

**Provisional Translation (as of December 2017) \***

PSEHB/ELD Notification No. 0705-1

July 5, 2017

To: Director of prefectural department (bureau) of health

Director of Pharmaceutical Evaluation Division,  
Pharmaceutical Safety and Environmental Health Bureau,  
Ministry of Health, Labour and Welfare  
(official seal omitted)

Approval Application with Electronic Common Technical Document (eCTD)

Guidance about handling of documents that should be attached to the approval application form for the approval application of a prescription drug (hereinafter referred to as “application data”) has been presented in PFSB Notification No. 1121-2 “Drug Approval Application” by the General-Director of Pharmaceutical and Food Safety Bureau, MHLW, dated November 21, 2014; PFSB/ELD Notification No. 1121-12 “Points to be Considered for Drug Approval Application” by the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated November 21, 2014; and PMSB/ELD Notification No. 899 “Guidance for Preparation of Documents that should be Attached to the Approval Application Form in a New Drug Marketing Approval Application” (hereinafter referred to as “CTD Notification”) by the Director of Evaluation and Licensing Division, Pharmaceutical and Medical Safety Bureau, MHLW, dated June 21, 2001. In addition, guidance for electronic submission of application data has been presented in PFSB/ELD Notification No. 0604001 “Electronic Common Technical Document Specification” (hereinafter referred to as “Electronic Specification Notification”) by the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated June 4, 2003; and PFSB/ELD Notification No. 0527004 “Handling of Electronic Common Technical Document Specification” (hereinafter referred to as “Electronic Handling Notification”) by the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated May 27, 2004.

Here, guidance for handling of approval application based on electronic Common Technical Document (hereinafter referred to as “eCTD”) in compliance with “eCTD

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Implementation Package” including guide for implementation of eCTD, a guideline agreed at the International Council For Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (hereinafter referred to as ICH), as well as specifications of electronic files included in eCTD (hereinafter referred to as “Specification for Submission Formats” or “SSF”), is summarized as follows. Please understand the content and inform thoroughly all the vendors concerned under your jurisdiction of the content. The date on which this notification becomes effective will be separately announced. In addition, on the above effective date, the “Electronic Specification Notification” and “Electronic Handling Notification” are abolished.

### Note

1. Handling of eCTD-based approval application and scope
  - (1) Proceed with eCTD-based approval application in principle if it is required according to 2. (5) a. in PFSB/ELD Notification No. 0427-1 “Notification on Practical Operations of Electronic Study Data Submissions” by the Director of Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, MHLW, dated April 27, 2015. In the other approval applications, the application data prepared in accordance with the CTD Notification may be submitted as eCTD.
  - (2) Prepare and submit eCTD as directed in Appendix 1.
  - (3) To do the above, prepare electronic files for eCTD as directed in Appendix 2.
  
2. ICH guidelines for eCTD
  - (1) Appendix 3 provides guide for implementation of eCTD agreed at ICH. The “eCTD Implementation Package” that includes guide for implementation of eCTD and lists requirements for preparation and submission of eCTD can be found at websites of ICH and Pharmaceuticals and Medical Devices Agency (PMDA).
  - (2) Appendix 4 provides SSF agreed at ICH.

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