International Journal of Research in Pharmacy and Pharmaceutical Sciences
ISSN: 2455-698X
Impact Factor: RJIF 5.22
www.pharmacyjournal.in
Volume 3; Issue 1; January 2018; Page No. 56-58

Overview of regulation of mutual recognition process as per United States and Europe

[*1] Dhara B Bhatt, [2] Pooja D Patel, [3] Dr. Dilip G Maheshwari
[1] Student, Quality Assurance and Pharm Regulatory Affairs, L.J. Institute of Pharmacy, Ahmedabad, Gujarat, India
[2] Assistant Professor, Quality Assurance and Pharm Regulatory Affairs, L.J. Institute of Pharmacy, Ahmedabad, Gujarat, India
[3] Head of the Dept., Quality Assurance and Pharm Regulatory Affairs, L.J. Institute of Pharmacy, Ahmedabad, Gujarat, India

Abstract
The Mutual Recognition is an effective way to ensure equivalency of "Good Manufacturing Practice" compliance Programme between different courtiers. The recognition process pre suppose the joint exercises to determine high standards of product safety and quality in order to increase communication between regulatory systems. This provision is applicable for all medicinal products manufactured in with GMP compliance, imported and exported to any regulatory authorized country. This paper high lights the regulatory requirements of United States and Europe for mutual recognition of medicinal products to establish working collaborative and strategical working to help ensure that patients have access to safe, effective and high-quality and more affordable medicines by minimizing duplication of inspection with better compliance activity.

Keywords: mutual recognition, agreement, regulation, GMP, medicine

Introduction [1, 2]

Brief overview of Marketing Authorization

An official document issued by the competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality which includes the name of the product, the pharmaceutical dosage form, the quantitative formula (including excipients) per unit dose (using INNs or national generic names where they exist), the shelf-life and storage conditions, and packaging characteristics. This process is performed with a legislative framework which defines the requirements necessary for application to the concerned regulatory authority and assessment procedure is based on quality, Safety, Efficacy criteria and grounds the approval or rejection of application.

Types of marketing authorization Procedure

There are four ways in which a medicinal product can obtain marketing authorization Procedure:

- Centralized procedure
- National procedure
- Decentralized procedure
- Mutual recognition procedure

The centralized procedure

The centralized procedure, which is set out in Regulation (EC) 726/2004, allows applicants to obtain wide marketing authorization that is binding on all Member States. Applications are made directly to the European Medicines Agency and are scientifically evaluated by the appropriate EMA is the Committee for Medicines for Human Use. It is compulsory for medicines such as those developed by biotechnological processes.

The National procedure

It can be used if applicant wants to marketing authorization to market a product in individual Europe member state.
There are many reasons where applicant can go for national procedure:

If Applicant wants to,

- Launch in one market only (Smaller/Local Company)
- Sort out continuous issue that might come up during assessment.
- Promote an overseas site inspection. (e.g.: GMP inspection of manufacturing site)

The decentralized procedure

It was introduced with newly revised Europe pharmaceutical directive 2004/27/EC in November 2005.This procedure is applicable in cases where marketing authorization does not still exist in other member state of Europe at the time of application. It is similar to mutual recognition procedure and relies on the recognition by national authorities of a first assessment performed in one member state. Identical dossiers are submitted in all member state where a marketing authorization is wanted.

The mutual recognition procedure [3]

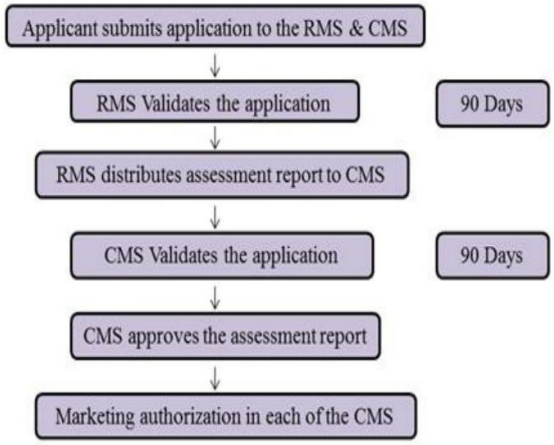
Mutual recognition is the principle of European Union law under which member states must allow goods which are legally sold in another member state also to be sold in their own territory. The procedure is followed by mutual recognition agreement by which two or more countries agree to recognize one another's conformity assessments. The traditional approach to product legislation in the Europe,

known as the Old Approach, was simply to write detailed regulations containing all the necessary technical and administrative requirements for each type of product. This reflected the existing national approach to product legislation. This approach is for foodstuff, Biocides, motor vehicles, chemicals, cosmetics, detergent and pharmaceutical products.
The Convention for the Mutual Recognition of Inspections for the Manufacture of Pharmaceutical Products was founded in 1995 and which was founded in October 1970 by EFTA (European Free Trade Association) to improve the operation of the Mutual Recognition Procedure and the work in the SmPC harmonization field.

Mutual Recognition Process [4]

The procedure is applicable when applicant has already received marketing authorization in any member state at the time of application for the intended medicinal product and applying for more than one member state. One member state is consider as "Reference member state" and they will decide to evaluate medicinal product at that time other member state which are known as "Concerned member state" suspend their own evaluation and wait for reference member state's decision on the medicinal product. If RMS's decision is favorable, then a report is communicated to CMS, who recognize the RMS's decision. In this process national licenses are issued through CMS and approved by RMS to establish mutually recognized in other countries for the determination of evaluation criteria are sufficiently harmonized with same standard.

Flow chart of Mutual Recognition Procedure



Regulations as per United States [5, 7]

The International Partnership Agreements for Compliance Activities establishes Policy regarding USFDA, Foreign Government Agencies, Domestic Trade Associations and Other Organizations.
To represents the agency's current thinking on establishing its partnership agreements which satisfies the requirements of applicable status and regulation. The committee will monitor the implementation of the Good Manufacturing Practice through mutual recognition agreement to determine technical and administrative arrangements for effective implementation.

It impacts the following principal areas

- ✓ Exchange of information between the FDA and other regulatory authorities.
- ✓ Trade of medicinal products and their constituent ingredients between the regions.
- ✓ GMP inspections.

The regulations that most directly affect Mutual Recognition are contained

- ➢ 21 U.S.C. §301-The Federal Food, Drug, and Cosmetic Act (2002) and The Food Quality Protection Act: Public Law (1996)
- ➢ 21 U.S. Code § 351 - Adulterated drugs
- ➢ 21 U.S Code § 355-New drugs- approval of Human Drug
- ➢ 21 U.S Code § 360-New drugs- approval of Animal Drug
- ➢ 21 U.S.C. 374 Inspection authority
- ➢ 21 U.S.C. 384 Recognition of foreign government inspections
- ➢ 42 U.S.C. 262. Regulation of Biologic Products
- ➢ 21 CFR Part 210 Current Good Manufacturing Practice in Manufacturing, Processing, Packing or Holding Drugs
- ➢ 21 CFR Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals
- ➢ 21 CFR Part 600 Subpart B (Establishment Standards) Subpart C (Establishment Inspection)

Regulations as per Europe [6, 7]

Mutual Recognition Agreements is an international regulatory co-operation (IRC) identified by the Organization of Economic co-operation Development (OECD). The aim of this Regulation is to strengthen the functioning of the internal market by improving the free movement of goods which includes specific conditions relates to the protection of public safety, health, or the environment.

For any country that need Mutual Recognition of its product in European Country has to fulfill following regulation

- ➢ **Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use**.
  - ❖ In the European Union a medicinal product needs a marketing authorization to be placed on the market. This application is subjected to Committee for Medicinal Products for Human Use (CHMP) So, this guideline are based on good manufacturing practice for investigational medicinal products for human use and arrangements of inspection which addresses specific issue and provide flexibility of any changes as knowledge to determine stages of development of products in order to promote harmonization of authorizations for medicinal products to enhance summary of product characteristics.

Classifications of Medicinal Products subjected to mutual recognition process

- ✓ A medicinal product subject to medical prescription.
- ✓ A medicinal product not subject to medical prescription.

- ✓ Medicinal products on medical prescription for renewable or non- renewable delivery.
- ✓ Medicinal products subject to special medical prescription.
- ✓ Medicinal products on restricted' medical prescription, reserved for use in certain specialized areas.

Other Regulations that most directly affect Mutual Recognition for Europe

- Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.
- Directive 2001/20/EC of European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
- Regulation (EU) 536/2014 of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
- Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use
- Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products
- Commission delegated Regulation (EU) 1252/2014 of 28 May 2014 of the European Parliament and of the Council with regard to principles and guidelines of good manufacturing practice for active substances for medicinal products for human use
- Current version of the Guide to good manufacturing practices contained in volume IV of Rules governing medicinal products in the European Union and compilation of the community procedures on inspections and exchange of information.

Conclusion

In this study, Mutual Recognition promotes trade between different countries and thus facilitates market access. The studied particulars of the regulatory bodies of the United States and Europe come out with rigorous regulations for the recognition of pharmaceuticals products in their country. Thus this article furnishes with information required to have faster access to new drugs already approved in one country with facts of potential risk-benefit associated with patients, in context of GMP compliance and other quality standards. More over this article brief that, both countries addresses regulatory compliance with greater sustainability and capability of achieving world class product quality standards by generating single inspection environment.

Acknowledgement

The authors are thankful to Dr. K. Pundarikakshudu, Director of L. J. Institute of Pharmacy; Ahmedabad, India for providing all the facilities and encouragement to carry out the work and also thankful to Dr. Dilip Maheshwari, Head of Department of "Quality Assurance & Pharm Regulatory Affairs" for providing support and knowledge.

References

1. Jawahar N, Nishit Shrivastava, Ramachandran, Baviya Priyadharshini. Procedures and Applications for Marketing Authorisation of Medicinal Products in European Union. J. Pharm Sci, India. 2015; 7(4):219-225.
2. Santosh Kumar Narla. Marketing Authorization of human medicinal products to European Union/European Economic Area, Formulation Regulatory Affairs, 2011; 10(1):1-9.
3. Pharmaceutical Inspection Scheme, 2011. https://picscheme.org/en/historyfile:///C:/Users/Compaq/Downloads/pics_01_95_rev_5_pic_scheme%20(2).pdf
4. Brussels. Procedures for marketing authorisation Chapter 2 Mutual Recognition, 2008; 2A(5):8-9. https://ec.europa.eu/health/sites/health/files/files/eudralex/vol2/vol2a_chap1_rev6_201612.pdf
5. 21 U.S.C. 355(d)(3); 21 U.S.C. 355(j)(4)(A) approval of human drug, http://uscode.house.gov/view.xhtml?req=(title:21%20section:355%20edition:prelim)
6. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://ec.europa.eu/health//sites/health/files/files/eudralex/vol1/dir_2001_83_cons2009/2001_83_cons2009_en.pdf
7. Commission Decision on determining the Union position for a Decision of Joint Committee set up under Article 14 of the agreement on Mutual Recognition between the European Union and United States of America in order to amend the sectorial annex on Pharmaceutical Good Manufacturing Practice. http://trade.ec.europa.eu/doclib/docs/2017/february/tradoc_155398.pdf