Maskus, Wilson and Otsuki, no date). Mandatory regulations imposed by governments at the border can produce distortions in commercial markets and are of particular concern to developing countries, given the costs involved in meeting those requirements. In principle, if not in practice, technical regulations imposed on trade in manufactured goods and agricultural products will affect trade patterns, the ability of producers to enter new export markets and consumer costs.

In much of the literature, no distinction is made between NTBs (NTBs are broadly defined as consisting of all barriers to trade that are not tariffs (Deardorff and Stern, 1998, p.3)) and non-tariff measures (NTMs). For example, Deardorff and Stern, (1998, Appendix 1) simply list the major categories of non-tariff measures and related policies and argue that NTBs “…also include a potentially unlimited plethora of policies, perhaps as yet not invented, that alter however indirectly the prices and/or quantities of trade” (Deardorff and Stern, 1998, p.3).

There is an important distinction to be made, however, between barriers that lie at the border and barriers that exist “within the border” (Trebilcock and Howse, 1999, p.135). There is a general agreement in the literature that there has been a steady growth in the regulations that relate to health, safety, consumer protection and the environment over the past thirty years or so and that these regulatory trends can be viewed “…as part of the elaboration of the modern welfare state in much of the industrialized world….” (Trebilcock and Howse, 1999, p.135). That such regulations may also be used to restrict trade is not in doubt and developing countries in particular may well see such regulations as discriminatory and as a means of offsetting their international comparative advantage in key sectors or activities.

NTMs may be formal in that they are stated explicitly in official legislation or government mandates but there are also informal barriers arising from administrative procedures and government regulations and policies and from national differences in market structure and
competition policies and differences in political, social and cultural institutions (Deardorff and Stern, 1998, pp.3-5). Other measures such as antidumping measures, countervailing duties and other types of investigation of alleged unfair trading practices may well have a directly protectionist intent, at least in the short run, and create a climate of uncertainty for foreign suppliers designed to bring about changes in foreign trade practices and policies.

The Role of Standards in International Trade

We need to distinguish between a regulation and a standard. A regulation is usually defined as a mandatory requirement imposed by public authorities on the characteristics of a product or its production process. The TBT Agreement uses the term ‘technical regulation’, to cover standards with which compliance is mandatory (Maskus and Wilson, no date; ITC/CS, 1999, Chapter 5). The term ‘standard’ is used to define a voluntary specification emanating from market forces. Although this is an important distinction (enterprises must comply with a regulation but may choose not to comply with a standard) in practice the term ‘standard’ or NTM (as defined by the Agreement on TBTs and SPSs) is used to cover both mandatory regulations and voluntary standards.

Standards cover: product characteristics, including those relating to quality; process and production methods (PPMs) that have an effect on product characteristics; terminology and symbols; and, packaging and labelling requirements as they apply to the product (ITC/CS, 1999, p.85). Standards permeate all business activities and “…the essential point of standards is to support market development and facilitate transactions. If they are effective in this regard, they promote economic development and integration with global markets…” (Maskus and Wilson, 2000, p.17).

However, standards can also become barriers to trade when they vary between countries. The costs of complying with standards may be higher for foreign than for domestic firms, implicitly creating a trade barrier. Where regulatory authorities require product testing in the importing country in order to ensure compliance with that country’s health or safety regulations, foreign suppliers will find themselves at a disadvantage if their products are subject to stricter tests or higher fees than those required for domestic products (ITC/CS, 1999, Chapter 5). This process is referred to as conformity assessment and some would argue that it presents the largest potential technical barrier to trade (Maskus and Wilson, 2000, p.18). Conformity assessment is vulnerable to non-transparency - delays, arbitrary inspection and redundant tests - and is susceptible to capture by domestic firms seeking protection. The costs of uncertainty in complying with such procedures may well persuade enterprises to withdraw from key markets.

Developing countries are in general less likely to have well developed testing facilities for certification and accreditation and they may find it very difficult to reach the standards
determined by other, usually developed market, economies. Trade between developing countries may well be constrained by both the inability to meet internationally agreed standards and/or the refusal to recognise the standards of other developing countries. The solution to this problem lies in harmonising standards at the international level and in developing guidelines for determining conformity to standards (ITC/CS, 1999, Chapter 5).

Empirical studies of the impact of standards on international trade have produced ambiguous results (surveyed in Maskus and Wilson, 2000, pp.21-26). There is some evidence that they have offsetting impacts on costs. By requiring enterprises that export to incur adaptation, testing and certification costs demanded in particular markets, importer-specific standards raise compliance costs and, ceteris paribus, should reduce trade. But simultaneously, both shared and country-specific standards reduce the cost of acquiring information about market preferences and product quality, serving an important signalling function and hence raising trade. As Maskus and Wilson (2000, p.26) point out, the reduction in information costs should be especially important in the case of manufactured goods which are characterised by greater heterogeneity. The cost-raising aspects of standards may be more significant for more homogeneous non-manufactures.

**Agreement on Technical Barriers to Trade**

The Agreement on TBT contains the international rules applicable to product standards used in the trade in goods and the procedures used for assessing conformity with such standards. The usefulness of standards in facilitating international trade depends on how far the buyer has confidence in the manufacturer’s statement that the product meets a particular standard. In most cases, buyers generally rely on the manufacturer’s declaration that the product meets the standard. In certain cases, however, manufacturers purchasing parts, components and materials may choose to get a neutral third party to certify that they meet the specifications of standards. In other cases, in relation to products that are regulated, the regulators often require that, before the domestically produced or imported products are offered for sale, there is a positive assurance from a recognised institution or laboratory that the products meet the safety, health or environmental requirements which the regulations prescribe.

The basic aim of the TBT Agreement is to ensure that technical regulations and standards (including packaging, marking and labelling requirements) and procedures used for assessing conformity with such regulations, requirements and standards are not formulated and applied so as to create unnecessary barriers to trade. It calls on member countries to use guidelines and recommendations developed by international standardization organizations as the basis for their own conformity assessment procedures. Where such standards have been used as the basis for a technical regulation, it is presumed that such regulations do not create an unnecessary obstacle
to trade. Where international standards or guidelines are considered to be ineffective or inappropriate, or where they do not exist, countries are free to develop their own national standards. In all cases, however, where such proposed measures are expected to have a significant effect on trade, countries must publish in draft form the proposed technical regulations, standards and conformity assessment procedures, give reasonable opportunity to other interested parties to comment on the draft and take into account those comments when finalising the draft.

In order to ensure that technical regulations and voluntary standards do not create unnecessary barriers to trade, the Agreement lays down certain procedures and rules. Technical regulations and standards:

- must be applied on a non-discriminatory basis (Most Favoured Nation principle);
- must not extend to imported products treatment less favourable than that extended to domestically produced products (national treatment principle);
- where relevant, they must be based on scientific and technical information;
- must not be formulated in a manner so as to cause “unnecessary obstacles to international trade” (ITC/CS, 1999, p.89).

The Agreement on the Application of Sanitary and Phytosanitary Measures

Imported agricultural products usually have to conform both to technical regulations and the importing country’s SPS measures. The later are adopted by countries to protect: human or animal life from food-borne risks which arise from the use of additives, contaminants, toxins or disease-causing organisms (and thus ensure food safety); human health from animal or plant-carried diseases, and, animals and plants from pests and diseases.

The term ‘sanitary regulations’ is used to cover types of regulations whose basic objective is to ensure food safety or to prevent animal-borne diseases from entering a country. Phytosanitary regulations ensure that imported plant varieties do not bring into the country plant-borne diseases (ITC/CS, 1999, p.91).

The basic difference between technical regulations and SPS measures arises from the objectives for which they are adopted. The aim of SPS measures is limited and specific - to protect human, animal and plant life. Technical regulations, on the other hand, are imposed for a variety of policy objectives - national security requirements, the prevention of deceptive practices and the protection of the environment. They may be adopted to protect human health or safety or animal or plant life for reasons other than those for which SPS measures are imposed.
The SPS Agreement requires countries to base their SPS measures on international standards, guidelines or recommendations developed by the Codex Alimentarius Commission, the International Office of Epizootics, relevant international and regional organizations operating within the framework of the International Plant Protection Convention and any other international organization that may be designated by the WTO Convention on SPS. SPS measures must be based on scientific evidence and must not be maintained without sufficient evidence;

Both the SPS and TBT Agreements contain provisions for the extension of special and differential treatment for developing countries. Developing countries had a two-year and least developed countries had a five-year transitional period (which expired 01.01.01). They also contain provisions for the WTO Secretariat and member countries to provide technical assistance to developing countries to assist them, inter alia, in developing the legal and institutional framework required for the application of technical regulations and SPS measures.

An issue that is becoming of increasing importance in international trade is the insistence of manufacturing industries on buying components, parts and other intermediate products from enterprises that operate viable quality management systems. The TBT Agreement encourages countries to adopt agreed quality management systems such as ISO 9000 (ITC/CS, 1999, p.97). Such systems do not evaluate the quality of the products themselves. Registration only supports the manufacturer’s claim that it has a system capable of delivering a product of consistent quality.

It was always recognised that the benefits of trade liberalization resulting from the Uruguay Round negotiations could be undermined or offset by the protectionist use of technical regulations, standards and conformity assessment procedures (UNCTAD, 2000, p.59). It is also clear that such regulations and standards may raise difficult issues for developing countries, given their limited technical capacities and financial resources. It is the view of developing countries, therefore, that certain provisions of both the Agreement on TBTs and SPSs should be amended to ensure that the risk of using technical regulations, standards and conformity assessment procedures as border protection instruments should be minimized, ensuring that all member countries can derive equal benefits from the Agreements.

**NTMs and Enterprise Strategies**

As developing countries increasingly liberalise and deregulate their economies and become more closely integrated into the global economy through trade, direct foreign investment and technology transfers, they have to maintain existing, and develop new, competitive advantages if their more outward-oriented development strategies are to succeed.
Global competitiveness depends overwhelmingly on national productivity levels and rates of growth as well as innovation and learning in developed and developing countries. (Porter, 1990) The imposition or upgrading of a technical regulation or standard by either governments or enterprises can be seen as an external shock or discontinuity or innovation. New technologies may lead to new product designs and marketing and production methods involving higher standards. New or shifting buyer needs, with respect, for example, to food safety, consistency and convenience, and changes in government regulations with respect to product standards and environmental controls, create at the same time both barriers to trade but also new competitive advantages.

Enterprises have to react positively and quickly to these changes in market conditions if they are to maintain or improve their competitive advantage. There are many possible firm-level reactions including lobbying, cost cutting measures and investments in internal technological capability. Of these, however, investments in technological capability - conscious efforts by enterprises to use imported technologies efficiently - are particularly critical to sustaining enterprise-level competitive advantage (Mytelka, 1999; Lall, 2001). Enterprise-level capability building is best seen as a type of active technological learning process that is incremental and cumulative but its outcome is unpredictable.

The enterprise-level strategies to be adopted in response to a change in market conditions brought about by the imposition of a NTM can be grouped into two types (Wignaraja and Ikiara, 1999, p.78):

*Offensive* where enterprises will respond “head on” to the imposition of the NTM by capability building - variously investing in new plant and equipment, upgrading product quality, introducing new products, making changes to production processes, acquiring new technology and/or seeking out foreign partners or initiating joint venture arrangements;

*Defensive* where enterprises “retreat” in the face of the NTM by moving back into the domestic market or seeking new export markets where the NTM may not apply, cutting costs by reducing wages or employment or by lobbying government to exert pressure to get the NTM removed or otherwise taken action to mitigate its effects.

Clearly there will sometimes be overlap between these two strategies. Enterprises may well use their industry or trade associations to lobby the government to get the NTM removed and at the same time attempt to extract resources from the government to help them cut costs, upgrade the product or acquire new technologies. At the same time, enterprises may of their own accord be putting in place the measures needed to adopt a more offensive strategy.
Public and Private Sector Support for Enterprise Restructuring

We have already noted the financial and technological constraints that face enterprises in developing countries, both with respect to meeting technical regulations and standards and challenging what might appear to be unfair or discriminatory measures targeted at the exports of particular firms or sectors. Meeting technical standards and conformity assessment procedures may impose significant costs on enterprises, along with “one-off” costs associated with product redesign and the creation of appropriate administrative systems. In addition, the governments of developing countries are likely to lack the resources to bring cases to the WTO.

The two Agreements contain provisions calling on the WTO Secretariat and member countries to provide technical assistance to developing countries to assist them in developing appropriate and effective legal and institutional frameworks to cope with TBTs and SPSs. It is difficult to see this as a solution to the problem however, given the demands that are likely to be placed on the limited resources available. As in so many other areas, developing countries will ultimately be forced to rely upon their own efforts and resources in order to deal with the problems raised by TBTs and SPSs.

With respect to assistance from the public sector, government ministries and departments may provide the assistance that enterprises need. Some countries, including India, have a well-developed network of standard setting bodies (SSBs), with the Bureau of Indian Standards (BIS) being the premier standard setting organization (Saqib, 2000). A variety of companies and agencies, in both the public and private sectors, both domestic and international, will perform a wide variety of functions associated with inspection, certification and compliance. Other things being equal, developing countries characterised by a strong institutional support system which is closely linked to companies are likely to perform better than countries lacking such an infrastructure (Metcalfe, 2003). Various kinds of technical assistance, different kinds of training services and the provision of market information are all vital in this respect.

In the private sector, enterprises may turn to the relevant industry or trade association for information or assistance. Overseas buyers obviously have a commercial interest in ensuring that suppliers meet all technical regulations and standards, and will provide market information and technical assistance. Entering into joint venture arrangements or technology transfer agreements with foreign companies is another way for domestic enterprises to develop new competitive advantages.
Since 1991, the Government of India has introduced a series of economic reforms, including trade liberalisation, deregulation, disinvestment of Public Sector Enterprises and changed policies towards direct foreign investment (DFI). The reform process has often been hesitant and incomplete (Bhagwati, and Srinivasan, 1993; Srinivasan, 2000). By Indian standards, however, there has been an improvement in the environment for manufacturing and exporting (Lall, 1999, p.1769) and most observers agree that significant trade liberalisation has occurred, the trade regime is more open and outward-looking, foreign equipment and technologies are more accessible and that there has been a rise in DFI (Lall, 1999; WTO, 1998; Panagariya, 1999).

Indian export growth appears to be tied to cycles in world trade and India has so far been unable to raise its global market share. As of 1997, India only accounted for 0.6 per cent of world exports in manufactures (UNCTAD, 2002, p.81). The weakness of India’s export performance in the second half of the 1990s is thus in part a reflection of exogenous factors (the slowdown in the rate of growth of world trade) but it is also in part the consequence of the longer–run problem of the technological structure of Indian exports.

Although India has a large and diverse industrial structure with impressive technological capabilities, India’s exports in the mid-1990s were still dominated by resource-based and low-technology products, accounting for over 83 percent of total manufactured exports in 1996 (as compared to 86 per cent in 1985) (Lall, 1999, Table 7, p.1779).

As of 1995, only medicinal and pharmaceutical products, classified as high technology, were present in the top ten exports of India. From a more dynamic perspective, only 19 per cent of Indian exports were in dynamic sectors of world trade (where growth was faster than the average) and where India was increasing its market share.

Lall (1999, p.1784) concluded that “…the long-term prospects for manufactured export growth by India are not very encouraging….Unfortunately, there seems to be little understanding among policy makers of the structural deficiencies involved. Unless widespread changes are undertaken, the export spurt could again prove to be weak and short-lived”.

The relatively strong performance of India’s pharmaceutical exports was maintained in the late-1990s. Our estimates suggest that its pharmaceutical exports grew at 10.2% per year (in current $) during 1995-1999. By 1999, the country’s pharmaceutical exports were about $ 1.1 billion (up from $0.72 billion in 1995). Equally striking was that India had emerged as the third largest
pharmaceutical exporter in the developing world, just behind China with $1.7 billion and Singapore with $1.2 billion. This is a creditable achievement in India’s export history and can be counted as one of the successes of economic reforms. The bulk of India’s pharmaceutical exports are destined to developing and transition economies (73.4% in 1998) while developed economies (EU 15.7%, USA 9.8% and Japan 1.1%) account for the rest.

Indian Perceptions of NTMs
Developing countries have argued that the WTO should ensure that any “international standard” with which they are expected to comply … must have been formulated with the effective participation of developing countries, and such effective participation must be an obligation for the concerned international organisations setting such standards’ (Mukerji, 2000, p.50)

The Government of India has been at the forefront in arguing that Non-Tariff Barriers (NTBs) (which include a wide variety of quantitative restrictions, prohibitions, non-tariff charges, antidumping duties, countervailing duties, subsidies and government procurement policies, as well as TBTs and SPSs ) are used in a discriminatory manner against the export interests of developing countries.

A Government of India, Ministry of Commerce Report (GOI, 1999), for example, argues that NTBs constrain the growth of a large number of important Indian exports, including cereals, coffee, tea, spices, edible fruits and nuts, fish and related items, chemicals including pharmaceuticals, footwear and tanning and dyeing items, some engineering products (iron and steel and related items) and vehicles.

Bhattacharyya (1999) attempts to quantify the incidence of NTBs on India’s exports. He argues that there is a close correlation between India’s export performance and the growth of world trade and concludes (contrary to Lall, 1999) that external demand and market access conditions effectively determine India’s export performance. From this it logically follows that the widespread and discriminatory use of NTBs and NTMs, mainly by the developed market economies, will have a negative impact on India’s export performance.

Using the UNCTAD Coding System of Trade Control Measures, Bhattacharyya (1999, p.9) estimates that, in 1996-97, 50.9 per cent of India’s exports to the EU were subject to single or multiple NTMs. Similar figures for the USA and Japan were 35.7 per cent and 46.8 per cent respectively. These figures are misleading, however. For example, in the case of the USA, only 11 per cent of India’s exports were facing SPSs (85 per cent of exports were subject to MFA restrictions which, strictly speaking, are not NTMs). MFA restrictions were also the most important constraint in the case of the EU. Only in the case of Japan were SPS measures significant, being applied to more than 50 per cent of India’s exports to Japan.
A study by the Rajiv Gandhi Institute (Saqib, 2000) identifies a number of problems that developing countries face with respect to TBTs including high costs of adaptation, the irrelevance of foreign standards to local conditions, the lack of timely and adequate information and consequent transaction costs, the difficulties of understanding the requirements as well as testing and monitoring them, the perceived lack of scientific data for specific threshold or limiting values and the uncertainties arising from rapidly changing conditions in overseas markets.

These studies conflate NTBs and NTMs and thus do not strictly estimate the impact of NTMs only. This is important to note because different types of NTBs and NTMs are subject to differing provisions under the WTO (the phasing out of the MFA in 2005 and the abolition of all other quantitative restrictions on trade, with certain exceptions, for example), and there are differing mechanisms to deal with the problems that they give rise to.

Second, no one questions the right of governments to impose regulations and enforce standards that relate to the health and safety of consumers, the health and safety of animals and plants, environmental considerations, issues that are perceived to relate to national security and the need for new regulations and standards that arise as the result of technical advances and technological innovations. The problems arise, in part, when such standards or regulations are applied in a discriminatory manner and when scientific evidence may not justify the imposition of SPSs. The Dispute Settlement Process of the WTO provides, at least in principle, the forum for the settlement of such matters.

Having considered concepts and secondary literature on NTMs, the reminder of the paper focuses on firm-level evidence in the Indian pharmaceutical industry.
4. INDIA’S PHARMACEUTICAL INDUSTRY: FIRM-LEVEL EVIDENCE

This section examines the incidence and impacts of non-tariff measures (NTMs) on a sample of Indian pharmaceutical firms. It highlights three important issues about the relationship between NTMs and firm behaviour in the Indian pharmaceutical industry: (a) what is the pattern of NTMs faced by enterprises across export markets; (b) to what extent do enterprises comply with the imposition of NTMs in export markets and what costs are involved; and (c) what sources of assistance are available to enterprises to assist them in complying with NTMs and how effective is this support.

Background and Export Pattern of the Sample

Ten pharmaceutical companies (located in and around New Delhi) were interviewed during fieldwork. The sample firms differ by size, ownership, specialisation and export patterns (see Table 1).

Table 1: Sample Firms’ Product and Export Patterns

<table>
<thead>
<tr>
<th>Name</th>
<th>Product (a)</th>
<th>Exports as a % of Sales (2000)</th>
<th>Value of Exports $ m. (2000)</th>
<th>Years of Export Experience in 2001</th>
<th>Main Markets</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>BD 28%, F (72%)</td>
<td>31(b)</td>
<td>67.4 (b)</td>
<td>26</td>
<td>US, EU, Japan, Argentina, Brazil</td>
</tr>
<tr>
<td>Lupin Laboratories</td>
<td>BD (70%), F (30%)</td>
<td>70</td>
<td>177.8</td>
<td>9</td>
<td>CIS, USA, EU, Japan</td>
</tr>
<tr>
<td>JK Drugs &amp; Pharmaceuticals Ltd.</td>
<td>BD (90%), F (10%)</td>
<td>60</td>
<td>26.7</td>
<td>6</td>
<td>SE Asia, USA, EU</td>
</tr>
<tr>
<td>Seagull Laboratories Pvt. Ltd.</td>
<td>F</td>
<td>5</td>
<td>0.2</td>
<td>1</td>
<td>Russia, Nigeria, Ghana, Nepal</td>
</tr>
<tr>
<td>Ahlcon Parenterals India Ltd</td>
<td>F</td>
<td>40</td>
<td>3.3</td>
<td>6</td>
<td>CIS, Russia, Ukraine, Kenya, Uganda, France, Switzerland</td>
</tr>
<tr>
<td>Om International</td>
<td>F</td>
<td>100</td>
<td>1.1</td>
<td>6</td>
<td>Georgia, Ukraine, Uzbekistan, Kenya, Algeria, Mauritius, Nigeria, S. Africa, Nigeria, Ghana, Liberia</td>
</tr>
<tr>
<td>Paam Drugs &amp; Pharmaceuticals Ltd.</td>
<td>F</td>
<td>40</td>
<td>n.a.</td>
<td>11</td>
<td>CIS, Nigeria, Kenya, Middle East</td>
</tr>
<tr>
<td>Cooper Pharma</td>
<td>F</td>
<td>50</td>
<td>1.4</td>
<td>7</td>
<td>Russia, Kenya, Nigeria</td>
</tr>
<tr>
<td>Pharmasynth Formulations Ltd.</td>
<td>F</td>
<td>15</td>
<td>0.2</td>
<td>4</td>
<td>CIS, Nigeria, Kenya</td>
</tr>
<tr>
<td>New Life Pharmaceuticals</td>
<td>F</td>
<td>60</td>
<td>0.6</td>
<td>7</td>
<td>Russia, Kenya, Nigeria</td>
</tr>
</tbody>
</table>

Notes: (a) BD = bulk drugs, F = formulations. (b) 1999.
Size and Ownership. Only one firm (Ranbaxy) has minority foreign equity (28%) and majority Indian private equity. Ranbaxy is a multinational research-based pharmaceutical company with headquarters in India. It has sales offices in over 40 countries, manufacturing operations in 7 (including the US and Ireland) and employs 7500 people world-wide (6000 in India).

The rest are Indian owned. Two have large Indian business groups behind them. Lupin Laboratories is a part of the Lupin Group (consisting of 4 companies including one in Thailand and one in the US) that is one of the country’s leading pharmaceutical groups with 3500 employees. The JK Organisation owns JK Drugs (650 employees), which is one of the country’s leading business houses and has 50 companies across many activities and employs 50,000 people. The remaining seven Indian-owned firms are typically SMEs (with under 150 employees) and are either stand-alone SMEs or belong to smaller business groups.

Products. The sample firms produce two broad types of products: bulk drugs (intermediates and active pharmaceutical ingredients which are used to make up finished goods or formulations) and finished formulations in various dosage forms. The three largest firms (Ranbaxy, Lupin and JK Drugs) produce a combination of low-cost bulk drugs and formulations for more demanding developed country markets. These firms are engaged in research and development activities and are attempting to move into more value added segments of the international pharmaceutical industry. Ranbaxy’s product mix is dominated by formulations (mostly value-added generics and novel drug delivery systems rather than conventional dosage forms) while the Lupin and JK Drugs largely concentrate on bulk drugs. The remaining 7 firms produce formulations based on conventional dosage forms for less demanding developing country markets. These formulations are mostly produced by “reverse engineering” existing pharmaceutical products and little original research and development is involved in this regard.

Export propensity and markets. The pharmaceutical firms fall into two even groups according to their export propensity. Lupin, JK Drugs, Om International, Cooper Pharma and New Life Pharmaceuticals which all export over 50% of their sales can be termed “principally export” firms. In terms of export value, the largest exporter by far is Lupin Laboratories while Cooper Pharma, Om International and New Life Pharmaceuticals are very small exporters. The others including Alhcon, Paam Drugs, Seagull and Pharmasynth are can be termed “principally domestic” firms as they export less than 50% of their sales. These firms typically have very small export values. Ranbaxy exports about 31% of its sales but has a relatively large value of exports ($67.4 million) by sample standards and is probably behaves more like an export-oriented firm than a domestic market-oriented one.

There is distinctive coverage of markets by the sample firms. Four firms -- Ranbaxy, Lupin and JK Drugs and to a lesser extent Ahlcon Parenterals -- export to the more demanding US, EU and
Japanese markets while the remainder export to transition economy markets and developing country markets (including Russia, Georgia, Nigeria, Ghana, Kenya and Nepal).

Overview of NTMS in Export Markets
The interviews suggested that several different types of non-tariff measures (NTMs) confronted Indian pharmaceutical export firms in overseas markets. Table 2 provides an overview of all the NTMs faced by the ten sample firms in their principal export markets and the individual firm-level findings are given in Table 3.

Table 2: NTMs Faced by Sample Firms in Export Markets

<table>
<thead>
<tr>
<th>Export Market</th>
<th>NTMs Faced</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>FDA approval for company and products</td>
</tr>
<tr>
<td>France</td>
<td>Company and product registration</td>
</tr>
<tr>
<td>Japan</td>
<td>Requirement for local clinical trials as a part of company/product registration</td>
</tr>
<tr>
<td>Georgia</td>
<td>Product registration, WHO-GMP certificate, Russian labelling regulation and pre-shipment inspection</td>
</tr>
<tr>
<td>Russia</td>
<td>Product registration, WHO-GMP certificate</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Product registration, WHO-GMP certificate, packaging and labelling regulations</td>
</tr>
<tr>
<td>Ghana</td>
<td>Import bans, WHO-GMP certificate</td>
</tr>
<tr>
<td>Kenya, Uganda, Algeria, Mauritius, South Africa</td>
<td>WHO-GMP certificate</td>
</tr>
<tr>
<td>Bangladesh</td>
<td>Product registration</td>
</tr>
<tr>
<td>Nepal</td>
<td>WHO-GMP certificate</td>
</tr>
<tr>
<td>Argentina</td>
<td>Discriminatory bilateral agreement for PIC Treaty countries</td>
</tr>
<tr>
<td>Brazil</td>
<td>Anti-dumping duties</td>
</tr>
</tbody>
</table>

Three interesting findings are suggested by the data in Table 2:

First, at least eight different kinds of NTMS seem to affect Indian exporters in overseas markets. 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. The individual NTMs will be discussed further below.

Second, the incidence of NTMs varies across export markets and a distinct pattern can be observed. Developed countries like the US, France and Japan tend to have one main type of NTM (e.g. company and product registration) while developing and transition economy markets appear to have entirely different types of NTMs (e.g. product registration only, WHO-GMP certification, packaging and labelling requirements, pre-shipment inspection, import bans etc). The finding that India’s major markets in developing and transition economies (about three-
quarters of pharmaceutical exports) have different kinds of NTMs to those in its relatively smaller developed country markets sheds some light on the requirements for market penetration across countries. As discussed below, there is some evidence to suggest that single NTMs in developed countries like the USA may be more difficult to surmount that multiple NTMs in developing country markets.

Third, within the developing world, there is some variation in the number and nature of NTMs, which are visible to firms. While many developing and transition countries have only one NTM, some seem to have multiple NTMs – for instance, Georgia seems to have four different types of NTMs; Nigeria has three; and Ghana and Russia have two. Product registration and WHO-GMP certificates appear to be the two most popular NTMs in developing and transition economies. Anti-dumping measures, import bans and discriminatory bilateral agreements are more rare.

**Nature of NTMs in Export Markets**

The details of the eight types of NTMs affecting Indian pharmaceutical firms in different export markets are as follows:

1. **Company and product registration.** Technical regulations and standards that have to be met by pharmaceutical products for sale on the domestic market as well as the companies producing them. According to the Indian pharmaceutical firms, the most stringent of these is US Food and Drug Administration (FDA) Approval. The approval procedure requires an Indian importer to submit a comprehensive drug master file on a given new drug (which details product, process, specifications etc) to the US FDA in Washington, to permit on-site inspection of his Indian plant by US FDA inspectors (to check conformity to Current Good Manufacturing Practice regulations) and for clinical trials on individual drugs to be conducted in laboratories in the United States. According to Ranbaxy, Lupin Laboratories and JK Drugs, US FDA approval procedures for company and product registration do not discriminate between Indian importers and US pharmaceutical firms.

   There is no common European Union company and product registration procedure and Indian importers are required to register in individual EU countries. Approval procedures in France and other EU countries are similar to USFDA approval in most respects except that on-site inspection of plants does not seem to be required. In regard to company and product registration in France, Ahlcon Parenterals suggested that there was evidence of discriminatory treatment of Indian importers and French firms. Ahlcon Parenterals suggested that Indian firms had to undertake company registration, registration of products and clinical trials in France but French firms only needed company registration and clinical trials (and not product registration).
There is a different kind of issue in Japan. According to Ranbaxy, Japanese company and product registration regulations requires Indian importers to repeat clinical trials on individual drugs done elsewhere. The argument used is that the existing test results may not be valid as the Japanese population profile (diet, height, weight etc) is different to that of countries where clinical trials on drugs have already been conducted (e.g. the US and India).

2. **Product registration only.** A variation of the above technical standards and regulations requires the registration of pharmaceutical products for sale on the domestic market with local drug authorities. This is less stringent than full-blown company and product registration. Product registration on its own requires some paperwork and payment of fees but typically onsite inspection of plants and clinical trials of individual drugs are not required. There are indications of national treatment violations in regard to product registration in several developing and transition countries.

One kind of issue relates to differential payment of product registration fees. In Georgia, for instance, Om International suggested that local firms pay one-tenth the product registration fees charged to Indian importers. Moreover, in Russia, Om International and Pharmasynth Formulations Ltd suggested that local firms pay minimal product registration fees or do not require product registration while Indian importers are liable for high product registration fees. Seagull Laboratories Ltd also mentioned discriminatory product registration fees in Nigeria for local firms and Indian importers.

Another kind of issue relates to product registration requirements. JK Drugs suggested that Bangladesh requires a product registration certification from a EU country or the USA for Indian imports but does not require it from domestic producers.

3. **WHO-GMP certification.** This is a system for ensuring that pharmaceutical products are consistently produced and controlled according to quality standards laid down by the World Health Organisation (WHO). It is designed to minimise the risks involved in pharmaceutical production that cannot be eliminated through testing the final product. Written procedures cover all aspects of production (including raw materials, premises and equipment, training and personnel hygiene of staff) and documented proof of adherence to procedures is required for certification. Countries are increasingly insisting on WHO-GMP certification for imports and domestic sales of pharmaceuticals. In an attempt to promote
their exports of pharmaceuticals, many countries have also formulated their own local requirements based on the WHO-GMP system (and have trained local inspectors in enforcing these requirements).

This seems to be one of the most important NTM issues facing Indian pharmaceutical firms particularly in developing and transition economy markets. WHO-GMP certification is required for imports into transition economies like Russia and Georgia, in a wide range of African economies (including Algeria, Kenya, South Africa, Uganda, Nigeria, Ghana and Mauritius) and South Asian economies like Nepal. In some of these markets, there seems to be discriminatory treatment of imports and local firms. According to Seagul Laboratories Pvt. Ltd, Nepal requires WHO-GMP certification is required for Indian imports but not for domestic sales by local firms. Om International also made the same point in relation to Georgia and Russia; Pharmasynth Formulations in relation to Kenya; and Cooper Pharma in relation to Ghana and Nigeria.

4. **Packaging and labelling regulations.** Rules and regulations governing the packaging and labelling of pharmaceutical products for sale on the domestic market. Two instances of this issue were reported by the Indian pharmaceutical firms. Om International mentioned that Georgia insists on Russian labelling for pharmaceutical imports. It seems that the firm knew of this market requirement prior to exporting to Georgia and could customise its packaging and labelling accordingly. This is not always the case, however. According to Cooper Pharma, Nigeria does not seem to have transparent regulations in regard to packaging and labelling of pharmaceutical imports. When it was attempting to export to Nigeria, Cooper Pharma experienced an arbitrary packaging and labelling demand by the Nigerian drug control authorities, which forced the firm to change the name of a product and make up completely new packaging and labelling material. Cooper Pharma said that this regulation was levelled against it to protect a Nigerian firm.

5. **Import bans.** Prohibitions on pharmaceutical imports can apply under all circumstances or be dependent on certain conditions. In some countries, there are widely applied prohibitions but imports may be permitted in special cases. In the case of conditional prohibitions, the import of certain goods may be prohibited under certain circumstances (e.g. prohibition of certain use and prohibition except for certain purchasers). These measures can apply for temporary periods or be for long periods. There seemed to be only one instance of this issue amongst the Indian pharmaceutical firms. Cooper Pharma said that arbitrary import bans had stopped two of its pharmaceutical imports -- Dexamethasone, (an anti-allegy tablet) and multi-vitamin tablet -- into Ghana. The import ban cost Cooper Pharma nearly US$ 100,000 in lost export sales per year. The firm
stressed that these measures were selectively applied to protect a new local start-up firm and did not amount to a total ban on Indian pharmaceutical imports across the board. Cooper Pharma went on to say that it was exporting other pharmaceutical products into Ghana.

6. **Anti-dumping duties.** Imposition of a special import duty when the price of imports is alleged to be lower than the price charged by the foreign firm in its domestic market or some measure of its cost of production. Minimum foreign prices may be established to facilitate anti-dumping investigations and actions. Duty rates may be enterprise specific (i.e. levied only on products from selected firms) or may be applied on a country-wide basis. The sample firms mentioned one case of anti-dumping duties. Ranbaxy said that Brazil had taken it to court on anti-dumping grounds and levied duties of 12-18% on its domestic sales in the country.

7. **Discriminatory bilateral agreements.** Preferential trading agreements that may selective by commodity and country. This category may include preferential sourcing agreements and other forms of international trade. There was one instance of discriminatory bilateral agreements mentioned by the sample enterprises. Ranbaxy said that Argentina only allowed pharmaceutical imports from PIC Treaty members and that this had kept out Indian imports.

8. **Pre-shipment inspection.** Inspection of goods in the importing country by an international pre-shipment agency prior to export and a pre-shipment inspection certificate is issued as an export requirement. One instance of pre-shipment inspection was mentioned by the pharmaceutical firms. Om International said that Georgia had instituted pre-shipment inspection procedures for Indian pharmaceutical imports and had appointed a specific foreign pre-shipment agency to conduct the work in India. Extra paperwork was involved and an inspection fee was payable.

**Compliance with NTMS at Firm-level**

As discussed in Section 2, two types of responses – offensive and defensive -- are possible at enterprise-level given the presence of NTMs in export markets. In the *offensive* response, a firm reacts positively to an NTM and attempts to comply with the regulation by making the requisite investments in technological capability, i.e., upgrading procedures, standards, products and processes. These investments may lead to an increase in the firms’ exports to a given market. In the alternative *defensive* response, a firm reacts negatively to an NTM and does not attempt to comply with its regulatory requirements via investments. In the latter case, the firm might either reduce its exports to a given market or even retreat back into the domestic market.
Table 3 provides data on NTMs faced by the firms in export markets, their responses, the compliance costs and comments by firms. The most significant finding is that the majority of Indian pharmaceutical enterprises (seven out of ten firms) in the sample seemed to be reacting offensively to NTMs in their principal export markets. In order to access the demanding US, France and Japanese markets, they were systematically attempting to register their companies as well as their products. In order to access developing and transition country markets, these firms were also trying to register products, upgrade plants to WHO-GMP standards and meet packaging and labelling requirements. Of the remaining three pharmaceutical enterprises, one seems to be showing a mixed response to NTMs (with some positive and negative aspects to its approach) while the other two seem to be reacting defensively. Typically, these three defensive-oriented firms sought to gain market access by lobbying the Indian Government and did not register products or obtain WHO-GMP certification.

Another interesting finding is that compliance with NTMs typically involved significant financial and time costs to the seven offensive-oriented Indian pharmaceutical enterprises. These financial and time costs are not fixed but varied by type of NTM faced and the market. Some examples are as follows.

*Company and product registration* involve by far the highest compliance costs in amongst NTMs in overseas markets. US FDA approval is particularly demanding according to Ranbaxy and JK Drugs. No application fee seems to be necessary for US FDA approval. The bulk of the compliance costs for US FDA approval comes from the requirement to conduct clinical trials on new drugs in the United States and the cost of clinical trial ranges from US$0.15 million to US$1.5 million depending on the type of drug being tested. Another component of cost (for which no estimate was available) is associated with payment for legal services required to submit Drug Master Files to the US FDA and to follow up on the approval process. The duration of US FDA approval process -- which involves a site visit to the Indian plant -- can also be quite lengthy. Ranbaxy said that its first FDA approval for an anti-biotic bulk drug took as much as 27 months but its current applications for formulations take an average of 14 months. JK Drugs said that their FDA approvals for bulk drugs can vary between 18-24 months.

The Indian pharmaceutical firms expressed similar sentiments about the compliance costs of company and product registration in France and Japan. In the case of France, Ahlcon Parenterals said that it took them nearly two and a half years to go through the approval process (company registration took about one year, product registration another year and the clinical trials 3-4 months). Ahlcon’s CEO had to make about 6 trips to France during this period. No information was available on company registration or the cost of clinical trials in France but the firm also said that product registration was quite expensive – it cost US$5000 to register a single product and it had to register around 20 products (a total of US$100,000). The approval issue in Japan,
according to Ranbaxy, is that clinical trials done elsewhere (e.g. in the United States) have to be repeated locally. Depending on the type of drug involved, Japanese clinical trials could add a further US$0.15 million to US$1.5 million to an Indian pharmaceutical enterprise’s costs.

WHO-GMP certification comes second in terms of relatively high compliance costs. WHO-GMP certification is an international standard set out by the World Health Organisation and the requirements for meeting them are similar across all export markets. They deal with all aspects of production (including raw materials, premises and equipment, training and personal hygiene of staff) and compliance generally involves upgrading plant, equipment and operating procedures in pharmaceutical firms. The initial standards of a given Indian pharmaceutical firm determines the extent of upgrading that is required in this regard and the duration of the WHO-GMP certification process. Some Indian pharmaceutical firms, with initial conditions quite close to WHO-GMP requirements, may need little upgrading to reach these standards while others lag far behind and have upgrade significantly. Paam Drugs probably belongs to the former category and had to invest a relatively small sum (US$12,207) in its plant and operating procedures to bring them to WHO-GMP levels. One person was also employed full-time to manage the process of obtaining WHO-GMP certification in Paam Drugs. In the former category too is Ahlcon Parenterals who used foreign consultants and in-house technical staff to upgrade the plant and the entire upgrading and WHO-GMP certification process took 6 months. Om International probably belongs to the latter category and upgrading involved a significant investment (US$30,000) and the entire process took eighteen months. Seagull Laboratories has obtained WHO-Certification for one plant and estimates that upgrading the second will cost about US$64,000. New Life Pharmaceuticals has not obtained WHO-GMP certification yet but estimates that it would cost at least US$10,000 and that the process would take between 3-12 months.

The compliance costs of product registration only can be quite high but these seem to differ considerably by export market. Compared with full-blown company and product registration discussed above, the procedures for product registration only can be relatively simple. In most cases, the Indian pharmaceutical firms had to file an application form (along with product samples) with the local drug authority of a given country and pay a set fee for product registration. There is a possibility that product samples might be tested by the local drug control authorities but seems to rarely happen in practice. Om International said that product registration in Russia was particularly difficult – registration costs were US$10,000 per product and the process took one year – affected market access. Pharmasynth Formulations confirmed the issue of relatively high Russian product registration fees which had discouraged them from entering this market. In contrast, Om International said that product registration in Georgia depended on the type of product being registered and entailed modest fees (either US$1500 or
US$2500). The problem with even relatively low product registration fees, however, is the significant upfront financial outlays which have to be made to gain market access – Om International registered 18 products, most at US$1500 and some at US$2500, and this cost them a total of US$30,000. Seagull Laboratories said that they had registered 3-4 products product registration in Nigeria at a cost of US$1000 per product.

### Box 1: Firm Size and Compliance Costs

Compliance to a particular regulation involves incurring considerable costs on the part of a firm. Compliance costs are generally assumed to be neutral to firm size. Evidence from the sample pharmaceutical firms shows that compliance cost is significantly higher for smaller firms than the larger ones. Compliance costs vis-à-vis sales value, i.e. accessibility costs, is also higher, according to the nature of the export market. This suggests that smaller firms cannot access developed markets because of stricter and tougher regulations which require higher expenditure to conform to those regulations. Access to developed markets is thus prohibitive for smaller firms in the sample like, Seagull, Om International, Pharmasynth, New Life, Cooper Pharma etc.

Only larger firms like Ranbaxy, Lupin and JK Drugs with their higher sales value can incur the compliance costs related to developed markets. Most of the developed market regulations like FDA approvals do not involve any fee but clinical trials associated with them can cost a firm between $500,000 - 1 m. Smaller firms are unable to muster the required capital to conform to developed market regulations. This inability partly stems from inaccessibility to current sources of finance for large investments. Thus market access is not scale neutral.

But smaller firms can still export to developing and transitional markets as the sample suggests. This is because the regulations and standards demanded by developing markets are not very tough and do not require heavy financial investments to comply. WHO-GMP is an important regulation that most of the developing and transitional markets demand. Compliance costs related to WHO-GMP vary considerably between different firms, for example, for Seagull the ratio between compliance cost and sales value is 32% and for Pharmasynth, the same ratio is 5%. This variation is due to the initial conditions of manufacturing in an individual firm. Other regulatory practices like product and company registration are mostly affordable by all the smaller firms. Most of these smaller firms anticipate that technical standards and regulations even in developing markets will get tougher and stricter in future and accordingly compliance costs will escalate. In order to keep pace with these developments, smaller firms would require improved access to sources of finance.

There was insufficient case study evidence to provide a comprehensive view on compliance costs associated with NTMs such as packaging and labelling issues, pre-shipment inspection and anti-dumping duties. However, a few anecdotes provide some insights. Cooper Pharma faced an arbitrary *packaging and labelling* demand in Nigeria when it wanted to export Coprex (a tablet to cure headaches) and was forced by the local drug authorities to change the product’s name to Codrex. This involved changing all the packaging materials and applying for Indian drug control approval for the name change. The total cost of the exercise was US$6,400. In the case of the *anti-dumping* issue in Brazil, Ranbaxy said that it had to pay anti-dumping duties of 12-18% on its domestic sales in the country and significant legal fees to contest the case. Om International said that Georgia’s *pre-shipment inspection* procedures for pharmaceutical imports from India involved an inspection fee of 2.7% of FOB value (which was paid by its foreign buyers) and a lengthy process, which delayed shipments by about 10 days.
<table>
<thead>
<tr>
<th>Name of the Firm</th>
<th>Main Export Markets</th>
<th>NTMs Faced</th>
<th>Response</th>
<th>Cost</th>
<th>Firm’s Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranbaxy</td>
<td>USA</td>
<td>FDA approvals (for company and products)</td>
<td>Now obtaining 10-12 FDA approvals per year.</td>
<td>14 month average approval time. No application fee but clinical trials on new drugs are expensive ($0.15-$1.5 Mn)</td>
<td>USFDA approval does not discriminate between local and foreign firms</td>
</tr>
<tr>
<td></td>
<td>Japan</td>
<td>Requirement for Japan based clinical trials as a part of company/product registration</td>
<td>Complied with requirement</td>
<td>Means repeating clinical trials done elsewhere. Additional costs of between $0.15-$2Mn</td>
<td>Japanese firms have do the same</td>
</tr>
<tr>
<td></td>
<td>Argentina</td>
<td>Excludes imports from non-PIC Treaty countries</td>
<td>Working with Indian Government to try to gain market access</td>
<td>n.a</td>
<td>This stops imports</td>
</tr>
<tr>
<td></td>
<td>Brazil</td>
<td>Anti-dumping duties (12%-18%) on Ranbaxy’s products</td>
<td>Legal action to contest anti-dumping duties</td>
<td>n.a</td>
<td>Brazil imposed them to protect local firms</td>
</tr>
<tr>
<td>Lupin Laboratories</td>
<td>CIS</td>
<td>Re-registration</td>
<td>Company is developing specialist resources to deal with these issues - in house, external and GOI.</td>
<td>Approval times vary between 18-24 months</td>
<td>USFDA approval does not discriminate between local and foreign firms</td>
</tr>
<tr>
<td></td>
<td>USA</td>
<td>Anti-dumping</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EU</td>
<td>Environmental issues</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Japan</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>JK Drugs &amp; Pharmaceuticals Ltd.</td>
<td>USA</td>
<td>FDA approvals (for company and products)</td>
<td>Complied with requirement</td>
<td>Approval times vary between 18-24 months</td>
<td>USFDA approval does not discriminate between local and foreign firms</td>
</tr>
<tr>
<td></td>
<td>Bangladesh</td>
<td>Product registration linked to having USFDA/EU product registration certification</td>
<td>Complied with requirement</td>
<td>n.a</td>
<td>Bangladeshi firms do not require USFDA/EU product registration</td>
</tr>
</tbody>
</table>
Seagull Laboratories Pvt. Ltd. Nepal Discriminatory WHO-GMP requirements Obtained WHO-GMP certification for one plant and will do so for a second plant Estimates that upgrading of second plant to WHO-GMP levels will cost about US$ 64,000 Nepalese firms do not need WHO-GMP certification

Nigeria Discriminatory product registration fees Has registered 3-4 products $1000 per product Nigerian firms do not have to register products or pay less fees than imports

Ahlcon Parenterals India Ltd. France Discriminatory company and product registration Has registered company and about 20 products in France Product registration costs about $5000/product. Entrepreneur made 6 trips to France for registration purposes. Company & product registration and clinical trials took 30 months. French companies only require company registration and not product registration.

Kenya/Uganda WHO-GMP certification Obtained WHO-GMP certificate Upgrading of plant to meet WHO-GMP standards took 6 months
<table>
<thead>
<tr>
<th>Country</th>
<th>Discriminatory product registration fees</th>
<th>18 products registered</th>
<th>Product registration at $1500 per product for 15 products and $2500 for 3 products.</th>
<th>Georgian firms have to register products but only pay 10% of fees charged for imports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russia</td>
<td>Discriminatory WHO-GMP requirement</td>
<td>Process of obtaining WHO-GMP certificate</td>
<td>Spent $30,000 on upgrading plant and process has taken 18 months</td>
<td>Georgian firms do not require WHO-GMP certification</td>
</tr>
<tr>
<td>Russia</td>
<td>Russian labelling requirement</td>
<td>Complied with labelling requirement</td>
<td>Cost $1000 per product for translation and certification</td>
<td>This is not a problem</td>
</tr>
<tr>
<td>Russia</td>
<td>Pre-Shipmen Inspection (PSI) requirement for imports</td>
<td>Complies with PSI requirement</td>
<td>Inspection fees (2.7% of FOB value) are paid by buyer. Shipments are delayed by 10 days as a result of PSI</td>
<td>Russian firms pay minimal product registration fees or do not require registration</td>
</tr>
<tr>
<td>Paam Drugs &amp; Pharmaceuticals Ltd.</td>
<td>Discriminatory product registration fees</td>
<td>Has not registered products yet</td>
<td>Cost of registration is likely to be $10,000/product and can take 1 year</td>
<td>Russian firms do not require WHO-GMP certification</td>
</tr>
<tr>
<td>Paam Drugs &amp; Pharmaceuticals Ltd.</td>
<td>Discriminatory WHO-GMP requirement</td>
<td>Process of obtaining WHO-GMP certificate</td>
<td>See Georgia case</td>
<td>Russian firms do not require WHO-GMP certification</td>
</tr>
<tr>
<td>Paam Drugs &amp; Pharmaceuticals Ltd.</td>
<td>WHO-GMP registration</td>
<td>Has decided to obtain the requirement. Certification expected in 1 month</td>
<td>Invested US$ 12,207 to upgrade plant to WHO-GMP standards</td>
<td>Russian firms do not require WHO-GMP certification</td>
</tr>
<tr>
<td>Company</td>
<td>Country 1</td>
<td>Country 2</td>
<td>Issue Description</td>
<td>Impact</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Cooper Pharma</td>
<td>Ghana</td>
<td>Nigeria</td>
<td>Arbitrary import ban on certain products</td>
<td>Has introduced other products to compensate for loss of previous market</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Ghana/Nigeria</td>
<td>Arbitrary packaging and labelling demand</td>
<td>Adhered to local labelling requirement</td>
</tr>
<tr>
<td>Pharmasynth Formulations Ltd.</td>
<td>Russia</td>
<td>Kenya</td>
<td>Discriminatory and high product registration costs</td>
<td>Did not register products</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Discriminatory WHO-GMP requirement</td>
<td>Lobbied Indian Government for changes in WHO-GMP requirements. Will concentrate on domestic market and try to shift into Ayurvedic medicines which do not require this certification for export.</td>
</tr>
<tr>
<td>New Life Pharmaceuticals</td>
<td>Russia</td>
<td>Kenya</td>
<td>WHO-GMP certificated needed in all the markets</td>
<td>Will go for WHO-GMP when absolutely necessary – not before.</td>
</tr>
</tbody>
</table>
Sources of Assistance to Enterprises

As the previous section indicated, compliance with NTMs in overseas markets frequently involved upgrading plant and equipment as well as products, processes and operating procedures in pharmaceutical enterprises. It also sometimes involved conducting clinical trials in foreign countries, changing packaging and labelling requirements, fighting anti-dumping disputes and lobbying. The interviews suggested that the Indian pharmaceutical sample sought technical and non-technical assistance from a range of sources in order to cope with NTMs in overseas markets. The following six sources of assistance were mentioned most frequently by the enterprises:

- **In-house technical staff.** All the pharmaceutical firms employed scientists in some form of R&D activities and in production. The larger ones tended to have elaborate R&D facilities with a concentration of scientific personnel while the smaller ones had a handful of scientists. In-house technical staff typically did research on existing products to improve them and developed some new products. They also worked with consultants to upgrade plant, equipment, standards and operating procedures (particularly for WHO-GMP certification and company and product registration).

- **Consultants.** Retired technical staff from large firms and central government drug control agencies seem to be a major source of assistance to upgrade plant, equipment, standards and operating procedures at enterprise-level. Some firms, particularly the larger ones, also have technical assistance contracts with foreign consultants. Furthermore, private law firms provide legal services to deal with company and product registration and anti-dumping disputes.

- **Equipment suppliers.** These provide information on sources of equipment, advice on installation and commissioning of equipment and equipment maintenance services.

- **Commercial labs.** These facilities conduct product testing for enterprises.

- **Chambers of commerce and industry associations.** In the main, business organisations lobby state and central government for changes in local and international regulations affecting enterprises and provide some information about overseas markets.

- **State and central government drug control agencies.** Government agencies inspect plants and certify them to WHO-GMP standards and local GMP standards. They also provide information on renovating plants to meet these standards.
Although a wide range of technical and non-technical support seems to be available for Indian pharmaceutical enterprises to deal with NTMs in overseas markets. Detailed discussions with enterprises suggested that these sources of support were insufficient in relation to enterprise needs. These gaps seem to apply both to private as well as public sector service provision. For instance, the commercial labs sometimes delay in returning test results for products and foreign buyers occasionally reject even these results. Business organisations seem to be largely engaged in lobbying and, in general, do not provide technical assistance to members. The central and state-level drug control authorities largely perform a regulatory function and do not seem to provide technical advice on product development and product testing services. The net result is that enterprises largely rely on in-house sources of assistance supplemented by private consultants. The failure of public institutions to provide greater assistance to individual enterprises is a reflection of the wider failure of the Indian Government industrial strategy to recognise the extent and depth of market failures and to devise appropriate institutional responses.
5. CONCLUSION

Issues of market access for developing country exports have been given increasing emphasis in recent rounds of multilateral trade negotiations. Progress has been made in reducing tariffs and non-tariff barriers but there appears to be a rise in non-tariff measures (NTMs) affecting developing country exports particularly regulations and standards connected with health, safety, consumer protection and the environment. Trade negotiators from developing countries claim that a plethora of NTMs in the developed country markets have had a negative impact on export growth and diversification in poor countries. Yet, in the main, these claims have not been backed by detailed industry and enterprise-level evidence from the developing world. The available evidence is typically anecdotal and incomplete.

This study of the Indian pharmaceutical industry is one of the first detailed attempts to shed light on the nature of NTMs and their effects on industry-level export performance in a developing country. It also examined the nature of technological capability building being undertaken by enterprises in response to NTMs. The absence of published information on NTMs in India prompted the collection of original data through interviews with a sample of pharmaceutical firms. The sample firms contained a range of size, product specialisation and export patterns. The research underlined an important methodological point about investigations into NTMs – namely, that detailed enterprise case studies can significantly improve our understanding of the workings of NTMs and their effects at industry and firm-level. It also revealed that data on enterprise behaviour and entrepreneurs perceptions has to be carefully interpreted by researchers.

The main findings in regard to the incidence of NTMs, compliance costs, firm strategies and institutional support in the Indian pharmaceutical industry are as follows.

First, there are about eight different kinds of NTMs, which seem to affect Indian pharmaceutical exporters in overseas markets. 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. Three of these NTMs (company and product registration, product registration only, WHO-GMP certification) seem to be particularly challenging impediments to Indian export growth in pharmaceuticals.

Second, the incidence of NTMs varies across export markets and a distinct pattern can be observed. Smaller developed country markets like the US, France and Japan tend to have one
The main type of NTM (company and product registration) for pharmaceuticals while the larger developing and transition economy markets appear to have entirely different types of NTMs (e.g. product registration only, WHO-GMP certification, packaging and labelling requirements, pre-shipment inspection and import bans). This finding sheds some light about the requirements for market penetration across countries. In particular, preliminary evidence suggests that single NTMs in developed countries like the US in particular may be more difficult to surmount that multiple NTMs in developing country markets. Further empirical research using larger samples of enterprises from India and other developing countries is required to confirm this important finding.

Third, the majority of the pharmaceutical enterprises in the sample appeared to have adopted offensive competitive strategies (via capability building) in relation to NTMs in major export markets. These firms have attempted to comply with the regulatory requirement by investing in new equipment, standards, products, processes, training and sources of technical assistance. This is a positive development and one that holds well for India’s export prospects in Pharmaceuticals. Of the few remaining enterprises, one seems to be showing a mixed response to NTMs (with some positive and negative aspects to its approach) while the others seem to be reacting defensively and did not make the requisite investments.

Fourth, compliance with NTMs has involved significant financial and time costs for the pharmaceutical enterprises. By far the greatest compliance costs are associated with obtaining US Food and Drug Administration approval – the cost of requisite clinical trials can range from US$0.15 million to US$1.5 million depending on the type of drug being tested and process can take up to two years. WHO-GMP certification can also involve relatively high compliance costs depending on the extent of upgrading required and a certification processing spanning between 3-12 months.

Fifth, the pharmaceutical enterprises seem to draw on half a dozen sources of technical assistance to comply with NTMs in overseas markets including in-house technical staff, consultants, equipment suppliers, commercial labs, chambers of commerce and industry associations and state and central government drug control agencies. However, interviews with the enterprises suggested that these sources of support were insufficient in relation to enterprise needs. These gaps seem to apply to both private as well as public sector service provision.

In the final analysis, the limited evidence from the Indian case suggests that NTMs can be an important impediment to exporting pharmaceutical products from developing countries but that they won’t stifle such exports altogether. Hence, the market access concerns of some developing country trade negotiators may be somewhat overstated. This does not mean, however, that developing countries should neglect the potential threats posed by NTMs in export markets. The
Indian case further suggests that success in coping with NTMs in export markets requires an offensive competitive strategy at enterprise-level with sustained investments in equipment and technological capabilities. It also requires a coherent infrastructure of support services to facilitate enterprise compliance with NTMs including information, consultancy services, standards, testing and certification, quality management and training. Developing countries that encourage their enterprises to adopt offensive competitive strategies and strengthen their infrastructure of support services are likely to witness better export performance than those that do not (see Metcalfe, 2003; Wignaraja, 2003).

Endnotes:

i For example, although industrial tariffs are now modest, with the trade-weighted average tariff on industrial goods in the developed countries standing at 3.5 per cent at the end of 2000 (UNCTAD, 2002, p.35), the low average conceals high tariff peaks and escalation with the stages of processing.

ii The discussion in this section depends heavily on ITC/CS, 1999.

iii Enterprises in developing countries may have particular problems in benefiting from ISO 9000 registration, however:

• they may be no or only few local firms which can provide guidance on introducing the system, assess and register companies to ISO 9000 and carry out the periodic audits needed;

• few developing countries have developed the legal framework and the institutions required for the accreditation of certifying firms;

• registration to ISO 9000 involves expenditure on registration fees and costs of administrating the system, especially if foreign firms have to be used;

• small and medium-sized enterprises may face special problems in these respects, but increasingly they are likely to find themselves compelled to seek ISO 9000 registration if they wish to maintain their position in existing markets or break into new ones.

iv Calculated from PC-TAS export database version 2.0 and 2.1 of the UNCTAD/WTO International Trade Centre.


vi This is a preliminary but potentially significant finding that needs to be confirmed in further research drawing on a larger sample of pharmaceutical firms from India and other developing countries.

vii The USFDA ensures the quality of drug products by carefully monitoring drug manufacturers’ compliance with its Current Good Manufacturing Practice Regulations (CGMP). The CGMP regulations for drugs contain minimum requirements for methods, facilities and controls used in manufacturing processing and packing drug products. During on-site inspection, FDA inspectors determine whether a firm has the necessary facilities, equipment, and skills to manufacture a new drug for which it has applied for approval.

viii As the import ban on selected products in Ghana (involving Cooper Pharma) and discriminatory bilateral agreement in Argentina (involving Ranbaxy) are designed to keep out imports altogether rather than provide market access with an additional compliance cost, these are not discussed here.

ix Ranbaxy said that a clinical trial for an anti-biotic could cost between US$0.15 million to US$0.3 million while that for a cardiovascular drug can range from US$0.5 million to US$1.5 million.
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