ISSN 0535-1405

No.526

INTERNATIONAL MEDICAL NEWS

International Medical Society of Japan
Since 1925

Nov 30, 2024

The 466th International Symposium on Therapy

The Zoom Webinar held the 466th International Symposium on Therapy on Sep 19, 2024. Dr. Takahisa Murakami, Director of the International Medical Society of Japan (IMSJ), presided over the meeting.

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T. Murakami, PhD. Managing Director, IMSJ

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The Reformation of Healthcare for 2040 in Japan

Manabu Yoshida, Visiting Chief Researcher
Tama University Institute for healthcare and long-term care solution

Acceleration of New Drug/Medical Device Approval

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The Current Topics on New Drug Review Systems in Japan: The challenges Against the Drug Loss issues

Kiyohito Nakai, PhD, Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau, Ministry of Health, Labor and Welfare

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Current status of medical device review

Shinichi Takae, Director, Medical Device Evaluation Division,
Pharmaceuticals Bureau, Ministry of Health, Labor and Welfare

Published by International Medical Society of Japan,
Chairman, Board of Directors: Kenichi Ishibashi, MD, PhD,
Editors: K. Ito, MD, PhD, T. Kondo, MD, K. Ichihashi, MD, PhD, T. Murakami, PhD,
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Acceleration of New Drug/Medical Device Approval

■Introductory Message from the Chair

T. Murakami, PhD. Managing Director, IMSJ

Lecture I

The Current Topics on new Drug Review Systems in Japan: The challenges Against the Drug Loss issues

Kiyohito Nakai, PhD

Director, Pharmaceutical Evaluation Division,
Pharmaceutical Safety Bureau, Ministry of Health, Labor and Welfare

We had a period during which the drug lag problem caused by delays in approval review was widely discussed, but the drug lag at the review stage has been greatly improved. However, the development lag that occurred at the development stage in Japan (when companies started development) was an issue.

In addition, in response to the COVID-19 pandemic, it has been pointed out that Japan's drug discovery capabilities have declined. It has also been pointed out that Japan's industrial structure has not kept up with the changes in the global drug discovery environment, such as the development of new modalities. In particular, Japan is lagging far behind the United States in the utilization of venture and academic seeds.

Recently, a phenomenon called drug loss, where drugs are not developed in Japan, has recently become apparent. This highlights the major issue that necessary drugs have not been reaching the medical field in Japan, a developed country possessing a world-leading universal health insurance system.

In response to various issues pointed out about Japan's pharmaceutical industry, such as a decline in international competitiveness in drug discovery, concerns about stable supply, which mainly of generic drugs, and increasing drug loss, the Ministry of Health, Labor and Welfare established the "Expert Review Committee on Comprehensive Measures to Realize a Rapid and Stable Supply of Pharmaceuticals" in September 2022, and after various discussions, compiled a report on the direction to be aimed for in June 2023. The report also pointed out issues to be addressed regarding pharmaceutical regulations. In response to this, the Pharmaceutical and Food Safety Bureau (currently

the Pharmaceutical Safety Bureau) established a "Review Committee on Pharmaceutical Regulations for Strengthening Drug Discovery and Ensuring Stable Supply" in July 2023, and compiled a report in April this year. Based on the discussions of the study group, the Ministry of Health, Labor and Welfare has issued notifications on the designation of orphan disease drugs, pharmaceutical reviews that contribute to promoting the development of pediatric drugs, and the need for Japanese clinical data in approval reviews in Japan.

The utilization of real-world data (RWD) is also extremely important. Disease registries and medical information databases are expected to be used in pharmaceutical applications from the perspective of improving the efficiency of clinical development. To date, notifications on the utilization of various RWD, including the "Basic principles for the utilization of registries in approval applications, etc." dated March 23 of 2021 have been issued, and principles for ensuring the reliability of RWD have been issued as well.

It is important to drug development with a focus on post-marketing drug monitoring. For example, in the oncology field, the target is increasingly becoming rare cancer, so it is necessary to consider the development package, including post-marketing drug monitoring. Considering the clinical data package including post-marketing should be considered for developing the unmet medical needs at the development stage.

When considering the trend in global pharmaceutical sales, Japan is considered to be the country that controls drug costs substantively. As a result, Japan's relative share of pharmaceutical sales in the world has been declining over the past few decades, and the decline in the attractiveness of the Japanese market has become one of the causes of drug loss. In such an era in which the share of the Japanese pharmaceutical market is declining relatively, I think it is necessary to change our mindset and consider measures that will motivate people to develop drugs and conduct clinical trials in Japan. To that end, more than ever, we need flat discussions between academia, industry, and regulatory authorities. I would like to continue the discussions in the future.

Lecture II

Current status of medical device review

Shinichi Takae, Director, Medical Device Evaluation Division, Pharmaceuticals Bureau, Ministry of Health, Labor and Welfare