October 31, 2014

Administrative Notice

To: Division of Pharmaceutical Affairs, Prefectural Health Department (Bureau)

Director of Safety Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Q&A on Adverse Drug Reaction and Malfunction Reports of Combination Products

The Q&A on post-marketing adverse drug reaction and malfunction reports based on Article 253 of the *Ordinance for Enforcement of Pharmaceutical Affairs Act* (MHW Ordinance No. 1, 1961) has been indicated in the "Q&A on Adverse Drug Reaction and malfunction Reports" (Administrative Notice by the Evaluation and Licensing Division/Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated July 29, 2010).

After the issuance of the *Act for Partial Amendment of the Pharmaceutical Affairs Act etc.* (Act No. 84, 2013. Hereinafter referred to as "Act for Amendment"), the "*Ministerial Ordinance Regarding Development etc. of Related Ministerial Ordinance for Enforcement of the Cabinet Order on the Development etc. of Related Cabinet Order and Interim Measures for Enforcement of the Act on Partial Amendment of the Pharmaceutical Affairs Act etc.*" (MHLW Ordinance No. 87, 2014. Hereinafter referred to as "Ministerial Ordinance for Amendment") has been issued in July 30, 2014, which will come into effect on the effective date of the Act for Amendment (November 25, 2014). The Q&A on adverse drug reaction and malfunction reports for combination products has been established as attached, and we ask you to inform relevant marketing authorization holders placed under your administration regarding this matter.

Please note that this administrative notice has also been sent to relevant organizations.

Attachment

Q&A on Adverse Drug Reaction and Malfunction Reports of Combination Products

Abbreviations

Act: *Act for Ensuring the Quality, Efficacy, and Safety of Drugs, Medical Devices and other products* (Act No. 145, 1960)
Ministerial Ordinance for Enforcement: *Ministerial Ordinance for Enforcement of the Act for Ensuring the Quality, Efficacy, and Safety of Drugs, Medical Devices and other products* (MHW Ministerial Ordinance No. 1, 1961)
Drugs etc.: Drugs, medical devices, and cellular and tissue-based products specified in the Ministerial Announcement
Agency: Pharmaceuticals and Medical Devices Agency

Q1: Should health damages caused by use of combination products corresponding to drugs be reported as either adverse drug reaction reports or malfunction reports?

A1: If it is not known whether the health damage was caused by an adverse drug reaction due to the drug or by a malfunction due to the device, it is necessary to submit both an adverse drug reaction report and a malfunction report.

Q2: For combination products corresponding to drugs, is it necessary to submit an adverse drug reaction report if it is apparent that the health damage was caused by malfunction of the device (broken needles, etc.) and not by the drug?

A2: Only the malfunction report shall be submitted.

Q3: For foreign corrective action reports and research reports related to the device of the combination product corresponding to drugs, how should they be submitted?

A3: Foreign corrective action reports and research reports related to the device may be submitted together as foreign corrective action reports and research reports of the drug.

Q4: If approval etc. of the device of the combination product corresponding to drugs has been obtained by a different medical device marketing authorization holder, should health damages due to that combination product be reported from the medical device marketing authorization holder?

A4: Reports on adverse drug reactions and malfunctions of combination products shall be reported by the marketing authorization holder of that combination product.

Q5: What shall be specified in the column for the brand name, non-proprietary name, and approval/certification number etc. of a medical device when submitting malfunction reports for the device of the combination product corresponding to drugs?

A5: Since the report will be submitted as the combination product corresponding to drugs, specify the brand name, non-proprietary name, and approval number etc. of the drug.

Q6: How should the reporting time frame be calculated when submitting periodic reporting on malfunctions in the device of the combination product corresponding to drugs?

A6: The initial date shall be the date in which the combination product was approved as a drug.