Regarding the Provision of Information for the Proper Use of Over-the-Counter Drugs and Other Medicinal Products, and the Implementation of Adverse Reaction Reporting for Suspected Cases of Dependence (Request for Dissemination)[1]

Authority: **Ministry of Health, Labour and Welfare (MHLW)**

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With regard to the sale, etc. of Over-the-Counter Drugs and Guidance-required Drugs (hereinafter collectively referred to as "OTC Drugs, etc."), in order to contribute to the appropriate selection and proper use of medicinal products, pharmacists shall be involved and provide necessary information in the case of Guidance-required Drugs and Category 1 Drugs, while pharmacists or registered salespersons shall be involved and provide necessary information in the case of Category 2 Drugs and Category 3 Drugs.

Furthermore, Designated Abuse Prevention Drugs are prescribed under Article 36-11 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 "PMD Act"), as amended pursuant to Article 1 of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, etc. (Act No. 37 of 2025) (hereinafter referred to as the "New PMD Act").

In addition, the obligations to be complied with by pharmacy proprietors, store-based retailers and household distribution service providers in connection with the sale, etc. of Designated Abuse Prevention Drugs are prescribed in Articles 159-18-2 through 159-18-7 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ordinance of the Ministry of Health and Welfare No. 1 of 1961; hereinafter referred to as the "New Enforcement Regulation of the PMD Act"), as amended by the Ordinance for the Development, etc. of Relevant Ordinances of the Ministry of Health, Labour and Welfare in Connection with the Partial Enforcement of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, etc. (Ordinance of the Ministry of Health, Labour and Welfare No. 117 of 2025).

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law.

The above provisions shall enter into force on 1 May 2026.

The provision of information for the proper use of OTC Drugs, etc., the implementation of adverse reaction reporting, and other related matters have been provided for in the "Regarding the Provision of Information, etc. for the Proper Use of Over-the-Counter Drugs and the Implementation of Adverse Reaction Reporting in Cases Suspected of Dependence (Request for Dissemination)" (Notice No. Yaku-Sei-Sō-Hatsu 0912 No. 3 and Yaku-Sei-An-Hatsu 0912 No. 1, dated 12 September 2019, issued jointly by the Director of the General Affairs Division and the Director of the Pharmaceutical Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare; hereinafter referred to as the "Previous Notice").

In consideration of the recent amendments to the relevant legislation, it has now been decided to revise the provisions as set out below. Accordingly, you are requested to disseminate this Notice to the relevant parties and related organizations under your jurisdiction, and to provide appropriate guidance and other necessary measures to pharmacy proprietors, store-based retailers and household distribution service providers under your jurisdiction (hereinafter collectively referred to as "Pharmacies, etc.").

This Notice shall apply from 1 May 2026, and the Previous Notice shall be abolished as of the same date.

Details

1. Provision of Information, etc. for Proper Use

When Pharmacies, etc. sell or otherwise provide Designated Abuse Prevention Drugs, the provisions of Articles 159-18-2 through 159-18-7 of the New Enforcement Regulation of the PMD Act shall be complied with.

In particular, in the "Survey on the Actual Status of the Medicinal Product Sales System" conducted annually by the Ministry of Health, Labour and Welfare, it was identified that there were cases in which certain Pharmacies, etc. had failed to take appropriate measures when purchasers attempted to purchase multiple quantities of Medicinal Products with a risk of abuse, etc. Accordingly, where a purchaser intends to purchase multiple quantities of such products, pharmacists or registered salespersons shall be instructed to ensure that the reason for such purchase is confirmed and that the sale or other provision is limited to the quantity deemed necessary for proper use.

In this regard, reference shall be made to the "Regarding the Enforcement, etc. of the Act Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, etc. (Matters Relating to Provisions Coming into Effect on the Date Specified by Cabinet Order within a Period Not Exceeding One Year from the Date of Promulgation (1 May 2026))" (Notice No. Iyakuhatsu 1226 No. 2, issued by the Director-

General of the Pharmaceutical Affairs Bureau, Ministry of Health, Labour and Welfare, dated 26 December 2025) and the "Regarding the Sale, etc. of Designated Abuse Prevention Drugs" (Notice No. Iyakuhatsu 1226 No. 16, issued by the Director-General of the Pharmaceutical Affairs Bureau, Ministry of Health, Labour and Welfare, dated 26 December 2025).

Furthermore, when selling or otherwise providing OTC Drugs, etc. other than Designated Abuse Prevention Drugs, where dependence or improper use is suspected, appropriate measures shall also be taken, including actively providing purchasers with necessary information and conducting necessary confirmations.

2. Implementation of Adverse Reaction, etc. Reporting

(1) Article 68-10, paragraph (2) of the New PMD Act provides that, where healthcare professionals, including physicians, dentists, pharmacists and registered salespersons, become aware of the occurrence of adverse reactions, etc. relating to pharmaceuticals, medical devices or regenerative medical products, and where such reporting is deemed necessary in order to prevent the occurrence or expansion of hazards to public health and hygiene, they shall report such adverse reactions, etc. to the Minister of Health, Labour and Welfare.

The information reported is analyzed or evaluated from a professional perspective, and necessary safety measures are implemented. In addition, by providing such information widely to healthcare professionals and other relevant parties, post-marketing safety measures are being ensured. Continued cooperation in this regard is therefore requested.

Detailed information concerning reporting methods and other related matters is provided in the "Guidelines for the Implementation of Reports on Adverse Reactions, Infections and Defects Relating to Pharmaceuticals, Medical Devices, Regenerative Medical Products, Quasi-drugs and Cosmetics by Healthcare Professionals, etc." (Notice No. Yaku-Sei-Hatsu 0318 No. 1 issued by the Director-General of the Pharmaceutical and Living Hygiene Bureau, Ministry of Health, Labour and Welfare, dated 18 March 2022), attached thereto as the "Guidelines for the Implementation of the Drug and Medical Device Safety Information Reporting System" (hereinafter referred to as the "Implementation Guidelines").

Reports shall be submitted to the Pharmaceuticals and Medical Devices Agency (PMDA). Furthermore, as reporting through the electronic reporting system is also available, its use is encouraged.

(Reference)

Reporting Submission Website on the PMDA Website

https://www.pmda.go.jp/safety/reports/hcp/0002.html

(2) Where healthcare professionals, etc. become aware not only of cases in which dependence resulting from the use of OTC Drugs, etc. has been diagnosed by a physician, but also of cases in which individuals are unable to discontinue the use of OTC Drugs, etc. despite attempting to do so, and where such reporting is deemed necessary in order to prevent the occurrence or expansion of hazards to public health and hygiene, an adverse reaction, etc. report shall be submitted pursuant to Article 68-10, paragraph (2) of the New PMD Act, by entering "Drug Dependence" or "Suspected Drug Dependence" in the "Name or Symptoms of Adverse Reaction, etc., or Abnormal Findings" section of Form ① of Annex 1 to the Implementation Guidelines.

Furthermore, where pharmacists, registered salespersons, or other relevant persons at pharmacies, stores, etc. become aware, in connection with the submission of an adverse reaction, etc. report, that a diagnosis has already been made by a physician, they shall endeavor to submit the report after sharing information with the medical institution that made such diagnosis.