

New drug approval process in Japan

Takao Hayakawa

Addresses

National Institute of Health Sciences, 1-18-1, Kamiyoga, Setagaya-ku, Tokyo 158-8501, Japan; e-mail: takao@nih.go.jp

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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.

New Drug Approval In Japan

Richard A. Guarino, Richard Guarino



New Drug Approval In Japan:

New Drug Approval in Japan William J. C. Currie, 1998-06-01 **New Drug Approval Process** Richard A. Guarino, Richard Guarino, 2016-04-19 The thoroughly revised Fifth Edition of New Drug Approval Process supplies readers with the latest global changes that affect pharmaceutical product approval and influence how new products are researched and marketed Updated chapters include advances in international regulatory requirements including ICH guidelines and harmonization a step by step **The Japanese Pharmaceutical Industry** Maki Umemura, 2011-03-02 Charting the development of the industry from post war devastation through good recovery in the 1960s and then up to the present the book explores why Japan despite being a world leader in many high technology industries is only a minor player in the global pharmaceutical industry *United States - Japan Trade* Burton Bouwkamp, 1998-10 An important contribution to the international relations and military studies literature this study considers the problem of conflict termination in Europe an area of immense strategic importance to both the United States and the Soviet Union The author argues that a well thought out policy for conflict termination is lacking within the NATO alliance which currently relies almost exclusively on policies that emphasize the prevention of war This lack of a conflict termination strategy Cimbala asserts leaves nations open to the danger of a quickly escalating nuclear conflict should prevention policies fail and a war in Europe actually occur In developing his arguments Cimbala considers the relationship between war and politics as perceived by Soviet and Western planners compares the superpowers likely views on the process of escalation and assesses the command control and communications perspectives implicit in Soviet and American writings and deployments and their implications for war termination Cimbala begins with an overview of the problems and choices involved in ending war in Europe under contemporary conditions Subsequent chapters examine such topics as the philosophical and practical issues related to the problem of preemption the problem of military stability and its specific applications to modern Europe and Western and Soviet approaches to the escalation and limitation of war Soviet perspectives on command and control as well as the Soviet view of war termination receive extended treatment in two chapters Finally Cimbala contrasts the orthodox view of mutual assured destruction with the strategic revisionism of defense dominance or mutual assured survival He concludes that policymakers and military planners must recognize that nuclear weapons will almost certainly be a part of any war in Europe and that termination must focus on limiting the use of these weapons before the pressures of in the field escalation tendencies begin to work against the early conclusion of a conflict Students and scholars of military policy will find Cimbala's work enlightening and provocative reading *The Japanese Pharmaceutical Industry* Lacy Glenn Thomas, 2001 Almost 90 per cent of new drugs are unavailable in Japan This book presents an analysis of the nature causes and consequences of this problem contrasting the Japanese situation with the drug lag experienced in the US The last chapters look at the various remedies available **Global Regulations of Medicinal, Pharmaceutical, and Food Products** Faraat Ali, Leo M.L.

Nollet,2024-07-05 Medicine regulation demands the application of sound medical scientific and technical knowledge and skills and operates within a legal framework Regulatory functions involve interactions with various stakeholders e.g manufacturers traders consumers health professionals researchers and governments whose economic social and political motives may differ making implementation of regulation both politically and technically challenging This book discusses regulatory landscape globally and the current global regulatory scenario of medicinal products and food products comprehensively Features Discusses how recent developments of medicinal and food products have opened up innovative solutions for many of the current challenges societies face presently Explores the manifold variations between the regulatory bodies in different countries that have not previously been collected to this extent Presents details on the substantial progress in analytical methodologies for labelling applications and the creation of appropriate test criteria for pharmaceuticals and their safety analysis Reviews how more worldwide collaboration and cooperation in the regulatory area is still required

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Regulatory Affairs in the Pharmaceutical Industry Javed Ali,Sanjula Baboota,2021-11-14 Regulatory Affairs in the Pharmaceutical Industry is a comprehensive reference that compiles all the information available pertaining to regulatory procedures currently followed by the pharmaceutical industry Designed to impart advanced knowledge and skills required to learn the various concepts of regulatory affairs the content covers new drugs generic drugs and their development regulatory filings in different countries different phases of clinical trials and the submission of regulatory documents like IND Investigational New Drug NDA New Drug Application and ANDA Abbreviated New Drug Application Chapters cover documentation in the pharmaceutical industry generic drug development code of Federal Regulation CFR the ANDA regulatory approval process the process and documentation for US registration of foreign drugs the regulation of combination products and medical devices the CTD and ECTD formats and much more Updated reference

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continuing education requirements out of state courses offered by a provider not approved by

california dental association boardofdentistry org - Jun 03 2022

web california state dental association since 1870 the california dental association has worked to empower the state s brilliant community of dentists as the largest state association in the ada they continue to innovate sustain and grow to support dentistry s best and brightest

california dental association files legal action against delta dental - Aug 05 2022

web jan 13 2023 dr blake the california dental association filed a legal action in late december 2022 against delta dental of california challenging delta s 2023 adjustments to premier and ppo provider agreements in california
regulatory compliance california dental association - Apr 13 2023

web this manual provides sample written plans and forms to assist a dental practice in cal osha compliance it also has information on waste management view the manual cures and opioid pain management cda continues to promote best practices and compliance with state and federal laws regarding opioid pain management view cures

dental board of california - Jul 16 2023

web dental board of california the dental board of california board licenses and regulates approximately 104 000 dental professionals the board licenses monitors and disciplines dentists registered dental assistants rdas and registered dental assistants in extended functions rdaefs

resources for consumers dental board of california - Jul 04 2022

web california organizations butte sierra district dental society california dental assistants association california dental association california dental hygienists association california society of pediatric dentists fresno madera dental society harbor dental society humboldt del norte dental society orange county dental society

dental hygiene board of california dhbc coronavirus updates - Dec 29 2021

web march 23 2021 at the board s march 6 2021 board meeting the board voted to temporarily extend the acceptance of the alternative mannequin based dental hygiene clinical examinations administered by adex crdts and wreb from march 31 2021 until august 31 2021 due to the current covid 19 environment

dental license applicants dental board of california - Feb 11 2023

web list of california approved dental schools below is a current listing of california dental schools accredited by commission on dental accreditation coda for predoctoral dds dmd dental education programs california loma linda university school of dentistry university of california at los angeles school of dentistry

contact us dental board of california - Mar 12 2023

web dentalboard dca ca gov dental assisting program da program dca ca gov complaint compliance unit

dentalboardcomplaints dca ca gov discipline coordination unit dcu dca ca gov anesthesia unit au program dca ca gov for lists of licensees including lists by branch of licensure and location such as county contact the following

board members dental board of california - Jun 15 2023

web yogita butani thakur dds ms of foster city was appointed to the dental board of california by governor newsom in august 2022 dr thakur is a board certified pediatric dentist serves as the chief dental officer at ravenwood family health network and holds hospital privileges at stanford children s hospital

california dental association wikipedia - May 02 2022

web the california dental association cda is a nonprofit professional organization representing organized dentistry in california founded in 1870 cda s membership currently consists of 27 000 dentists in 32 local dental societies throughout the state of california making it the largest constituent of the american dental association

about cda presents california dental association - Oct 07 2022

web the california dental association s biannual conventions were established more than 100 years ago cda presents the art and science of dentistry is held twice each year in northern california in the fall and southern california in the spring

information for applicants dental board of california - Nov 08 2022

web a website for the state of california department of consumer affairs dental board of california