

## UNDERSTANDING TECHNICAL BARRIERS TO TRADE AGREEMENT

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### REVIEW ARTICLE

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#### ABSTRACT

Signing of formation of World Trade Organization has transformed trade, services and intellectual property into a mutual, predictable exchange of trade and intellectual property protection among member countries. Countries who have become members of WTO have accepted simultaneously several agreements that are multi-lateral or plurilateral. The current article is relating to one of the WTO's imbibed agreement relating to technical barriers to trade emphasizing its role on Good Regulatory Practice.

**Keywords:** WTO Agreement Series, Technical Barriers to Trade, Good Regulatory Practice (GRP)

#### INTRODUCTION

The objectives of formation and administrative structure of WTO (GATT) were discussed earlier<sup>1, 2</sup>. Currently, WTO has a total of 164 countries as members and India has become an initial member to GATT in 1948 and continued its membership even after GATT transformed to WTO in 1995. A single WTO agreement led to understanding and agreeing of about 60 multilaterals and several plurilateral. The word 'technical' means 'aspects involved or concerned to applied and industrial sciences'. Relating to pharmaceuticals technical aspects are relating to national or international legislations, guidelines, standards set for quality of products, various protocols for application, scrutiny and approval processes etc.

The fundamental concept of economics runs on two words that are 'need' and 'want' leading to manufacturing of a product, leading to trade, leading to economic growth of the individual/company as well as the country. In pharmaceuticals need and want of legislations raised due to past bitter experiences of lethality of drug products availability in the market. This led to vesting, implementation of legislations. In due course drug regulatory authority, establishment of pharmacopoeia and their role were well defined. Countries like India have pioneered in manufacture of quality

pharmaceuticals that comply not only to national but also with international levels. The current article is an understanding of how already established legislations, guidelines, protocols are fine tuning towards harmonization and to some extent uniformity.

#### Objectives of Technical Barriers to Trade (TBT) agreement:

With the prime objective of protection of human, animal or plant life or health, of the environment, the agreement is an international understanding to improve efficiency of production, facilitate international trade, develop and encourage international standards and conformity assessment systems, does not create unnecessary obstacles to international trade with respect to technical regulations and standards, no member country should not be prevented from taking measures necessary to ensure the quality of its exports with simultaneous monitoring of deceptive practices at the levels the country considers appropriate, prevent discrimination between countries, respecting countries for taking measure for protection of its essential security interest, respecting international standardization that can make transfer of technology from developed to developing countries, assisting developing countries by developed countries in achieving technical regulations. It is also indicated that purchasing or procurement by government

bodies for production or consumption by government bodies and aspects relating to sanitary and phyto-sanitary are not under the purview of the current agreement under discussion. As a whole, TBT works to establish technical regulations, standards and conformity assessment procedures with the basic principle of harmonization, transparency, non-discrimination, avoid unnecessary barriers, international standards, assisting developing countries etc. (1)

### **Key aspects of the agreement-In brief**

Agreement on Technical Barriers to Trade (TBT) is applicable to both industrial and agricultural products. The agreement consists of 15 articles and 3 annexes.

### **Non-discriminative measures:**

The agreement indicates that members should not discriminate imported like products with the domestic products and treat them as equal. Regulations are framed for quality and reliable products and prevent from deceptive practices and such regulations should not be an obstacle to international trade.

### **Establishment of international standardization bodies:**

As a part of harmonization, members should adopt in establishing international standardizing bodies. Where ever necessary members are expected to adopt international regulations which differ from the domestic and fulfil the requirements.

### **Avoidance of un-necessary trade barriers:**

It is clearly indicated that technical regulations framed are meant for quality of products and their exports, while such regulations are expected not to impart any obstacles to trade.

### **International standards:**

Keeping in view of un-necessary obstacles to international trade, member countries are expected to bring out regulations, standards, protocols where needed with the international already existing. However, where certain international standards are not suitable to local needs some flexibility is observed (especially

for geographical, climatic etc.). The agreement also recognizes developing country members should not be expected to use international standards that are not appropriate to their development, financial and trade needs.

### **Transparency**

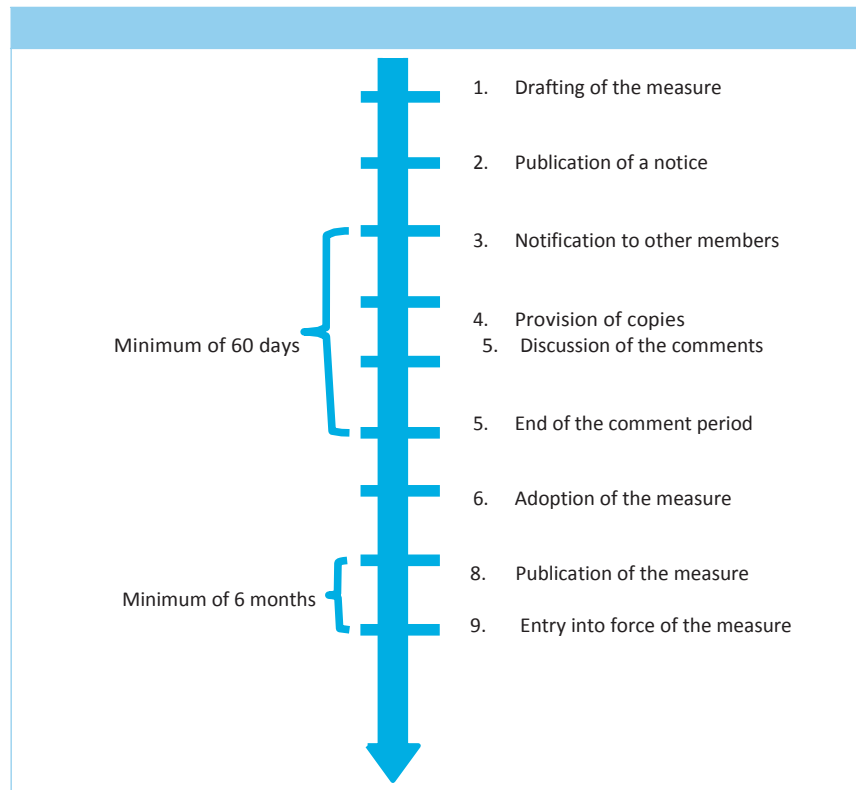
In order to establish a new regulation for a product, as a part of transparency, one among the country's central government authority (mutual understanding among the government and non-government authorities), a notification is drafted (English, French or Spanish) fulfilling harmonized system (or International Code of Standards format) and published along with objective and rationale. Upon circulation through bi-lateral or TBT committee or at enquiry points or at TBT Information Management System (TBT IMS), interested members may provide their comments and finally upon discussion, necessary changes are made leading to adoption, publication and entry into force. Figure 1, illustrates the time line, which indicates at least one year from drafting to entry into force. Within a member country, a state government authority upon circumstances, through the secretariat initiate the process and upon urgency may cut-short the time line process. The agreement also insists in practicing 'Code of Good Practice' in order to bring out regulation at the central level with mutual understanding among the central/state government / non-government standardizing bodies. (2)

### **Role of TBT Committee:**

The members of the TBT committee are the representatives of capital based trade officials and officials from national regulatory and standardizing bodies. The committee is regularly scheduled with three meetings per year and with intermittent delegate un-official meetings. In addition to these, the committee is scheduled with special meetings and workshops dealing with special issues. The prime objective of the committee is to exchange information, discuss specific trade, laws, regulations, procedures that are concerned in effecting the trade. The committee meetings helps in reviewing, strengthening of the agreement for its effective and efficient implementation. About

400 trade concern issues (from 1995, until end of 2013) were discussed with prior notifications and it has been observed that multilateral platform composing of technical experts is found to be an effective measure for reducing potential trade conflicts. The agreement clearly indicates that if a trade concern is not settled at the committee level, delegations are not precluded from using the formal WTO dispute

settlement procedures. One of the committee's latest reviews in the year 2012 is the issue of "Good Regulatory Practice" where in the TBT agreement ensures in establishing effective regulations, standards and conformity assessment procedures with simultaneous avoidance of creation of un-necessary obstacles to trade. (3)



**Figure 1: TBT Transparency Requirements**

### Objectives and Role of Good Regulatory Practice:

Expecting helpful to developing countries, Good Regulatory Practices (GRP) are developed by government and organizations to improve the quality of regulation. The agreement clearly indicates that relating to GRP, major work was done at WTO, at Asia-Pacific Economic Cooperation (APEC), at Organization for Economic Co-operation and Development (OECD), at the World Bank etc. With a goal of open-trade, Good Regulatory Practices (GRP) are developed for a consistent high-quality, cost-effective regulations. Thus, Good Regulatory Practices (GRP) helps in establishment of common, predictable framework for regulatory

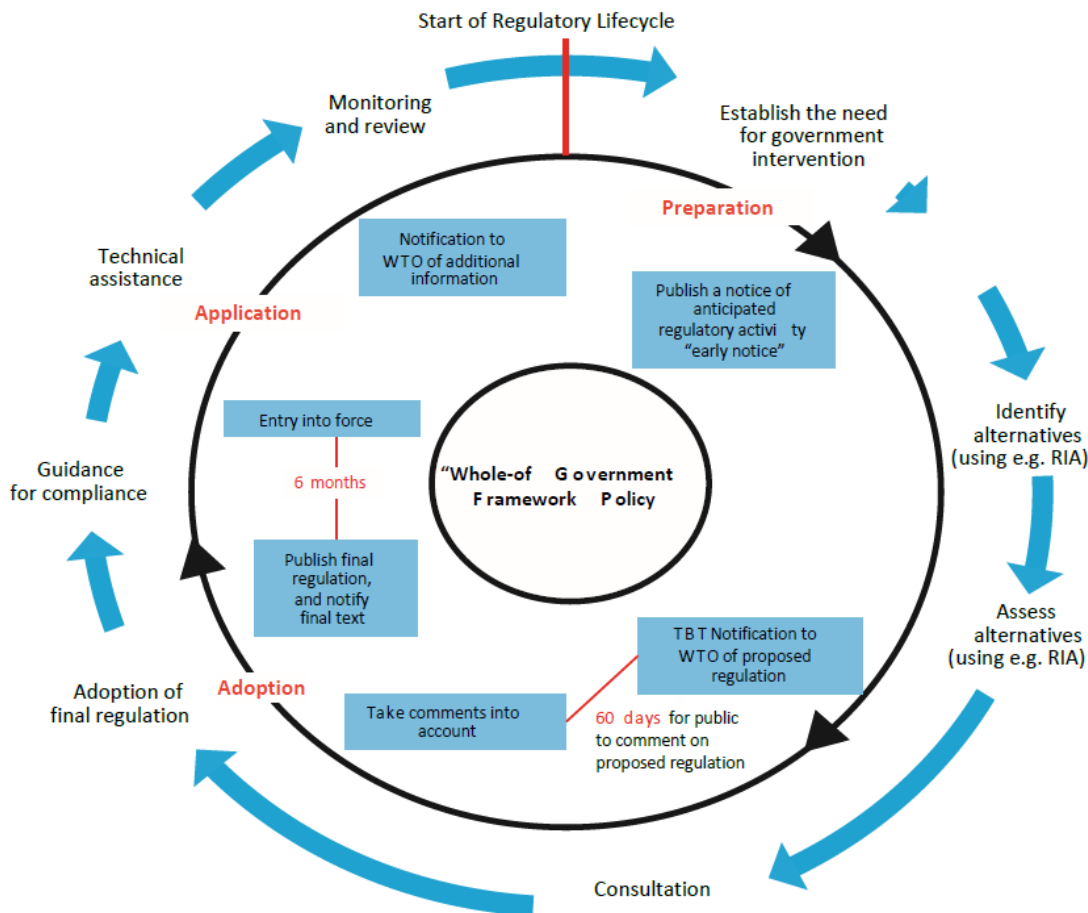
intervention which in turn facilitates global regulatory cooperation and harmonization.

One of the key TBT committee reviews in establishing Good Regulatory Practice (GRP) is on strengthening of transparency and accountability of regulatory processes (so as to achieve un-necessary trade restrictive regulatory outcomes), design of simple, responsive and flexible regulations. Figure 2, illustrates a self-explanatory regulatory life-cycle as a Good Regulatory Practice (GRP) in fulfilling the fundamentals of transparency and consultations. The core inner circle anchors the central importance of 'whole-of-government' approach to Good Regulatory Practice, at the next level, the procedural obligations contained in the TBT

agreement (boxes) that lead to transparency and coordination. Finally, the outer circle comprises elements of GRP across the regulatory lifecycle, starting with an analysis of the need to regulate, an assessment of alternatives (including through

regulatory impact assessment, RIA), publication, implementation and enforcement, and review.

### Applying Good Regulatory Practices to the Life-cycle of a TBT measure:



**Figure 2:** Applying good regulatory practice to the lifecycle of a TBT measure: an illustration

## CONCLUSION

Good Regulatory Practice (GRP) of the TBT agreement is expected to bring out a balance by reducing un-necessary regulatory diversity across countries and by limiting (or reducing) the costs associated with necessary regulatory diversity. The agreement is expected to reduce barriers to trade associated with negative economic impacts. TBT agreement can be considered as a balance mechanism relating to trade and regulatory practices. Once a measure has entered into force, it is difficult to make changes to the commitments made. Negotiations and dispute mechanism are regularly in force to resolve issues. Technical Barriers to Trade (TBT) agreement is expected

to prevent unnecessary ban of products (for a genuine product) for a risk free cause and insists on the necessity of infrastructure. World Trade Organization Secretariat plays a key role in resolving the communication gap by regularly organizing regional, sub-regional, national seminars and workshops so as to make the countries fulfill the obligations at the earliest. Gazette notification procedures are well established in India.

## ACKNOWLEDGEMENT

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## CONFLICTS OF INTEREST

The authors declare that there are no conflicts of interest.

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