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A Review on Drug Approval Process for USA, Europe and India

Sahil Sanjay Varpe

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ABSTRACT: It takes a lot of research in chemistry, manufacturing, controls, preclinical science, and clinical trials to develop a new drug. Before a drug product is authorized for importation or the production of a new drug, it must be safe and effective for use in humans. Each nation has its own regulatory body that is in charge of issuing guidelines to control the marketing of pharmaceuticals and enforcing laws and regulations. The FDA is the regulatory body in charge of approving drugs in the US. The European Medicines Agency (EMA) is the primary regulatory body in charge of medicine approval in Europe. The CDSCO is the regulatory body in charge of approving drugs in India. The drug approval procedures in the USA, Europe, and India are the main topic of this article.

Keywords: USFDA, EMA, CDSCO, MAA, NDA

I. INTRODUCTION:

At the moment, different nations must adhere to various regulatory standards in order for new drugs to be approved. By regulating a product's safety and effectiveness, the regulatory affairs department serves as a liaison between government organizations and pharmaceutical corporations, protecting the public's health. It actively participates in every phase of a new product's development, from discovery to post-marketing initiatives. As a result, understanding the legal requirements for MAA in each nation is essential. This essay therefore highlights the regulatory strategies employed by the US, EU, and India**[1,2,3]**.

Figure: 1: Regulations of Drug Approval Process

1) USA-

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Application-

1) Investigational New Drug Application
2) New Drug Application

These above two application was submitted to USFDA for review and evaluation.

1) Investigational New Drug Application-

This application was submitted to the FDA in order to obtain approval for using human subjects in product testing. The IND application must be submitted to the FDA by the sponsor, organization, or business. The IND phase is a clinical stage during which safety and effectiveness information regarding the possible medication compound is acquired to determine whether or not it is suitable for human usage**[5,6]**.

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Content-

1. Cover Letter
2. Table of contents
3. Form FDA 1571
4. Form FDA 1572
5. Letter of authorization
6. Clinical Protocol
7. Investigational brochure
8. Informed Consent
9. Statement about product development
10. Additional information

Types-

1. Investigational IND
2. Emergency IND
3. Treatment IND

2) New Drug Application-

The producer submits a New Drug Application if clinical research demonstrates that a novel medication is generally safe, effective, and won't put patients at unjustified risk. This application asks the FDA to authorize and permit the drug's production and sale in the United States. The FDA reviews the application within 60 days**[7]**.

Content-

1. Index
2. Administrative documents
3. Summary of NDA
4. CMC information
5. Non-clinical data
6. Clinical data
7. Stability data
8. Labelling and Packaging
9. Safety update report

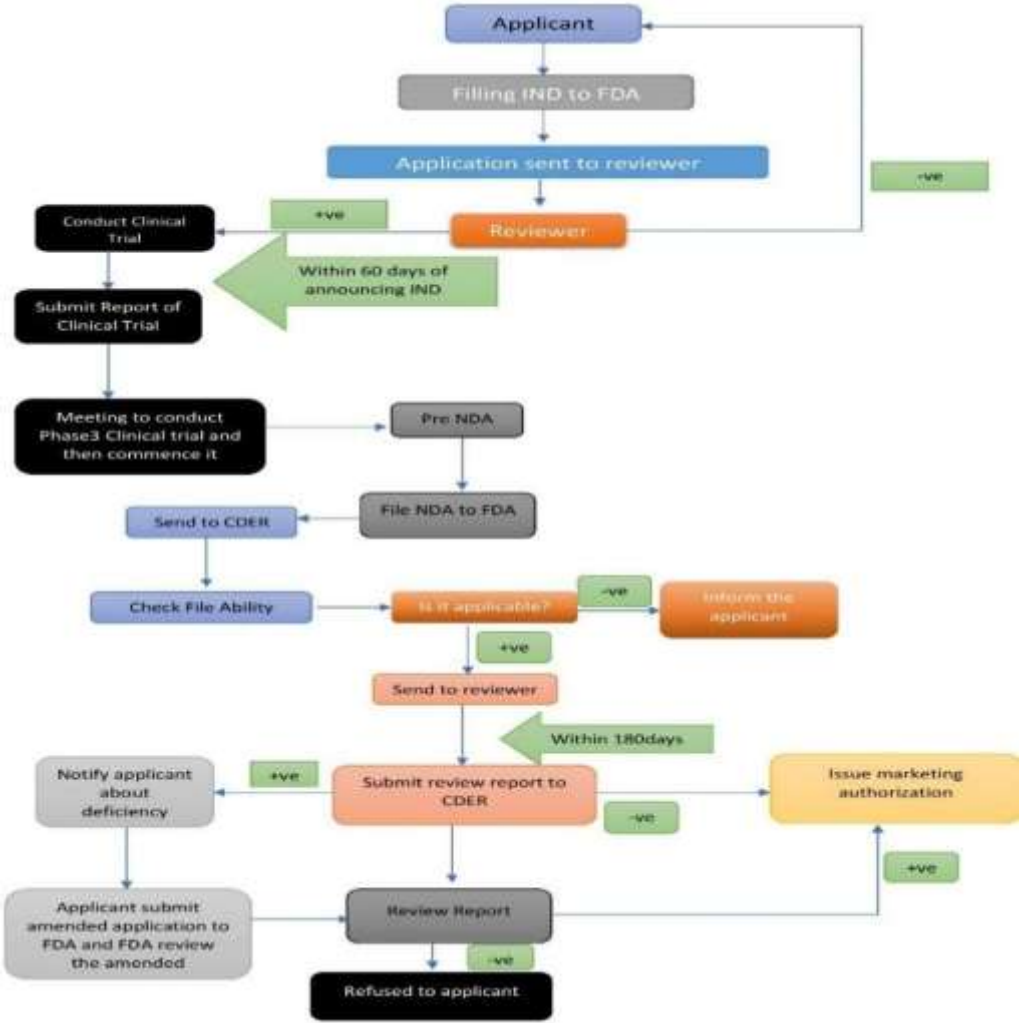

Figure-2: Drug Approval Process In USA

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2) Europe-

The main body in charge of approving new drugs in Europe is the European Medicines Agency (EMA). The European Union is made up of 28 member nations. EMA assesses and tracks medication use in the EU. participate significantly in the certification ceremony and approval process as well. Pharmaceutical businesses must apply for marketing permission from EMA in order to gain market access. The EMA offers marketing authorization in four different ways**[8,9]**.

a) Centralized Procedure
b) Nationalized Procedure
c) Decentralized Procedure
d) Mutual Recognition Procedure

a) Centralized Procedure-

This is a legitimate way to obtain EMA marketing permission. The applicant can obtain EMA approval to market the product in the EU with a single application. This procedure is crucial to expediting the regulatory approval procedure. For some medications, such as genetically modified pharmaceuticals, orphan drugs, and medications for HIV, cancer, diabetes, etc., a centralized process is required**[10]**.

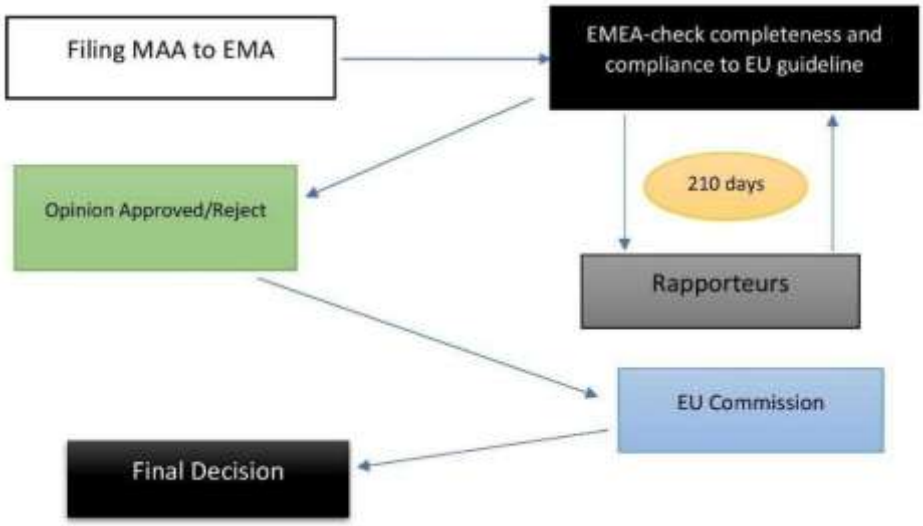

Figure- 3: Centralized Procedure

b) Nationalized Procedure-

Every nation in Europe has its own regulatory body. A national procedure is a series of laws that have been passed by each nation separately. As a result, candidates can only be granted a marketing license in one member state. An application must be made to the Member State's appropriate authority in order to receive a national marketing license**[11,12]**.

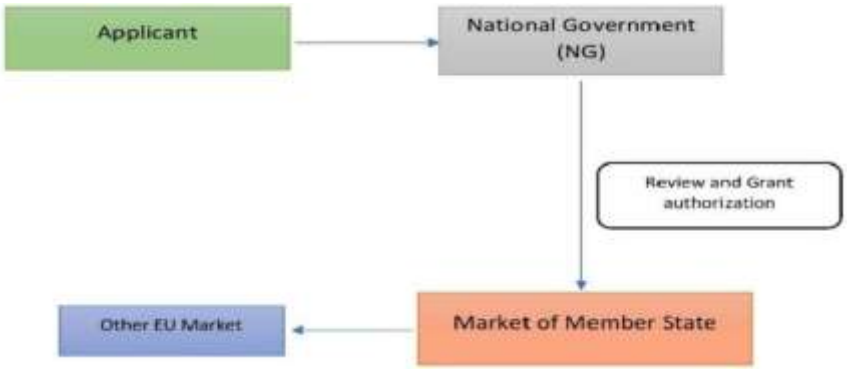

Figure- 4: Nationalized Procedure

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c) Decentralized Procedure-

Through this process, a corporation can concurrently request for authorization in multiple EU nations for products that have not yet received EU approval. It is regarded as a very effective strategy. In order to ensure a consistent judgment among participating nations, the Reference Member State (RMS) and Concerned Member State (CMS) work together to award marketing authorization based on the assessment report and comments**[11,12]**.

Figure- 5: Decentralized Procedure

d) Mutual Recognition Procedure-

There is no need for duplicate registrations when a product is approved in one nation and instantly recognized and accepted in another. Pharmaceutical businesses' administrative load and expenses are decreased by this procedure**[13]**.

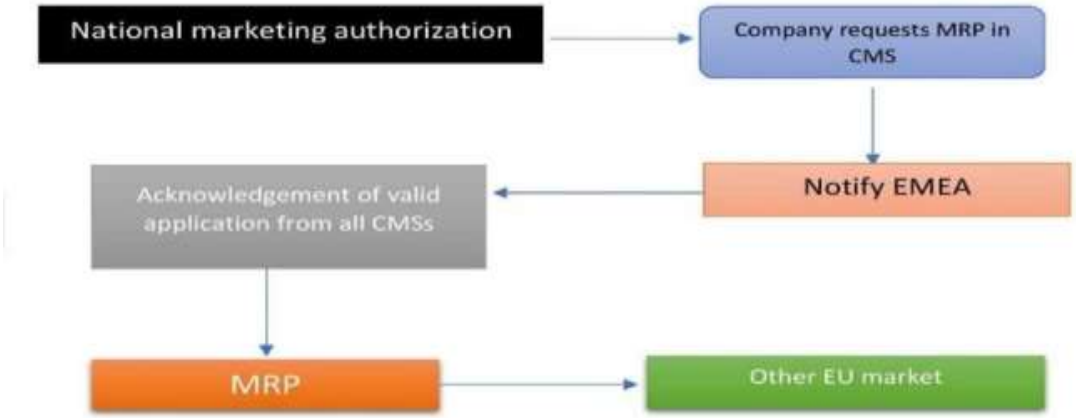

Figure- 6: Mutual Recognition Procedure

3) India-

The Drug Controller General of India (DCGI), India's licensing organization, authorizes and permits the production and sale of new pharmaceutical products in the country. A government organization called the Central Drug Standard Control Organization (CDSCO) assesses the safety and effectiveness of the proposed new drug product and provides DCGI with the review report. In order to get authorization from the

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licensing authority (DCGI) to produce or import a new pharmaceutical product, a company in India must fill out Form 44 and provide the data specified in Schedule Y**[14,15,16,17]**.

The new drug approval process is divided into two phases:

A. Phase I-

1. Application for Investigational New drug is submitted along with CMC data and pre-clinical data to the CDSCO.
2. One copy of IND submitted ethical committee.
3. The examination and evaluation of new drug is done by CDSCO.
4. The notified committee is review and reports submitted to DGCI.
5. Ethical committee also submit their report to DGCI.
6. DGCI review both reports and take decision in accordance to IND.
7. INDA approved by DGCI and give permission for conduct clinical trials study.

B. Phase II-

1. Clinical trials study is done.
2. Filing new drug application for registration including detailed data of non-clinical trials and clinical trials.
3. The application is reviewed and evaluated by CDSCO and DGCI.
4. If the new drug is compliance with CDSCO standards and regulations then it gets approval for manufacturing and marketing authorization in India.
5. If application does not get approval, then deficiency letter sends to company or applicant.

Rule-

The rules to be followed under The Drugs and Cosmetics Rules 1945 are:

1. **Rule 122 - A:** Request for authorization to Import New Drug.
2. **Rule 122 - B:** A request for authorization to produce novel medications other than those listed in Schedules C and C (1).
3. **Rule 122 - D:** Authorization to produce or import a fixed-dose combination.
4. **Rule 122 - DA:** Request for authorization to carry out clinical studies for experimental or new drugs.
5. **Rule 122 - DAB:** Compensation in the case of injury or death during clinical trials**[18]**.

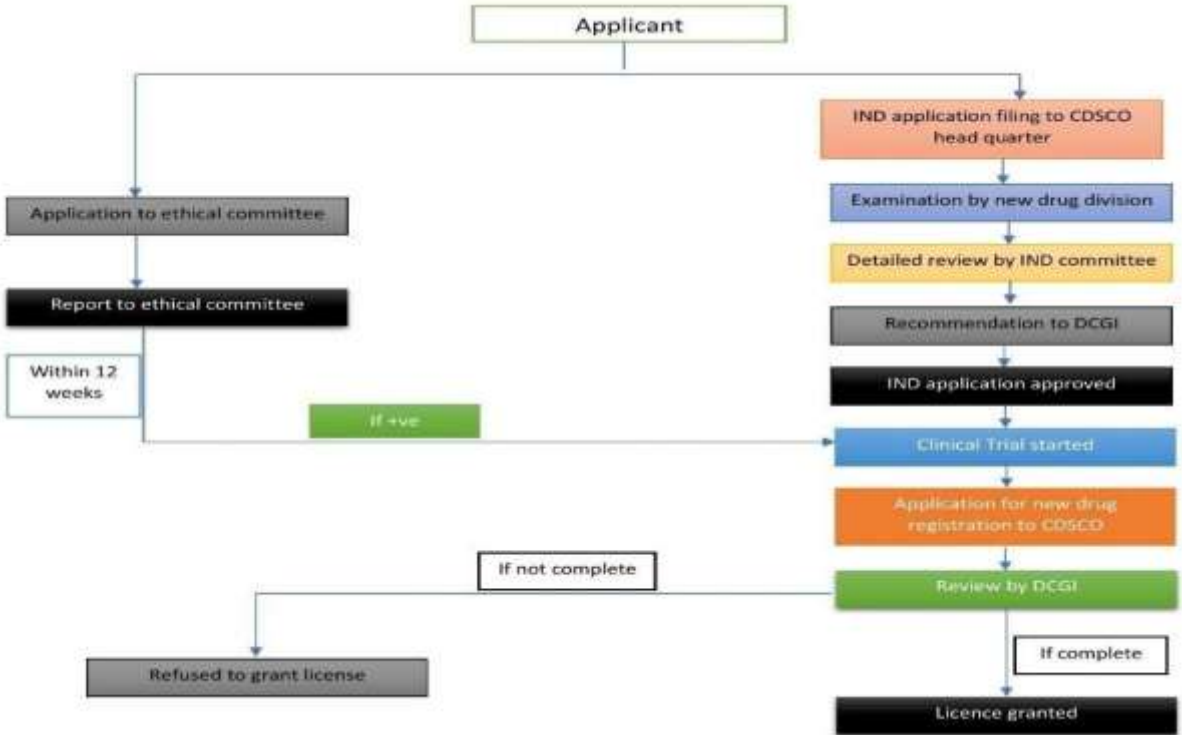

Figure- 7: Drug approval process in India

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II. CONCLUSION:

The drug approval process in USA, Europe and India is complicated in place to make sure new medications are safe and effective before they get marketed. In these countries they have their own regulations, guidelines, laws and regulatory requirements for approval of new drug. USDFA, EMA & CDSCO play a very crucial role from the development of a drug to its manufacturing.Thus, these regulatory bodies are very essential in providing safety to a consumer.

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