September 28, 2015

Administrative Notice

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

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

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

Q&A on Post-marketing Reports of Adverse Drug Reaction, etc. and Clinical Trial Reports of Adverse Drug Reaction, etc. Conforming to Implementation Guide of E2B (R3)

"Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs) E2B (R3) Data Elements and Message Specification" (hereinafter referred to as "Implementation Guide of E2B (R3)") has been summarized in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Handling, etc. of the post-marketing reports on adverse drug reaction and clinical trial reports on adverse drug reaction based on this guide has been specified in PFSB/ELD Notification No. 0917-1 and PFSB/SD Notification No. 0917-2, by the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau and by the Director of Safety Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, dated September 17, 2013) "Post-marketing Reports on Adverse Drug Reaction and Clinical Trial Reports on Adverse Drug Reaction Conforming to Implementation Guide of E2B (R3)." The Questions and Answers (Q&A) have been summarized as shown in the Attachment and shall apply from April 1, 2016. This notification asks for your understanding and cooperation in making these widely known to affiliated vendors as a reference for the services.

In addition, the administrative notice issued by the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau and by the Safety Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, dated February 26, 2014, "Revision of Q&A on Reports on Adverse Drug Reaction" (hereinafter referred to as "Q&A on E2B (R2) for Japan") shall be abolished as of April 1, 2016, associated with the issuance of this administrative notice. However, until March 31, 2019, the Q&A on E2B (R2) for Japan shall apply when the reports on adverse drug reaction are submitted according to the PFSB/ELD Notification No. 0331022 and PFSB/SD Notification No. 0331009, by the Director of Evaluation and Licensing Division,

Pharmaceutical and Food Safety Bureau and by the Director of Safety Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, dated March 31, 2006, “Post-marketing Reports on Adverse Drug Reaction and Clinical Trial Reports on Adverse Drug Reaction”

Furthermore, the administrative notice including the same content has already sent to the Federation of Pharmaceutical Manufacturers' Associations of JAPAN, etc.