

HARMONIZATION & ADVANCEMENT IN PHARMACEUTICAL INDUSTRY

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REVIEW ARTICLE

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ABSTRACT:

The urgent requirement to rationalize and harmonize regulation was impelled by instance of rising cost of Health care, Research and Development and need to meet the public requirement to approach for the safe and efficacious treatments to patient in need. ICH committee has given priority to harmonize the format of reporting data for quality, safety and Efficacy in the application dossier.

ICH also provides different Guidelines under the topic Quality, Safety, Efficacy and Multidisciplinary to control the quality safety and efficacy of Pharmaceutical and Biotechnological products.

For the dossier application part CTD provides harmonized format for product application. Earlier all the submissions sent to regulatory authorities in CTD, Paper format but it was a tedious job requiring lot of Time to review ,documentation and paper work.

Due to the advancement in Information technology, regulatory authorities from regulated countries throughout the globe started to accept data in electronic format either in eCTD (Electronic common technical document)/ NeeS (Non eCTD electronic submission).

The eCTD was developed subsequently by the ICH M2 Expert working group and allows for the electronic submission of the CTD from the applicant to regulator and provides harmonized technical solution for CTD electronically. Many regulatory authorities completely eliminated the Paper submission and made eCTD mandatory.

This is the centralized approach, saves time, cost, facilitate review process and greater transparency can be achieved via central processing of submissions.

Harmonization can also be seen in IPR stream by treaties and conventions. These international treaties and conventions contribute to the process of harmonization of patent laws.

Key words: ICH, CTD, eCTD, NeeS, Multidisciplinary, WTO, IND, NDA, ANDA, BLA, DCP, CP, MRP, ACTD, PLT.

Introduction:

Regulatory Affairs as profession is broader than registration of products, they advise companies both strategically and technically at the highest level. Their role begins right from development of a product to making, marketing and post marketing.

There is harmonisation of the common technical format and its content for product registration for every region in the world but apart from this there are few things that also need overall global harmonisation. Such as fees structure, approval timings, regulatory systems (US, EU, Japan, Asian countries (ACTD), Rest of the World (Row), different terminologies used for

same types of applications (e.g. IND / IMPD, or ANDA / ANDS).

For getting a product registered across the globe, an applicant has to go through various cumbersome filing and submission process along with country-specific requirements, form fee, agents fees, different formats, legal documentation etc which is really time consuming, costly and tedious. US & Europe follows different regulatory submission process like US follows IND / NDA / ANDA / BLA etc. whereas Europe follows national procedure, DCP, CP, MRP etc.

Similarly South Africa follows MRF-1/2 process whereas south East Asian countries (Group of 10 countries) follows ACTD format

along with their country-specific system and fees.

Gulf countries (6 countries) like UAE, follows their own MoH system whereas 'RoW=Rest of the World' have their own registration guidelines & process for registration.

Common Technical Document

CTD has been accepted by three agencies namely Japan, Europe and US. CTD being a common format for the technical documentation is projected to save time and which eases the application review process and aids communication amongst the regulatory authority and the applicant. It also simplifies the exchange of regulatory data among regulatory agencies. CTD has been obligatory requirement in US, Europe and Japan. [1]

They help companies save a lot of time and money in developing the product and marketing the same.

Electronic Submission:

The Registration documents that needs to be filed with the regulatory agencies is in a format called CTD (Common Technical Document) & more so now as an electronic version that is called e-CTD. The content of the CTD/e-CTD is the same.[4]

Electronic submissions are a more robust and "valuable" entity for understanding the products regulatory history and using it for information retrieval because of hyper-text linking, searching, access and life-cycle.

Due to the advancement in Information technology, regulatory authorities from regulated countries throughout the globe started to accept data in electronic format either in eCTD (Electronic common technical document)/ NeeS (Non eCTD electronic submission).[3]

eCTD is a software programmed based submission which is easier, faster & convenient. Most of the agencies have made this format of submission compulsory now.

Advantage of eCTD:

- This type of submission saves Paper & therefore environment friendly.

- Tools needed to create & view submissions have matured and provide robust functionality
- Common format for US & EU provide for relatively simple changes to create submissions for both.
- Life-cycle provides complete submission history and provides easy knowledge transfer for product.
- Companies have already invested in training and a tool for electronic submissions—adding additional countries is easier.
- Expertise has been developed within companies and they are comfortable with electronic submissions.
- Standardized processes for creation of electronic submissions will allow for easier outsourcing of these activities and further reduce cost.
- Delivery via gateways will speed up delivery and reduces costs.
- Centralized creation provides greater transparency to national submissions.
- This is the centralized approach, saves time, cost, facilitate review process & greater transparency can be achieved via central processing of submissions.[2]

Regulatory profession has been largely driven by:

- Expanding scope and global expand of industry
- Need for global regulatory compliance
- Complexity of disease targets areas for development
- Need for innovative, Research & Development, & electronic submission process.
- Need for robust global regulatory strategies

Role of Global Regulatory Affairs

- IND/Clinical Trial Applications, NDA, ANDA, MAA.
- Regulatory strategy compatible with Drug developments & registration plans.
- Interactions with regulatory authorities throughout development and registration phases.
- Planning and preparation for regulatory meetings
- Coordination, review and electronic publishing of all regulatory review process.

- Post-marketing commitments and promotional/advertising regulations
- Management of the Life Cycle Optimization.
- Technology transfer & adhering to rules & regulation for updates.

Harmonisation in countries :

In regulated countries like US, EU, Japan, Australia, New Zealand & Canada etc., CTD/eCTD causes certain level of Harmonisation for submission of new or Generic application for marketing of Drug Product/API.

Currently, the registration documentation can be either

- EU-CTD (EU Region)
- CTD (US)
- Regional format (RoW countries)

However, some harmonisation occurs in some clusters e.g. ASEAN, Gulf countries.

CTD format is not accepted in all RoW countries but must be reformatted after translation. Format not officially decided, but will resemble the old EU submission in Parts.

Some countries like India, Russia, Ukraine, South Africa uses the format which is almost the same as EU-CTD format. Which also seems to become harmonised in regards of formats to be submitted there.

Intellectual Property Rights and Public Health

In recent years, there has been a rapid increase globally in technological and economic potential, implying an enhanced ability to overcome problems related to poverty and poor health. The advances in biotechnology, underpinned and enabled by the parallel revolution in digital information technologies and the Internet, have opened up enormous opportunities to promote human health.

The Patent Law Treaty (“PLT”) is a multilateral treaty on patent law, which was concluded on June 1, 2000, in Geneva, Switzerland. The PLT came into being to harmonise certain patent application procedures in order to eliminate formalities and the potential for loss of rights. The aim of PLT is to harmonise formal patent

filing procedures such as the requirements to obtain a filing date for a patent application, the form and content of a patent application.

The PLT is the result of many years of negotiations on harmonizing global patent systems.

World Trade Organization (“the WTO”) was created in 1995 as a global body to promote liberalization of trade in goods and services. Under the WTO, the global application of minimum standards for intellectual property under the Agreement on Trade-Related Aspects of Intellectual Property Rights (“the TRIPS Agreement”) has been accepted in regard to its potential impact on public health.

International bodies such as WIPO (World Intellectual Property Organization) and WTO (World Trade Organization) are trying to create a patent system that assures patent protections all over the world.

The WIPO simplifies and reduces the cost of making individual applications or filings in all the countries where a patent protection is sought through such treaties. By providing a stable environment for the marketing of intellectual property products,

WIPO drafted The Patent Cooperation Treaty (PCT), which was established in 1978. PCT introduced “a single centralized filing system,” which allows an inventor to file a single application at the Patent Office of any member nation for patent protection in the signatory nations. Forty countries that account for over 90% of the total number of world filings are signatories [5]

Thus the above said bodies make the countries to participate for harmonization requirements for IPR.

Conclusion:

Due to the advancement in Information technology, regulatory authorities from regulated countries throughout the globe started to accept data in electronic format either in eCTD (Electronic common technical document)/ NeeS (Non eCTD electronic submission).

The international protection of IPR assumes far greater importance today because of the huge

amount of cross-border business. As such, the role of organizations, such as the World Intellectual Property Organization, becomes very important in order to seek harmony amongst national laws. The international treaties have formulated rules in relation to areas such as international filing, disclosure, and compulsory licensing. These treaties and conventions contribute to the process of harmonization of patent laws.

The urgent requirement to rationalize & harmonize regulation was impelled by instance of rising cost of Health care, R & D & need to meet the public requirement to approach for the safe & efficacious treatments to patient in need. ICH committee has given priority to harmonize the format of reporting data for quality, safety & Efficacy in the application dossier.

Advancement in terms of quality of Pharmaceutical products can be achieved through Quality management system that confirms to international quality standards like FDA, MHRA, WHO GMP & in terms of technology can be achieved improving local R & D capabilities & ICH Q 11- QbD (Quality by design).

Hence, experts from all regions should go with harmonization of regulatory requirements throughout the globe & produce a single harmonized marketing application for registration of drug product/API that will be used by all health authorities worldwide.

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