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PFSB Notification No. 1002-20

October 2, 2014

To: Prefectural Governors

Secretary-General,  
Pharmaceutical and Food Safety Bureau,  
Ministry of Health, Labour and Welfare

## **Reports of Adverse Drug Reactions, etc. of Pharmaceuticals**

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.” (Ministry of Health, Labour and Welfare (MHLW) Ordinance No. 87 of 2014; hereinafter referred to as the “Ministerial Ordinance for Amendment”) was issued on July 30, 2014 and will come into effect on the day of enforcement (November 25, 2014) of the “Act for Partial Amendment of the Pharmaceutical Affairs Act etc.” (Act No. 84 of 2013; hereinafter referred to as the “Act for Amendment”).

Consequently, “Reports of Adverse Drug Reactions, etc. of Pharmaceuticals” (hereinafter referred to as the “New Notification”) was established as an attachment, with its outlines etc. as mentioned below and shall be applied after the enforcement day of the Act for Amendment. You are requested to notify the related businesses in your administration of this matter.

With the enforcement of the New Notification, the notification by the Secretary-General of Pharmaceutical and Food Safety Bureau (PFSB), MHLW, PFSB Notification No. 0317006 dated March 17, 2005, “Enforcement of the Ministerial Ordinance and Other Rules on Partial Amendment of the Pharmaceutical Affairs Act Enforcement Ordinance (regarding Adverse Drug Reaction Reports or Other Case Reports)” (hereinafter referred to as the “Former Notification”) will cease to be effective as of November 25, 2014.



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- 1 In the “Ministerial Ordinance for Enforcement of Act on Securing Quality, Efficacy, and Safety of Pharmaceuticals, Medical Devices etc.” (MHW Ordinance No. 1 of 1961; hereinafter referred to as the “Enforcement Ordinance”), after revision by Ministerial Ordinance for Amendment, provisions were newly established regarding reporting of malfunctions in devices of drugs approved for integral marketing with devices (combination drugs), and the provisions regarding judgment criteria and reporting time frame of malfunctions in medical devices (in Article 228-20, paragraph 2 of the Enforcement Ordinance) were to be applied to the reporting of the combination drugs (Article 228-20, paragraph 3 of the Enforcement Ordinance). Therefore, provisions regarding combination drugs were established, including glossaries in paragraph 3 in the New Notification (Paragraphs 1-(3), 2-(3), and 3-(3) of the New Notification).
- 2 In the Act for Ensuring Quality, Efficacy, and Safety of Drugs and Medical Devices etc. after revision by the Act for Amendment (Act No. 145 of 1960; hereinafter referred to as the “Act”), “regenerative medicine products” were newly defined (Article 2, paragraph 9 of the Act), and mandatory reporting of adverse reactions etc. was established regarding regenerative medicine products (Article 68-10 of the Act). Consequently, provisions on the judgment criteria and reporting frame were established for malfunctions of the regenerative medicine products in the Enforcement Ordinance (Article 228-20, paragraph 4 of the Enforcement Ordinance). Therefore, glossaries in Article 228-20 as well as provisions regarding regenerative medicine products were specified in the New Notification (1-(4), 2-(4), and 3-(4) of the New Notification).
- 3 Regarding the provisions related to the glossaries (Item 3 of the Former Notification), reporting time frames etc. (Item 4 of the Former Notification) and reporting forms (Item 5 of the Former Notification) for drugs, quasi-drugs, and cosmetics in the Former Notification, which will cease to be effective as of November 25, 2014, similar provisions are established in the New Notification. With regard to the glossaries (item 3 in the Former Notification), reporting time frame (item 4 in the Former Notification), and reporting forms (item 5 in the Former Notification) concerning the reporting of adverse reactions, etc. of quasi-drugs and



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cosmetics provided in the Former Notification, similar provisions are established in the New Notification. With regard to the reporting of the adverse reactions of quasi-drugs and cosmetics pursuant to Article 228-20, paragraph 5, item 1 and Article 228-20, paragraph 2, item 1, please note that the “Enforcement of Ministerial Ordinance of Partial Revision of the Ministerial Ordinance regarding the Enforcement Ordinance of the Act and Standards for Post-marketing Safety Management of Drugs, Quasi-drugs, Cosmetics, and Medical Devices (Reporting of adverse reactions, etc. of quasi-drugs and cosmetics)” has been established (Secretary-General’s Notification; PFSB Notification 0227 No.3, dated February 27, 2014).