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REVIEW ARTICLE

Study & Comparison of Drug Approval Process for Different Countries in Relation to Authorisation Agency & Clinical Trials

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ABSTRACT

In this review paper we are discussing drug approval process for different countries i.e. USA, EU, Australia and India. It is a known factor that different countries are having different drug approval processes worldwide. The basic aim of present work is to study the Comparison of Drug Approval Process for Different Countries in Authorisation Agency & Clinical Trials.

Keywords: U.S. Food and Drug Administration, Clinical Trials, Drug Approval Process, Marketing authorization application, Investigational New Drug Application

INTRODUCTION

In the present time, countries have different regulatory requirements for approval of any new drug. The single regulatory approach for marketing authorization application (MAA) of a new drug product applicable to different countries (on the basis of single dossier) is very difficult. So one should have the knowledge of exact and detailed regulatory requirements for MAA of each country to establish a suitable regulatory strategy. The purpose of this policy is to provide guidance in determining whether or not an Investigational New Drug Application (IND) needs to be filed with the U.S. Food and Drug Administration (FDA).[1]

Drug Approval Process for Different Countries

A regulatory process, by which a person / organization / sponsor / innovator gets authorization to introduce a drug in the market, is termed as drug approval process. In general, drug approval processes have various stages: application to conduct clinical trials, conducting clinical trials, application to marketing authorization of drug and post-marketing studies. Every country has its own regulatory authority, which is responsible to proper enforcement of the rules and regulations and issue the guidelines to regulate the marketing of the drugs.

Drug Approval Process in USA

In 1820, the new era of USA drug regulation was started with the establishment of U.S. Pharmacopoeia. In 1906, Congress passed the original Food and Drugs Act, which require that drugs must meet official standards of strength and purity [3]. However, in 1937, due to sulphanilamide tragedy, the Federal Food, Drug and Cosmetic Act (of 1938) was enacted and added new provisions that new drugs must be shown safe before marketing. Further, in 1962, the Kefauver-Harris Amendment Act was passed which require that manufacturers must prove that drug is safe and effective (for the claims made in labelling)[4,5].

Drug Approval Process in Europe

In European Union (EU), the medical products were approved for marketing at the National level initially. The mutual recognization procedure was introduced in 1983 and a single national review in case of pharmaceutical/medicinal product for marketing authorizations in all EU's countries was made feasible. The initial aim of this procedure was to establish a united standard for product review among national regulatory authorities. In 1987, for high-technology or biologically derived products, the concentration procedure was established by directive 87/22, in which product assessment should be completed by Committee for Proprietary Medicinal Products (CPMP)

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besides the normal national regulatory review. Further, in 1993, by council regulation (EEC) 2309/93, the concentration procedure was replaced with centralised procedure, by which all the high-tech and biologically derived product was reviewed and granted EU's wide marketing authorization by the EU's CPMP [6]. After completing of all three phases of clinical trials, marketing authorization application is filed including all data of animal and human studies, its analyses, as well as pharmacokinetics, manufacturing and proposed labelling. In the EU's countries, the company have a choice of following regulatory procedures:

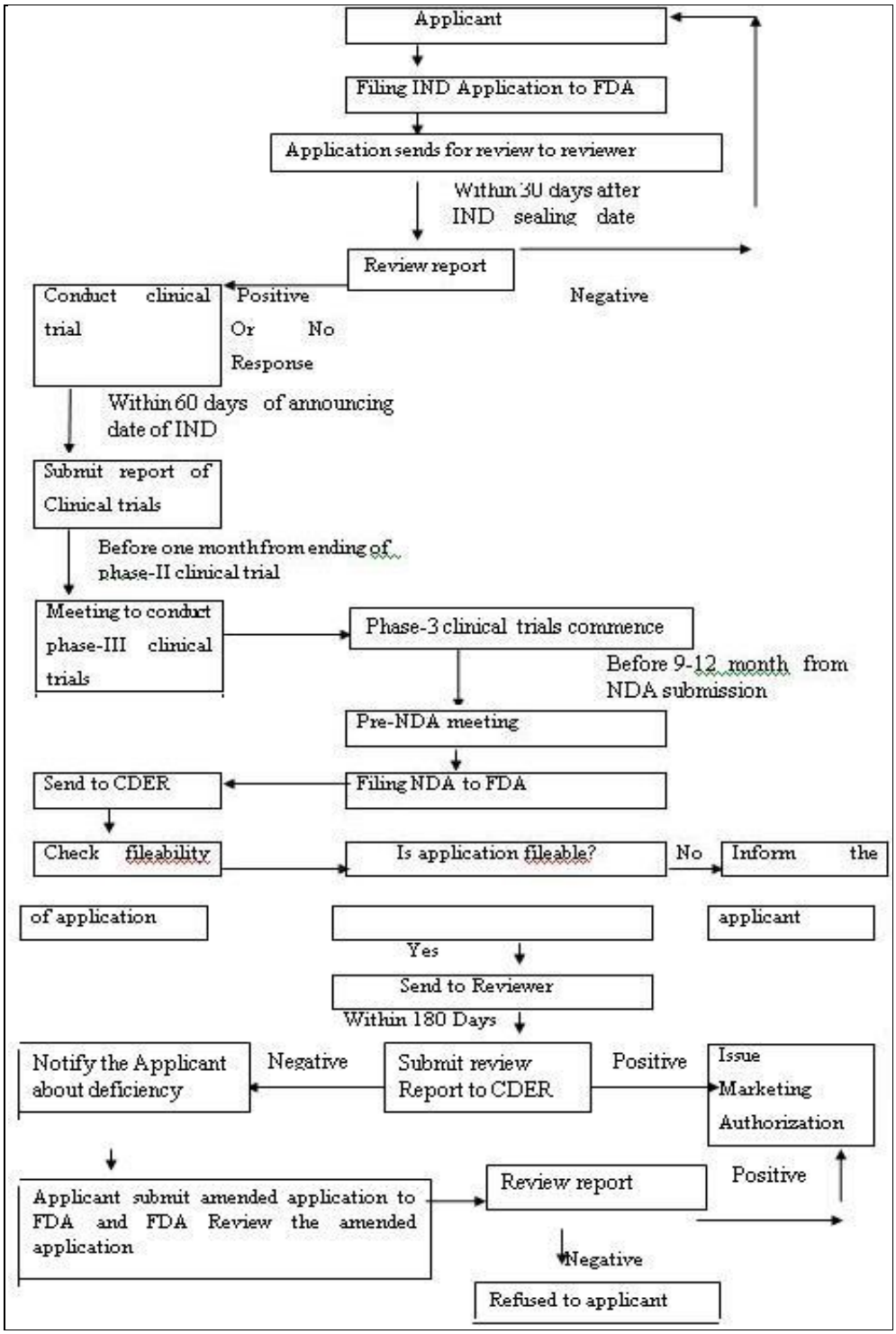

Figure 1: New Drug Application Approval Process of FDA

IND-Investigational New Drug, FDA-Food and Drug Administration, NDA-New Drug Application, CDER-Centre for Drug Evaluation and Research [2]

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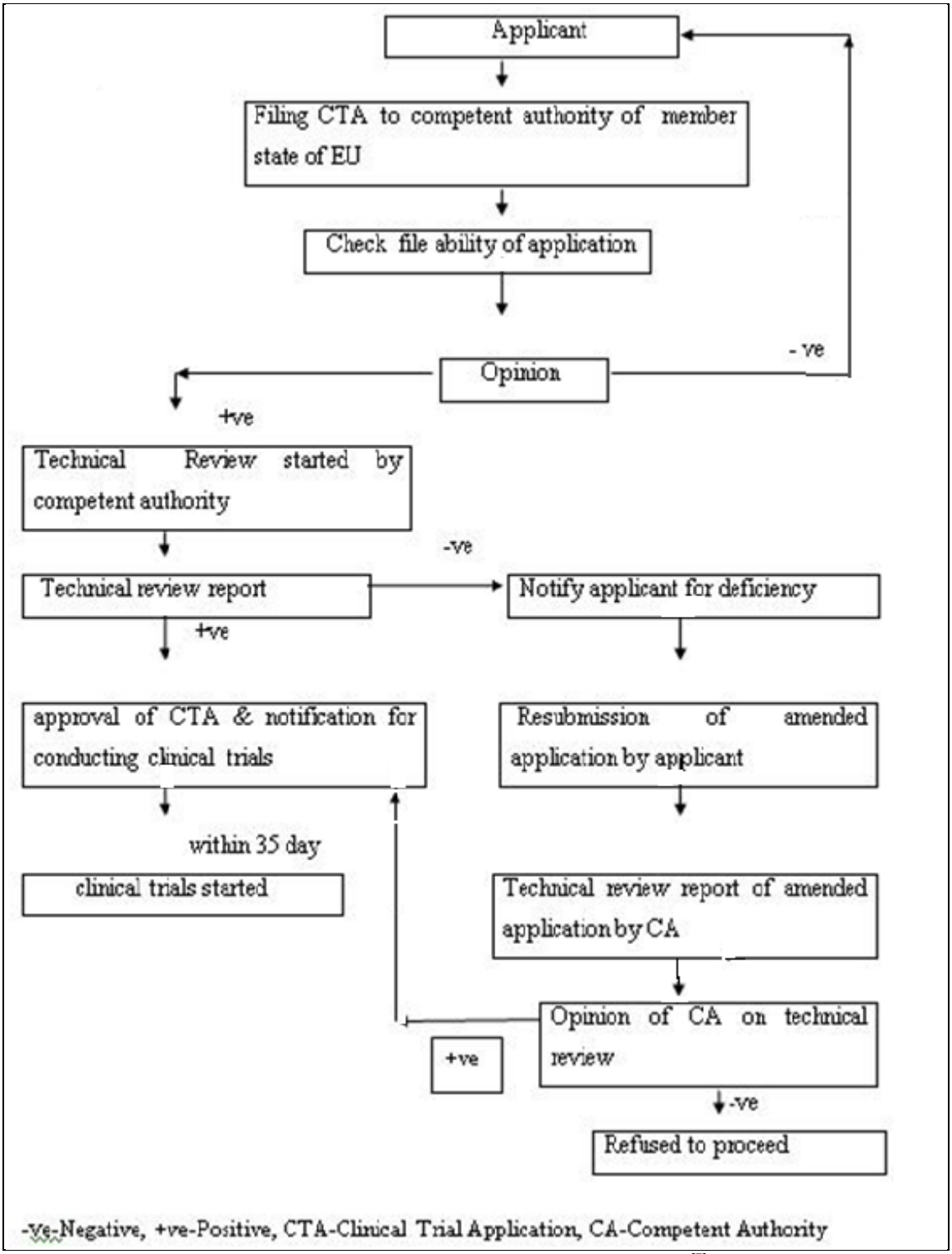

Figure 2: Clinical Trial Authorization Process of EU [7]

Centralized Procedure

The Committee for Human Medicinal Products (CHMP) evaluate the applications received by the EMEA. In view of the applicant's preference, CHMP contracts out assessment work in one of the member states (the "rapporteur"). After the complete evaluation and assessment, the CHMP deliver opinion to EU Commission within 210 days. After receiving a positive opinion from CHMP, the EU Commission requests comments from other member states. The other member states can respond within 28 days.

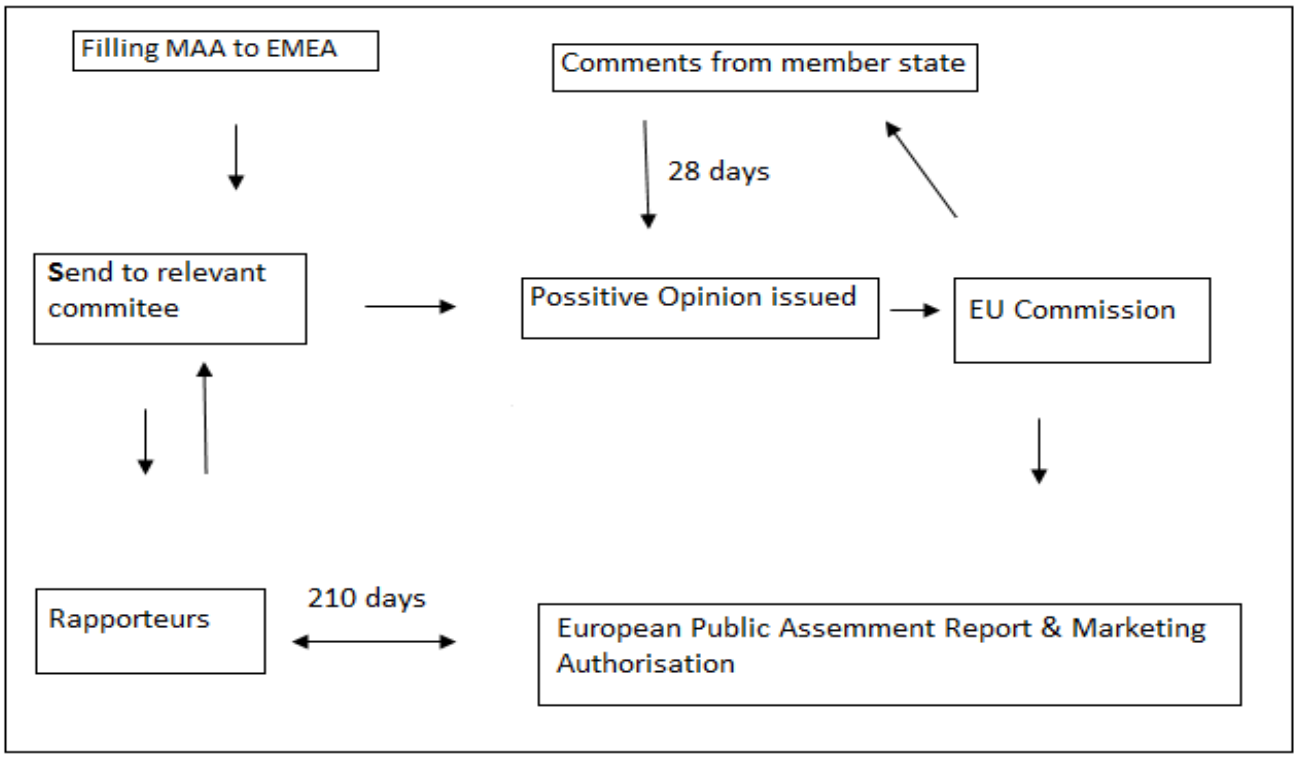

Figure 3: Centralized Procedure for Marketing Authorize

MAA-Marketing Authorization Application, EMEA-European Medicine Evaluation Agency, EU-European Union ion in EU

Decentralised Procedure

In order to obtain marketing authorizations in several member states, the centralised procedure is not mandatory; in such case the decentralized procedure is to be used. An application is submitted to competent authorities of each of the member states, where a marketing authorization is to be required. The information like quality, effectiveness, safety, administrative information shall be submitted and a list of all Concerned Member States (CMSs) and one member state to act as Reference Member State (RMS). A draft evaluation report on the medicinal product is prepared and the CMSs and the RMS validate the application within a time frame of 14 days.

National Procedure

This type of authorization is established on country-by-country basis by the competent authorities, in each member state. Products only planned for one market and not obliged to use the centralized procedure [19].

Mutual Recognition Procedure

The mutual recognition procedure (MRP) is similar to the de-centralized procedure with some differences. The mutual recognition practice is applicable to medicinal products which have received a marketing authorization in any member state whereas the decentralized procedure is applicable to those products which were never approved in any member states of the European Union. The MRP is used to obtain marketing authorizations in various member states. The assessment of application by RMS can be taken within 90 days instead of 120 days (in decentralized procedure).

Drug Approval Process in China

In 1963 the Chinese Ministry of Health, planned drug regulation for the management of new drugs. The China's State Pharmaceutical Administration in collaboration with Ministry of Health, in 1979, published the New Drug Management Regulations which states that there is no need to conduct systematic scientific experiments on new drugs. In view of protecting the public health and promoting the economic developments in pharmaceuticals, the first comprehensive Drug Administrative Law was framed in 1985. This law was amended in 1999 by two additional provisions for new drug approval and provisions for new biological product approval. The approval process of New Drug Applications (NDA) includes sufficient preclinical data for verification of drug's safety and justification of the commencement of clinical trials [10].

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Drug Approval Process in Australia

Thalidomide disaster was a key factor in the history of drug regulatory system in Australian. In 1948, the first advisory committee to review drugs was set up and further in 1964, the first Commonwealth advisory committee in Australia was established. The first federal act relating to therapeutic goods was enacted in 1965. In response of lacking control over locally manufactured products, the Therapeutic Goods Act was changed in 1989 and the Therapeutic Goods Administration (TGA) was formed [11].

Drug Approval Process in India

The Drug and Cosmetic Act 1940 and Rules 1945 were passed by the India's parliament to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The Central Drugs Standard Control Organization (CDSCO) and the office of its leader, the Drugs Controller General (India) [DCGI] were established. In 1988, the Indian government added Schedule Y to the Drug and Cosmetics Rules 1945. Schedule Y provides the guidelines and requirements for clinical trials, which was further revised in 2005 to bring it at par with internationally accepted procedure [12].

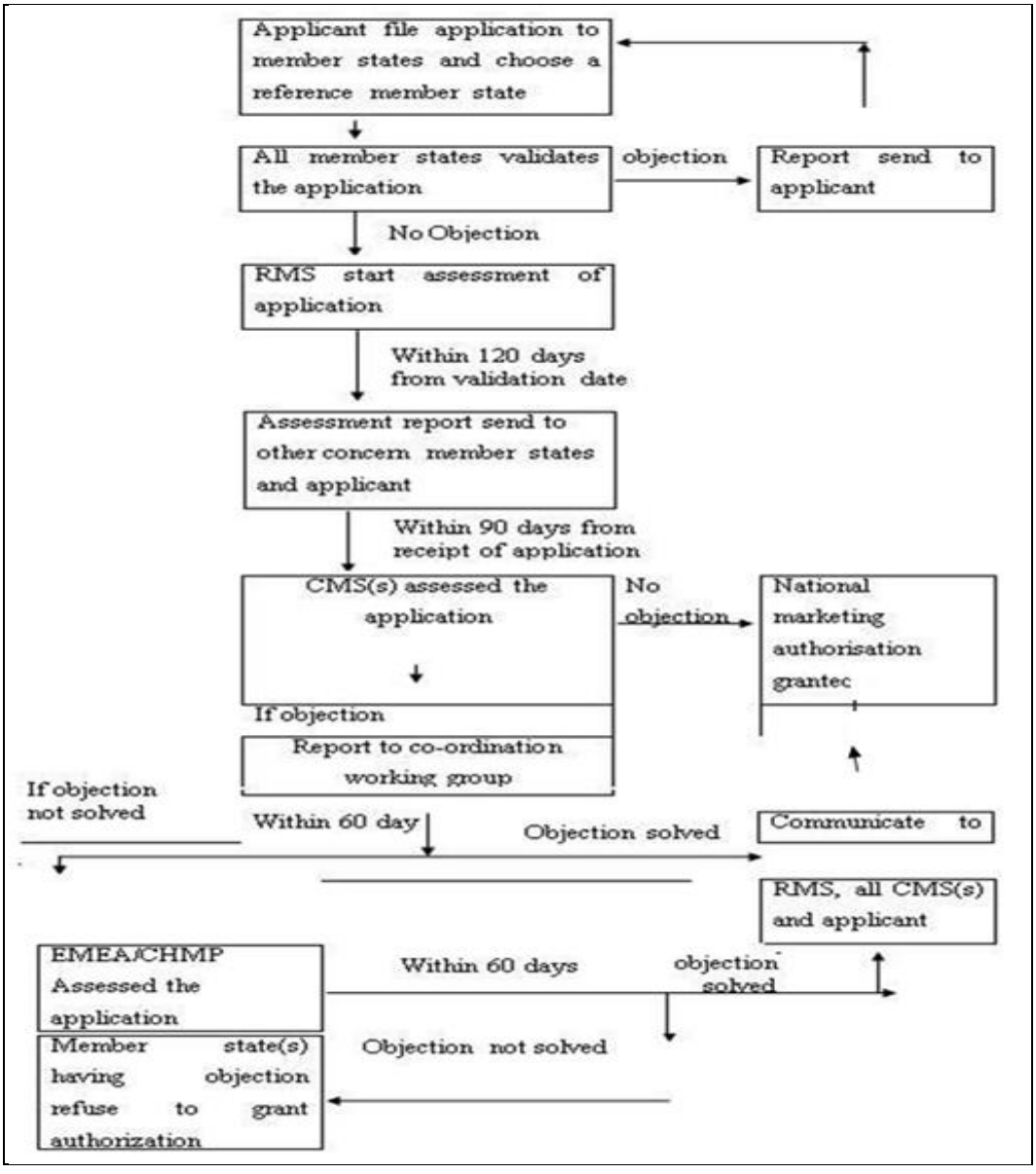

Figure 4: Decentralised Procedure for Marketing Authorization in EU[8]

CMS(s)-Concerned Member State(s), RMS-Reference Member State, CHMP-Committee for Human Medicinal Products.

CONCLUSION

Normally, the drug approval process comprised mainly two steps; first is submitting application to conduct clinical trial and second is application to competent regulatory authority for marketing authorization of drug. The new drug approval process of various countries is similar in some of the aspects whereas it differs in some aspects.

For the purpose of harmonisation, the International Conference on Harmonisation (ICH) has taken major steps for recommendations in the homogeneous understanding and application of technical guidelines and requirements. This step will eventually reduce the need to duplicate work carried out during the research and development of new drugs.

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