

PSEHB Notification No. 0217-1

February 17, 2023

To: Prefectural Governors

Director-General of Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Amendment of the Instructions for Electronic Package Inserts Regarding
Results of Studies Using Medical Information Database

Use of a medical information database for post-marketing pharmacovigilance has been notified through the "Basic Principles on the Use of Medical Information Databases in Post-marketing Pharmacovigilance" (PSEHB/PED Notification No. 0609-8 and PSEHB/SD Notification No. 0609-4, Joint Notification by the Director of Pharmaceutical Evaluation Division and the Director of Safety Division, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare (hereinafter referred to as MHLW), dated June 9, 2017. Hereinafter referred to as Joint notification) and other notifications. From the viewpoint of proper use of drugs, etc., it is desired to take the initiative to enhance the information provision on studies using a medical information database through electronic package inserts (hereinafter referred to as "e-PIs") by utilizing the characteristics of the medical information database shown in the joint notification. This initiative is considered highly significant especially for some patient groups corresponding to the section "9. Patients with Specific Backgrounds" in e-PIs of prescription drugs for which sufficient safety data have not been obtained.

Based on this idea, a partial revision has been made to "Instructions for Electronic Package Inserts of Prescription Drugs" (PSEHB Notification No. 0611-1, issued by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated June 11, 2021) as shown in the comparison table of old and new descriptions below.¹⁾ Please understand the content, and make it thoroughly known to the relevant

¹⁾ The full text of the PSEHB Notification No.0611-1 after the partial revision has been omitted from this English translation.

This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

organizations under your jurisdiction. Please note that a copy of this notification will be issued to each relevant organization specified in the appended list.

Revised language is underlined.

New	Old
<p>I II (Omitted)</p> <p>III Instructions</p> <p>A. to G. (Omitted)</p> <p>1. to 16. (Omitted)</p> <p>17. CLINICAL STUDIES</p> <p>(1) (Omitted)</p> <p>(2) “17.2 Post-marketing Surveillance, etc.”</p> <p>(i) <u>Concerning studies using a medical information database in patients with specific backgrounds, results useful for clinical practice shall be described.</u></p> <p><u>(ii) (iii)</u> (Omitted)</p> <p>(3) (Omitted)</p> <p>18. to 26. (Omitted)</p> <p>IV (Omitted)</p>	<p>I II (Omitted)</p> <p>III Instructions</p> <p>A. to G. (Omitted)</p> <p>1. to 16. (Omitted)</p> <p>17. CLINICAL STUDIES</p> <p>(1) (Omitted)</p> <p>(2) “17.2 Post-marketing Surveillance, etc.”</p> <p>(Newly established)</p> <p><u>(i) (ii)</u> (Omitted)</p> <p>(3) (Omitted)</p> <p>18. to 26. (Omitted)</p> <p>IV (Omitted)</p>

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Appended list

President of the Federation of Pharmaceutical Manufacturers' Associations of Japan

President of Japan Pharmaceutical Manufacturers Association

Chair of the Japan Based Technical Committee of the European Federation of Pharmaceutical Industries and Associations, Japan

Chairman of the Japan-Based Executive Committee of the Pharmaceutical Research and Manufacturers of America

Chairman of Japan Chemical Industry Association

Chairman of the Japan Chemical Exporters and Importers Association

President of Japan Kampo Federation

Chairman of the Japan Federation of Medical Devices Associations

Chairperson of the American Medical Devices and Diagnostics Manufacturers' Association

Chair of the EBC Medical Equipment and Diagnostics Committee

Representative Organizer, Association of Registered Certification Bodies under PMD Act

Chairperson of the Forum for Innovative Regenerative Medicine

Chairman of the Japan Chamber of Commerce and Industry