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Research Article

Comparative study of medicinal products registration in USA and Europe

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ABSTRACT

A pharmaceutical drug regulatory Affairs is mainly involved in registration process parameters of different pharmaceutical products and new drug application. Regulatory affairs professionals play vital roles in a pharmaceutical field as; it is related to healthcare products. The present article mainly focuses to provide similarities and differences in the registration of medicinal products in USA and European countries. This also provide details to protect public health in terms of safety, quality, and efficacy of products like medical devices, pharmaceuticals, veterinary medicines, pesticides, cosmetics & complementary medicines, agrochemicals, etc.

Keywords: USFDA, Regulatory Affairs, Pharmaceuticals

INTRODUCTION

Regulatory affairs is a profession developed from the desire of governments to protect public health by controlling the safety and efficacy of products in areas including pharmaceuticals, veterinary medicines, medical devices, pesticides, agrochemicals, cosmetics and complementary medicines, and by the companies responsible for the discovery, testing, manufacture and marketing of these products wanting to ensure that they supply products that are safe and make a worthwhile contribution to public health and welfare. The regulatory affairs (RA) department of a pharmaceutical company is responsible for obtaining approval for new pharmaceutical products and ensuring that approval is maintained for as long as the company wants to keep the product on the market. It serves as the interface between the regulatory authority and the project team, and is the channel of communication with the regulatory authority as the project proceeds, aiming to ensure that the project plan correctly anticipates what the regulatory authority will require before approving the product. It is the responsibility of RA to keep abreast of current legislation, guidelines and other regulatory intelligence. Such rules and guidelines often allow some flexibility, and the regulatory authorities expect companies to take responsibility for deciding how they should be interpreted. The RA department plays an important role in giving advice to the project team on how best to interpret the rules. During the development process sound working relations with authorities are essential, e.g. to discuss such issues as divergence from guidelines, the clinical study programme, and formulation development. The present article mainly focuses to provide similarities and differences in the registration of medicinal products in USA and European countries.

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Regulatory guidelines for registration of medicinal products in United States of America:

USA is the major market for the pharmaceutical industry. The food and drug administration (FDA) within the U.S. Department of Health and Human Services regulates the drug approval system in United States with help of six product centers including Center for Drug Evaluation and Research (CDER).

TYPES OF APPLICATIONS
Investigational New Drug Application (IND)
New Drug Application (NDA)
Abbreviated new drug Applications (ANDA)
Biologic License Application (BLA)

Laws, Regulations, Policies and Procedures:
The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer's health, safety, and pocketbook

A) Code of Federal Regulations (CFR): It is the final regulations published in the Federal Register (daily published record of proposed rules, final rules, meeting notices, etc.) is collected in the CFR. The following regulations apply to the NDA process:

- 21 CFR part 314 applications for FDA approval to market a new drug or antibiotics drug.

B) MAPPs: CDER's manual of policies and procedures (MAPPs) provide official instructions for internal practices and procedures followed by CDER staff to help standardize the new drug review process and other activities, both internal and external.

NDA Forms and Electronic Submission:

- Form FDA-356h: Application to Market a New Drug, Biologic, or an Antibiotic Drug For Human Use.
- Form FDA-3397: User Fee Cover Sheet
- Form FDA-3331: New Drug Application Field Report
- Guidance document for electronic submission.
- For more information on electronic submissions, follow Electronic Regulatory submission and review(ERSR).

Proper Instructions must be followed for filling out form fda 356h application to market a new (or)abbreviated new drug or biologic for human use

Filing of CTD Application:
New Drug Applications (NDAs), Abbreviated NDAs (ANDAs), and Biologics License Applications (BLAs), must be submitted using eCTD format.

CTD (Common Technical Document)
The CTD is an internationally agreed format for the preparation of applications regarding new drugs intended to be submitted to regional regulatory authorities in participating countries.
The Paper CTD is destined to be replaced by its electronic counterpart, the eCTD.

The CTD is comprised of the following modules:
• Module 1: Administrative information.
• Module 2: CTD Summaries.
• Module 3: Quality.
• Module 4: Nonclinical study reports; and
• Module 5: Clinical Study

Regulatory Guidelines for Registration of Medicinal Products in Europe:
The EU has one of the most highly regarded regulatory systems in the world. The system comprises of European parliament, the council of ministers, and the European Commission. The following requirements to be submitted for the regulatory bodies for granting market authorization. For the European country the application for the Abbreviated new drug product is submitted to marketing authorization application agency (MAA).

Legal basis for applications in Europe: The eligibility and the requirements are set in the commission regulation (EC) No 726/2004 and defined in articles 8 and 10 are of the Directive 2001/83/EC.

Types of Submission Procedures:
Pharmaceutical companies of EU are use three approval procedures to market their pharmaceuticals
1) A centralized procedure
2) National procedure
3) A decentralized procedure
4) Mutual recognition procedure

Centralized procedure: In the European Union (EU), a company may submit a single application to the European Medicines Agency (EMA) for a marketing authorisation (licence) that is valid simultaneously in all EU Member States, plus Iceland, Liechtenstein and Norway. This is called the centralised (or community) authorization.

National procedure: Each EU Member State has its own procedures for the authorization of medicines that fall outside the scope of the centralized procedure. Applicants must submit an application to the competent authority of the Member State. In the UK, this is the MHRA.

Decentralized procedure: Using the decentralized procedure, companies may apply for simultaneous authorization in more than one EU country of products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

Outline of Decentralised Procedure

The Decentralised Procedure is divided in five steps:

- Pre-procedural step, including validation phase
- Assessment step I
- Assessment step II
- Discussion at the CMDh, if needed
- National step

Mutual recognition procedure: In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, further marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

Changes to an Approved NDA Reporting Categories

Section 506A of the Act and § 314.70 provide for four reporting categories that are distinguished in the following paragraphs.

1) Major change: A major change is a change that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product as these factors may relate to the safety or effectiveness of the drug product.

2) Moderate change:A moderate change is a change that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

3) Minor changes: A minor change is a change that has minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product.

Table 1: Comparative requirements between USA and EU

Requirements	**USA**	**EU**
Agency	USFDA	EMEA CHMP National Health Agencies
Application	ANDA/NDA	MAA
Registration process	One registration process	Multiple: Centralised (European community) Decentralized (Atleast 2 member states) Mutual recognition (Atleast 2 member states) National (1 member state)
Debarment classification	Required	Not Required
Number of copies	3	1
Approval time line	18months	12months
Presentation	eCTD and Paper	eCTD
Post-approval changes	Post-approval changes in the approved drug: Minor changes Moderate changes Major changes	Post-Variation changes in the approved drug: Type lA variation Type lB variation Type ll variation

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