10. Non Tariff Barriers & International Co-operation

10.1 International Cooperation

In its bilateral and multilateral trade agreements in the future, India ought to pay greater attention to extracting concessions on services, allowing for Indian medical professionals to practice outside, thereby increasing awareness about Indian healthcare as well as popularizing Indian System of Medicine, etc. India is in the process of negotiating several such agreements. In order to give impetus to our pharmaceutical industry, these agreements need to articulate our concerns by addressing them as follows:

i. Partner countries may not include pharmaceuticals in their sensitive lists.

ii. Drug registration process in partner countries may be harmonized and should not become a Non-Tariff Barrier (NTB).

iii. NTBs such as sanitary and phyto-sanitary regimes may not be adopted or if adopted may be harmonised.

iv. A mutual pharmaceutical cooperation regime can be negotiated which can complement each other's capacities. Since United States adopts a market restrictive approach in respect to pharmaceutical exporting countries which do not have free trade agreements with United States, it may be a good idea to examine the likelihood of entering into an enabling agreement with the US which would negate this artificial barrier created by US

10.2 Technical Barriers to Trade

In the interest of safety, efficacy and affordable medicine to the general population every country in the world regulates pharmaceutical industry in their respective countries. The regulation is all pervasive from price controls to reimbursement of pharmaceutical expenses to the consumers through national health protection/insurance schemes to drug registration, market authorization, quality control, quality standards, imports & distribution, packaging & labelling, intellectual property and even mergers and acquisitions in some countries.

While the countries are free to impose such regulation in keeping with their sovereign status, some of the regulation is excessive and non-justifiable. Some of the technical barriers to trade in various major

pharmaceutical markets are briefly elaborated below which will illustrate the entry barriers being faced by Indian manufacturers and where government intervention is required.

10.2.1 Multiple Approvals by Various Drug Regulatory Authorities

The multiplicity of drug approval agencies in various countries such as US FDA, UK MHRA, the European Medicines Agency (EMEA), European Directorate for Quality Medicines (EDQM), Ministry of Health, Labor, and Welfare (MHLW), Japan, The World Health Organization (WHO), Therapeutics Goods Administration (TGA), Australia, MCC, South Africa, etc. has raised drug registration costs and site inspections costs. These regulatory agencies insist on pharmaceutical standards & quality procedures of their country, which often varies from country to country.

Many countries including, EU, USA, Canada, Japan, etc., also have concluded mutual recognition agreements with countries with equivalent levels of GMP and registration standards. These agreements are meant to assure the quality of drugs imported into country issuing market authorization through mutual acceptance of GMP inspection results and exchange of information on drugs distributed in the two countries. However, India is not signatory to many of these mutual recognition agreements hindering the exports of the country's exports.

Automatic Approvals for Indian Facilities Recognised by Countries with Mutual Recognition Agreements

For products manufactured in USA and Australia there is a mutual acceptance. However, the same US FDA approved product in India will still need a plant inspection by Australian authorities. As Australia accepts US facility in situated in & approved by US FDA with out any inspection the same should be extended to US approved facility in India in an auto mode. We may negotiate such mutual agreements. Further, we should take up a bilateral discussion to accept Indian facilities approved by US or EU or TGA or HPB Canada or MCA South Africa without further inspections by various countries in the ROW. For example, even Nigeria, Ghana, etc.; want to inspect our facilities although our facilities are already approved by US or EU, etc. There is a justification to inspect if such facilities are not approved by any eminent countries.

The documentation to register drugs is extremely detailed and often is very expensive to provide such dossiers such as DMFS or ANDAS, etc. The review procedures of such documentation are very stringent and do not permit any low cost approach. The complete process details, site plans and all intricate details are demanded and have to be provided. This not only costs lot of money but also provides a free access to knowledge to employees in such agencies which diffuses into their systems. India on the other hand offers very little or almost no such restrictions making it easy for foreign manufacturers to enter the country. Our documentation reviews, inspections, etc., are meant to enhance the access of importation. .

While retaining such a broad objective, we have an urgent need to enhance our entry standards and inspections, etc., to enhance the standards in country.

Legislation for Import Permissions Should be Strengthened

Indian regulation for drugs & pharmaceutical products for imports is very simple in comparison with many major pharmaceutical markets. There is a case for reviewing the same and to bring it in line with international standards for imports

10.2.2 Bioequivalence Studies for Generics in Local Populations – An Emerging Technical Barrier

Japan, Mexico and now Thailand, etc., want the bioequivalence to be studied in their local populations in their countries. A bio-equivalence study merely compares the drug levels as compared to the original drug in-vivo. There is no clinical efficacy evaluation. Indian exports will suffer extensively if this technical barrier is adopted in more countries. US, Canada, Europe, South Africa, Australia and various countries accept BE studies conducted in India as per International guidelines. As each additional BE study costs more than Rs.50lacs for each additional country, this new NTB can adversely effect the product exports.

Negotiating NTB of Local BE Studies

India should immediately negotiate with countries such as Japan, Thailand, Mexico, etc. to accept Indian bioequivalence studies conducted in BE centres accepted by US FDA, etc. Concerned countries can inspect the bioequivalence centers. If required, we should engage international experts on bioequivalence to make a case for our negotiations.

10.2.3 Drug Registration Fees

Countries in European Union charge exorbitant fees for granting drug registration and approvals. This is so even with countries such as Japan, Russia, South Africa, Australia, Singapore, etc. This is in sharp contrast with USA which does not charge any such fees for filing DMFs & ANDAs. While a few countries of Europe seek the fees after due examination of the applications, many countries require the payment of fees in advance.

A fee has to be paid for each strength and variation. In EU countries if the registered contents of the dossiers (or drug master files (DMF)) are changed known as 'variation', (for example sourcing of Active Pharmaceutical Ingredient from one approved manufacturer to another approved manufacturer of the same API, or indications or packaging, etc.) an application to change the DMF or a slight modification notification must be submitted. When an application to change of the DMF is submitted, the applicant

must also submit a partial change application for the MF. If the variations are significant, EU countries (as also USA) often require filing of new application for license altogether.

The fees for registration is as high as US$99,000 in Singapore and it is approximately US$2,00,000/- to obtain registration for all strengths of one product in 25 countries of European Union. The bio-equivalence studies required for these registrations are costly and range between Rs.30lakhs to Rs.150lacs.

Realigning Registration Fees for Formulations APIs and Intermediates on par with other countries

It is suggested that we may realign our drug registration fees in line with other countries and use those funds to beef up our foreign inspection systems, introduce stringent dossier review systems, etc.

10.2.4 Reference Standards

Many countries insist on innovator standards of their countries. This is to say that Japan accepts reference standard of innovator product registered in Japan, Brazil accepts reference standard of innovator product registered in Brazil and so on. This implies to register a generic molecule such as paracetomol in a country such as Japan or Brazil, we have to obtain reference standards of paracetamol of the innovator company registered in Japan or Brazil. Often this places additional difficulties on exporters to obtain reference standards of different countries.

Generally small companies find it difficult to obtain innovator drugs in various countries due to several difficulties.

Procurement of Reference Standards in Foreign Countries

Possibilities for Indian embassies to help the companies in procuring the reference standards for R&D work to promote the exports should be examined.

In addition to challenge of obtaining these, they have to be pre-approved by DCGI called as test license. The conceptual role of DCGI in permitting these licenses especially for drugs that are registered in the country may be re-examined.

Test licenses approval system for drugs that are already approved in India should be immediately dispensed with. Test licenses for drugs that are already approved by US FDA or UK MHRA or other acceptable countries by DCGI can be delegated to state FDA to simplify the system.

10.2.5 Requirement for Local Presence

Japan requires tie-up with a local manufacturer or distributor for registration as also clinical trials for bio-equivalence studies (from three batches) in Japan which turns to be very expensive . For example in USA, we can submit ANDAs or DMFS with out a local establishment or a local partner. We simply need an FDA agent located in USA.

Negotiating for Waiver of Mandatory Local Presence

While negotiating with countries, India should get a concession to avoid requirements of local presence such as local manufacturer/subsidiary/company for entering the market. A local resident may be appointed as FDA agent to safeguard their concerns.

10.2.6 Government Procurement

Bidding for government tenders (e.g. USA) in many countries requires the exporting country such as India to be signatory to WTO agreement on Government Procurement.

Participation in US Government Business

The US Government business runs into billions of dollars due to availability of contract opportunities under Veterans' Administration (VA) procurement and other similar programmes. India is not a party to agreement on government procurement. Therefore, this opportunity is not readily available to us. It is, however, necessary to examine approaches which could open this opportunity for us, *albeit* indirectly.

The U.S. continues to be an attractive market for Indian firms, despite the challenges of price erosion and inability to bid for government purchases. The U.S. is in the process of negotiating or has concluded Free Trade Agreements with several countries which are Pharmaceutical producers, e.g. Thailand, Morocco, Chile etc. These agreements stipulate IPR related provisions such as data exclusivity, which have the effect of prohibiting pharmaceutical exports from other countries such as India. These stipulations by U.S. in its FTAs with different countries may be going beyond TRIPS and obviously such FTAs have implications for export of generic medicines from countries like India. To illustrate this – under the India-Chile FTA, while Chile can export pharmaceuticals at preferential terms to India, it is likely that India may not be able to export pharmaceuticals to Chile on those terms, in view of IPR stipulations in the US-Chile FTA. This needs to be addressed urgently.

India should comprehensively analyse the re-distribution effect of the RTAs in favour of member countries in pharmaceutical sector and negotiate tariff reductions on tariff lines of pharmaceutical products to neutralise the advantage accruing to the participants of the regional group.

10.2.7 Counterfeit & Spurious Drugs

There are variations in the definitions of counterfeit & spurious drugs in various regulated markets resulting in seizure and award of punitive damages against Indian Exporters. Especially in European Union the definition covers even generic versions of innovator drugs with out authorization even if they meet quality standards and also trademarks and copyrights leading to monopolistic practices. Even exports of such drugs to a country where patents are not granted to them and fully legal are liable for seizure if such products touch European ports during transit.

Products from some of the Indian SMEs were reported to have been seized in various European ports. Mention needs to be made to a recent case during a recent international trade fair Indian manufacturers were arrested and had legal action initiated against them in a major European Union country for mentioning in publicity material of the manufacturer a product patented in that country though it was mentioned in publicity material that the product is offered only in a country not having IPR restrictions. The concerned country's IPR regulation holds even such mention also as a violation.

10.2.8 Drug Regulatory Information Availability

Information availability in African countries is a major problem as many of these countries provide them in their local languages. This holds true with many European, CIS, LAC, Asean and other countries also. In the absence of websites in English language, information on drug registration, registrations granted, markets, etc. is not freely available to Indian exporters.

10.2.9 Specific Non-Tariff Barriers in Various Countries and Regions

Some of the specific restrictive factors acting as trade barriers to various countries and regions are given below;

Most of Latin American Countries (LAC) do not provide clear cut guidelines for drug registration or at least these are not available in public domain imposing avoidable hurdles on the manufacturer exporters seeking entry into these countries. For example check list of quality & efficacy tests, documents is not available in most of the Latin American Countries barring Brazil. Indian exporters in the absence of these check lists come to be aware of many requirements after submission of dossiers resulting in queries and resubmissions. To take a specific example, the specifications for drug registrations such as shelf life, stability tests, etc. are not available in public domain. Similarly, clear cut timelines or 'clock stops' for registration processes is also not available with many Latin American countries. Colombia on the other

hand has clearer guidelines and also insists on cGMP inspection of the sites. The country also does not insist on cGMP inspection and accepts valid recent inspection and approval certificates issued by a few other countries such as US FDA.

In Commonwealth of Independent States (CIS) countries, the queries raised during the registration & approval process vary from reviewer to reviewer. The standards in these countries also vary and it takes practically as long as 2 years for drug registration in these countries. The testing procedures in these countries are also long. Batch tests are performed before acceptance of documents for approval and again batch test are performed after review of submitted documents. Drug registration fees are also high in these countries. Only Ukraine has site inspections for cGMP while many other CIS countries do not insist on the same.

Many African countries insist on labelling and indications on the products in local languages. Many of the West & North African countries, numbering around 20, which are former French colonies and having substantial presence of French manufacturers, insist on indications to be printed in French language. Further many African countries do not want to promote imports of pharmaceutical products that are manufactured domestically as a measure of protection to domestic manufacturers or a measure to save foreign exchange. This restricts the trade in these products in those countries.

Centralised Regulatory Support for Export Promotion

It is very expensive to undertake drug registration at firm level and the knowledge and skills are generally not available in many firms. There is a compelling case to set up a strong regulatory affairs support cell in Pharmexcil which provides consultancy on regulatory matters in respect to various countries.. Such a cooperative effort will help institutionalization of knowledge and hasten the export registration in several countries. A central knowledge base with respect to regulatory matters in each and every country that not only keeps track of all regulations but actually undertakes registration work for Indian firms can be a substantial milestone in the evolution of pharmaceutical industry. Further, this is only way SMEs can afford to penetrate foreign countries faster. Similarly, these countries should be sensitized to accept valid GMP inspection certificates issued by other countries.

10.2.10 European Regulation of 'REACH' - an Emerging Barrier

The recent promulgation of 'REACH' regulation by EU has very deep impact on Indian exports of drug intermediates in particular and chemicals in general to Europe. The regulation not only adds to the cost of Indian manufactures making them uncompetitive but also poses several non-tariff barriers. The pharmaceutical SMEs and traders in drug intermediates may find it difficult to access European markets.

Many other countries such as USA, Canada, Australia, etc., are also undertaking exercises to introduce similar legislation.

REACH Regulation

An exercise should be undertaken with the European authorities to iron out technical barriers to Indian exports posed by 'REACH' till satisfactory solutions are reached.

India should consider introducing similar legislation in India.

Government should also actively follow similar legislation being introduced by other countries to thwart the threat posed by them.

10.2.11 Miscellaneous Barriers

Many small countries insist on attestation of all test certificates, export documents by their diplomatic missions. For example exports to Guatemala would require attestation of manufacturing license, quality certificate, etc. by their diplomatic mission. Many of these small nations do not have diplomatic mission in India posing hurdles for Indian exporters.