Provisional Translation (as of April 2024)*

PSEHB Notification No. 0831-11
August 31, 2020

To: Prefectural Governors

From: Director, Pharmaceutical Safety and Environmental Health Bureau
(Official seal omitted)

# Re-Examination Period of Prescription Drugs

The re-examination period of prescription drugs has been shown in "the Enforcement of the Law for Partial Revision of the Pharmaceutical Affairs Act and the Act on the Fund for Adverse Drug Reaction Relief and R&D Promotion" (PAB Notification No. 725 dated August 25, 1993 by Director-General of Pharmaceutical Affairs Bureau, hereinafter referred to as "1993 Notification by Director-General"), "the Enforcement of the Law for Partial Revision of the Pharmaceutical Affairs Act and the Act on the Fund for Adverse Drug Reaction Relief and R&D Promotion" Joint PAB/NDD Notification No. 92, dated October 1, 1993 by Director of New Drug Division, Director of Medical Device Development Division, Safety Division, Pharmaceutical Affairs Bureau, hereinafter referred to as "Joint Notification by Directors"), "Enforcement of Ministerial Ordinance of Partial Revision of the Ministerial Ordinance on Good Post-Marketing Surveillance Practice and Revision of Post-Marketing Surveillance in Relation to Re-Examination of Drugs" (PMSB Notification No. 1324 dated December 27, 2000 by Director-General of Pharmaceutical and Medicinal Safety Bureau, Ministry of Health and Welfare, hereinafter referred to as "2000 Notification by Director-General"), "Re-Examination Period of Drugs" (PMSB/ELD Notification No. 1813 dated December 27, 2000 by Director, Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, Ministry of Health and Welfare, hereinafter referred to as "the Notification by Director") and "Re-Examination Period for Drug with a New Active Ingredient" (PFSB Notification No. 0401001 dated April 1, 2007 by Director-General of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare).

"Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, and Other Acts" (Act No. 63 of 2019; hereinafter referred to as the "Amendment Act") was promulgated on December 4, 2019, and it has been decided that this shall come into effect as from September 1, 2020. In light of the fact that the designation system for drugs for specific use has been stipulated by the Amendment Act, the re-examination period of prescription drugs has been determined

* This English version of the Japanese Notification is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

as shown below. We ask you to understand and inform related parties under your administration.

In association with this, the 1993 Notification by Director-General, Joint Notification by Directors, and third note in the 2000 Notification by Director-General are abolished.

This notification shall apply from September 1, 2020.

Note

Re-examination period

1 The investigation period of new drugs specified in Article 14-4 (1) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960, hereinafter referred to as "the Act") is as shown below. Re-examination must be conducted within 3 months after this investigation period.

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| (1) | New drugs that meet the following | Separately specified period from >6 years to ≤10 |
| | (A) Orphan drugs | |
| | (B) Innovative drugs (designated under the SAKIGAKE system) | |
| | (C) Other drugs than those in the above (A) and (B) which are designated by Minister of Health, Labour and Welfare as a drug specified by the Ordinance of Ministry of Health, Labour and Welfare after hearing the opinion of Pharmaceutical Affairs and Food Sanitation Council | |
| (2) | New drugs that meet the following | Separately specified period of <6 years |
| | (A) Drugs for specific use | |
| | (B) Drugs that are clearly different from approved drugs only in terms of indications (except drugs listed in the above (1)) | |
| | (C) Other drugs than those in the above (A) and (B) which are designated by Minister of Health, Labour and Welfare as a drug specified by the Ordinance of Ministry of Health, Labour and Welfare after hearing the opinion of Pharmaceutical Affairs and Food Sanitation Council | |
| (3) | New drugs other than those listed in the above (1) or (2) | 6 years |

2 Drugs that are regarded as equivalent to a new drug in terms of their active ingredients, contents, administration, dosage, indications, efficacy etc., and approved during the investigation period of the new drug must be re-examined within a period designated by the Minister of Health, Labour and Welfare to coincide with the period to apply for re-examination of the new drug.

3 For the details of the re-examination period, separate notifications should be referred to.