

## AN OVERVIEW OF CHINESE DRUG REGULATORY SYSTEM: A REVIEW

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### REVIEW ARTICLE

Nadipineni Ashok Kumar\*, Dileep KG, Ravindra CK, Suthakaran R.

Vijaya College of Pharmacy, Munaganoor (V), Hayathnagar (M), Hyderabad-501511, India

\*Corresponding Author's E-mail: [nashokkumar30@rediffmail.com](mailto:nashokkumar30@rediffmail.com)

#### ABSTRACT

The Drug regulatory authority of China was renewed from state pharmaceutical administration of China (SPAC) to state food and Drug administration (SFDA) with the announcement and declaration of Chinese ministry of health, the established regulatory standards of SFDA were keen to keep with international standards of EU, Japan and USA, the Drug registrations and Drug approvals are carried with established affiliated units for fast track evaluation within prescribed period ordered by SFDA, the state food and Drug administration is developed stringently and modified its standards according to the US healthcare regulatory system, in this review the permanently keeping standards of regulatory functions were detailed, and the untiring responsibilities of affiliated units of SFDA were to be recognized where their performance was a key aspect.

**Keywords:** SFDA, SPAC, EU, Japan, USFDA, ICH-CTD.

#### INTRODUCTION

The National Drug regulatory authority of China was state food and Drug administration (SFDA) which is under the control of ministry of health's department of Drug administration. The SFDA was founded by the Chinese ministry of health in March 1998, the SFDA was previously known as state pharmaceutical administration of China, SFDA mainly oversees the Drug manufacturing, trading and registrations. The implementation of a single Drug regulatory authority was important step to direct foreign access; the SFDA also contains affiliated departments which plays a key role in Drug regulatory administration. The SFDA is uninterruptedly evolving by knowing its deficiency and it is trying to keep its standards according to the standards of EU, USA, and Japan Chinese regulatory authority is

maintaining its protection of intellectual property, and also making its more efforts on regulatory clarity, Chinese regulatory authority is striving for emphasis on innovation, and to start progressing on Drug regulation, to ensure safety and effective usage, SFDA is giving importance for developing innovative Drugs as well as generic Drugs (which are bioequivalent to that of innovator Drugs). (1)

#### AFFILIATED UNITS OF SFDA

The Chinese Drug regulatory authority SFDA was developed and modernized after the USFDA which is under the supervised control of ministry of health, the SFDA was established to restructure and replace state Drug administration (SDA), and the SFDA is in charge for all Drug registrations and approvals. The SFDA has 5 affiliated units to coordinate the activities.

**Table 1: Affiliated units of SFDA & their function**

Affiliated units of SFDA	FUNCTIONS
NICPBP	National institute to control the Pharmaceuticals and Biological products (NICPBP) department mainly conducts sample examination on Drugs and verifies the Drug product standards.

<b>CDE</b>	Center for Drug evaluation (CDE) department plays a vital role in conducting scientific review such as pharmacology data review, toxicology data review, clinical related data review and pharmacy related review
<b>CCD</b>	Certification committee for Drugs, CCD-committee was established by Chinese Drug regulatory authority for preparing the standards to GLP (Good laboratory practices), GCP (Good clinical practices), GAP (Good agricultural practices), GSP (Good supplying practices), and GMP (Good manufacturing practices), it also conducts inspections on requirements for conducting studies
<b>CDR</b>	Center for Drugs re-evaluation (CDR) committee was mainly developed to provide technical support for SFDA, and it takes the responsibility of re-evaluation of Drugs, it takes responsibility on reviewing of safety of the Drugs in the market and to abolish unsafe Drugs, and also to monitor adverse Drug reactions.(2)
<b>CPC</b>	Chinese pharmacopoeia commission (CPC) mainly compiles Chinese Pharmacopoeia which is an official compendium of Drugs, it gives information of each Drug based on standards of dosage form, description test, purity, storage and strength. (3)

## DRUG REGULATIONS AND LAWS

The Drug regulations for pharmaceutical industry are derived into two essential basic laws, these laws mainly governs and regulates in the areas of Pharmaceuticals which includes mainly the Drug manufacturing, packaging, price fixing, advertising and post-marketing surveillance. The Drug administration regulations and laws are came into effect from Dec 1<sup>st</sup> 2001 onwards these laws governs R&D, manufacturing to marketing areas and circulation of Drug products from 1985, the first edition onwards this was the basis for whole Drug regulatory system of China.

### Regulations for product registration

It is founded that Drug regulations for registration of products in China has been undergone for several revisions from 1985 onwards, the Drug regulatory revisions are:

1985- first revision  
 1999-second revision  
 2002-third revision  
 2005-fourth revision  
 2007-fifth revision

The order 28 enacted fifth version during 1<sup>st</sup> October 2007, this new regulation mainly involves changes to standardize the safety,

efficacy and quality of Drugs, for ensuring registration process. This regulatory system is based on joint accountability system and challenge or responsibility assigning system, and the main impact of this new regulation was it mainly encourages the innovation and brings limitations for generic Drug applications. (4)

### Drug registration categories and applications

It was found to be that According to the regulations of SFDA and order 28, a Drug should be under three categories and several classes they are namely, small molecule (New chemical Drugs) is 6 classes, Biological product (Biological Drug) is 15 classes, and Chinese traditional medicine is 9 classes. The Drug registration applications are classified into 3 types based on article 11 of SFDA order 28, they are:

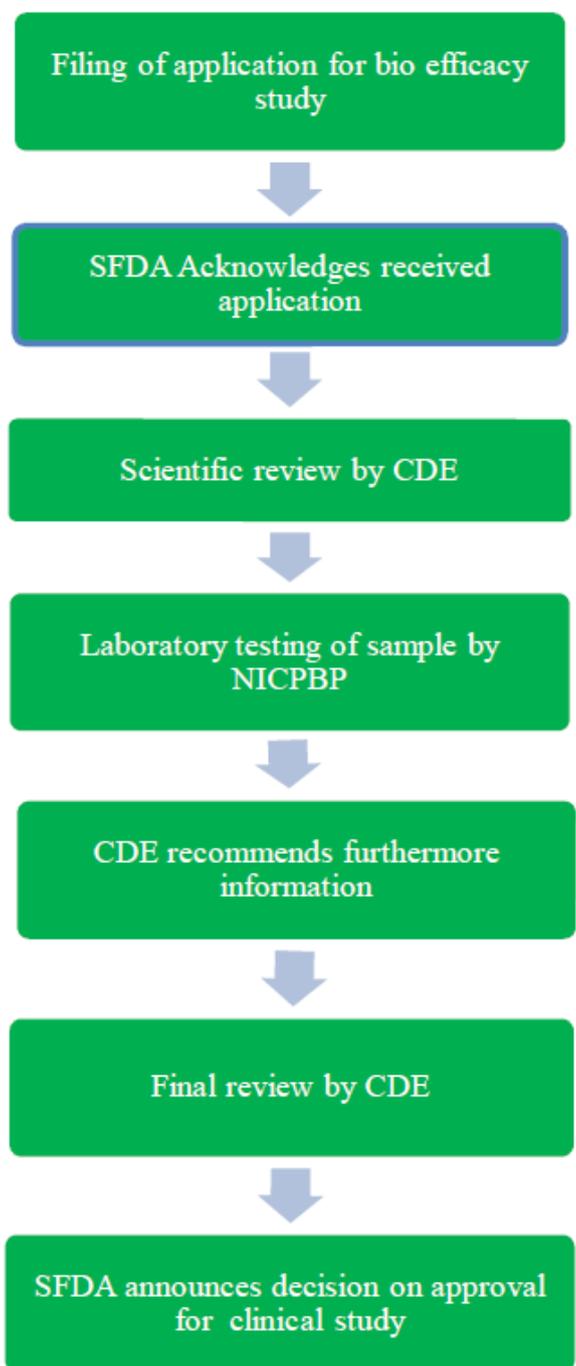
- i. Domestic new Drug application for registering a Drug product which is not marketed before in China
- ii. Imported Drug application is for outsiders of China
- iii. Domestic generic Drug application is a registration application for already implemented official standards by SFDA.

**DRUG REGISTRATION PROCESS:**

It is well known that Drug approval process is much different when compared with European Union and northern America, the different steps of Drug approval process are:

**Phase 1:** In the first phase the application is submitted to the SFDA. SFDA receives the application for preliminary review for acknowledging the dossier content, the center for Drug evaluation (CDE) department or committee receives the application and reviews

pharmacology, toxicology, and clinical related data and requests further information for review and national institute for the control of Pharmaceuticals and Biological products (NICPBP) conducts sample examination, it also sends recommendations to CDE, it takes 120 days period time for both NICPBP and CDE to review the application after CDE review, the further recommendations were sent SFDA to make decision on approval for clinical trial, the decision period is mostly 20 days or 30 days, after the decision on approval the final result is delivered to the applicant



**Figure 1:** Flow chart of clinical studies approval (Bio-efficacy test)

**Phase 2:** Phase 2 mainly involves processing of clinical studies for conducting clinical trials, it takes 12 to 18 months for clinical trials and 3 to 6 months for bioequivalence trials (bio efficacy test) after these clinical and bioequivalence trials the applicant should ready for preparing Drug approval application.

**Phase 3:** The phase 3 process is final approval step, the application dossier is submitted to SFDA, and after submission the SFDA conducts basic review on the received application dossier for verification, after that CDE department conducts the scientific review for evaluation and

further recommendations were send to SFDA, the decision on final approval completed within 20 days, after the final approval the decision result will be send to the applicant. (1,5)

### Requirements for Drug registration:

The documents are represented in the form of dossier, the dossier file is submitted to the state food & Drug administration, in China the registration file or dossier is submitted to SFDA in the format of ICH-CTD (International conference on harmonization-common technical document) and it contains five modules they are (5):

**Table 2: CTD modules & their description**

CTD modules content	Description
<b>Administrative (legal) information and prescribing information:</b>	It contains legal information and documents of application forms or proposed labels for use in the specific region.
<b>The summaries of Common technical document (CTD):</b>	It mainly begins with general introduction to pharmaceutical and pharmacological class such as name of the company, Drug product, and strength of dosage, routes of administration for Drugs, safety, efficacy and quality summaries, this module plays an important section of CTD
<b>Quality information reports:</b>	According to the guidance of M4Q, the pharmaceutical, chemical and Biological information on quality should be described in structures format which is described in the guidance, in this module the relevant quality documents are produce for manufacture, chemistry, and controls of Drug product.
<b>Reports of nonclinical study:</b>	According to the guidance of M4S the safety should be presented in a prescribed structured format, this module contains typical analysis of the non clinical data
<b>Reports of clinical study information:</b>	The information related to efficacy should be presented in a structured format according to the guidance of M4E; this module contains summaries of clinical information such as: information on Pharmacodynamics, Clinical pharmacology, Clinical safety & efficacy, Pharmaceutics and Pharmaco-kinetic studies. (5)

### CONCLUSION

China is becoming one of the leading producer of Pharmaceuticals, the development of regulatory system according to the basis of USFDA lead to established centralized system and became more transparent in healthcare regulatory propaganda. It was concluded that China has established a quite streamlined Drug regulatory system from nearly zero base during the last 30 years along with its national policy of

reform and opening-up. SFDA and its affiliated units played a key role in this system, they make decisions on approvals, the SFDA is continuously evolving with rectifying by knowing its deficiency and the SFDA is keeping its standards permanently with reference to that of the world class regulatory standards of EU, USA and Japan, the established affiliated units of SFDA playing major role in evaluating Drug registration applications and it was founded that these affiliated departments or units were

centrally controlled by the SFDA where their role was a key aspect in evaluating and approving the Drug registration applications

### **ACKNOWLEDGEMENT**

This is matter of great pride to pursue my Master of Pharmacy from Vijaya College Of Pharmacy.

I would like to express my sincere gratitude to my guide Dr. R. Suthakaran & other authors, who gave me the appropriate guidance and has shown interest and encouraged me to carry out work on this review article.

### **CONFLICT OF INTEREST**

Author declares that there are no conflict of interest.

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