

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
NINS	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

Burton Bouwkamp



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 **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 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 on drug approval processes in key global markets Provides comprehensive coverage of concepts and regulatory affairs Presents a concise compilation of the regulatory requirements of different countries Introduces the fundamentals of manufacturing controls and their regulatory importance 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 *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 *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 **National Trade Estimate ... Report on Foreign Trade Barriers** United States. Office of the U.S. Trade Representative,2004 **Japanese Takeovers** W. Carl Kester,2003-11 This is a reprint of a previously published work It deals with japanese mergers and acquisitions which reached a zenith in the 1980s Impact of Non-tariff Barriers on the Ability of Small Business to Export to Japan United States. Congress. Senate. Select Committee on Small Business,1980

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 - The Rise of Digital Reading New Drug Approval In Japan
 - Advantages of eBooks Over Traditional Books
2. Identifying New Drug Approval In Japan
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an New Drug Approval In Japan
 - User-Friendly Interface
4. Exploring eBook Recommendations from New Drug Approval In Japan
 - Personalized Recommendations
 - New Drug Approval In Japan User Reviews and Ratings
 - New Drug Approval In Japan and Bestseller Lists
5. Accessing New Drug Approval In Japan Free and Paid eBooks
 - New Drug Approval In Japan Public Domain eBooks
 - New Drug Approval In Japan eBook Subscription Services

- New Drug Approval In Japan Budget-Friendly Options
- 6. Navigating New Drug Approval In Japan eBook Formats
 - ePub, PDF, MOBI, and More
 - New Drug Approval In Japan Compatibility with Devices
 - New Drug Approval In Japan Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of New Drug Approval In Japan
 - Highlighting and Note-Taking New Drug Approval In Japan
 - Interactive Elements New Drug Approval In Japan
- 8. Staying Engaged with New Drug Approval In Japan
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers New Drug Approval In Japan
- 9. Balancing eBooks and Physical Books New Drug Approval In Japan
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection New Drug Approval In Japan
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine New Drug Approval In Japan
 - Setting Reading Goals New Drug Approval In Japan
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of New Drug Approval In Japan
 - Fact-Checking eBook Content of New Drug Approval In Japan
 - Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends

- Integration of Multimedia Elements
- Interactive and Gamified eBooks

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