

New drug approval process in Japan

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Abbreviations

ADR	adverse drug reaction
CPAC	Central Pharmaceutical Affairs Council
GCP	Good Clinical Practice
ICH	International Conference on Harmonization
MHW	Ministry of Health and Welfare
NDA	New Drug Application
NIH	National Institute of Health
NHIS	National Institute of Health Sciences
NID	National Institute of Infectious Diseases
PAB	Pharmaceutical Affairs Bureau
PAL	Pharmaceutical Affairs Law
PCD	Pharmaceuticals and Cosmetics Division
PMDEC	Pharmaceuticals and Medical Devices Evaluation Center
PMSE	Pharmaceutical and Medical Safety Bureau

Introduction

Recently, several new measures have been taken by Japan's Ministry of Health and Welfare (MHW) to ensure that good quality, safe and effective pharmaceuticals are developed and registered in a more efficient and rational manner. These new measures include amendments to the Pharmaceutical Affairs Law (the fundamental law regulating drugs) and other related laws, construction of a new system of drug review, and updating technical requirements for new drug registration based on the achievements of the International Conference on Harmonization (ICH). This paper will describe the current situation in Japan regarding the approval process for new drugs.

The legal basis of drug evaluation/registration and review system

Pharmaceutical administration in Japan is conducted according to a number of laws. For the implementation and management of these laws, detailed regulations are prepared by governments and ministerial ordinances and notices, and notifications are issued by the Director General of the Bureau of the MHW or the directors of the Division in charge [1,2]. Among these laws and related regulatory documents, the Pharmaceutical Affairs Law (PAL) is the supreme law.

The purpose of the PAL is to regulate matters pertaining to drugs, including biotechnological/biological products, quasi-drugs, cosmetics, and medical devices, to ensure their quality, efficacy and safety. It also promotes the development of drugs for rare diseases.

The principal legal basis of the drug evaluation/registration and review system is described in the PAL. The PAL

has been revised several times since it was enacted in 1960 in order to meet, firstly, scientific developments in the pharmaceutical field, secondly, public needs and demand for better quality, safe and effective pharmaceuticals, and finally, movement towards international harmonization on technical requirements for the registration of pharmaceuticals [3,4]. Some specific features of revisions of the PAL, and other related laws, which have recently been made, are as follows [4]:

1. The amendments strengthened the regulations concerning clinical trials performed both for new drug applications (NDAs) and post-marketing surveillance (PMS). Manufacturers are legally required to adhere to Good Clinical Practice (GCP) regulations, with legal repercussions if they do not. The legal bases for GCP inspections have also been fortified. At the same time, the Organization for Drug Adverse Drug Reaction (ADR) Relief, Research and Development Promotion and Product Review (the Drug Organization), a semi-governmental body authorized by MHW, has been legally empowered to perform consultations on clinical trials with the sponsors.

2. Improvement in the NDA/PMS review system.

3. The clinical and non-clinical NDA and post marketing data submitted have to meet the legally stipulated standards. This reflects an improvement in the data to meet recent advances in the related sciences that are embodied in the ICH guideline.

4. The requirements concerning ADR reports both during clinical trials and after marketing have been documented.

Organizations involved in the new drug application review and restructuring of the review system

Japan's MHW is in charge of improving and promoting social welfare, social security and public health. The MHW consists of home offices and external bodies. The home offices comprise the Minister's Secretariat, nine Bureaus, local branch offices and affiliated institutions. Up to 1997, three different organizations were mainly involved in NDA review: firstly, the Pharmaceutical Affairs Bureau (PAB), one of the nine MHW Bureaus; secondly, affiliated institutions of MHW, namely the National Institute of Health Sciences (NIHS) and the National Institute of Health (NIH), which was renamed as the National Institute of Infectious Diseases (NIID) in 1997; and finally, the Central Pharmaceutical Affairs Council (CPAC), an advisory body to the Minister of Health and Welfare, which is composed of experts working in medical and pharmaceutical institutions and universities. The CPAC examines and reviews important pharmaceutical matters.

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