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

Office of GMP/QMS inspection,
Pharmaceuticals and Medical Devices Agency

New Application Procedure for GMP Certification between the European Union and Japan

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) would like to inform an outline of the new operational method for GMP certification under the provisions of the Mutual Recognition Agreement (MRA) between European Union (EU) and Japan. In the new procedure, contents of GMP certification are registered into EudraGMDP database provided by the European Medicines Agency (EMA) in lieu of issuing a certificate in conventional paper form. The new procedure will come into effect from October 1, 2013 based on the amended notification dated June 28, 2013 issued by the Director General of Pharmaceutical and Food Safety Bureau (PFSB), MHLW.

＜Outline＞

1. GMP certification under the MRA using EudraGMDP database

1-1. Recipients of the certification

GMP certification under the MRA is not directed to any specific single state, but valid in all the EU member states specified in the scope of the MRA.

1-2. Registration on the EudraGMDP database

Based on the information submitted to PMDA by an applicant, PMDA will register the contents of certification on EudraGMDP database (http://eudragmp.ema.europa.eu/) provided by the EMA. As a general rule, the registered information will be open to the public on EudraGMDP database.

1-3. Notice letter of the certification

The contents registered on EudraGMDP database will be notified to the applicant by the letter specified in the Form 15 of the PFSB notification.

2. Guide on filling items regarding the contents of certification

2-1. “ DUNS Number” in “Part 1”

DUNS number is a business entity identification number assigned by Dun & Bradstreet, Inc. If a manufacturing site has the number, the applicant can voluntarily enter it.

2-2. “Manufacturing Operations” in “Part 2”

This section is required as essential information for the EU member states in the original input form defined by the EMA. The items that describe manufacturing operations in the form set out by the EMA are slightly different from those in Japan. Adequate items are to be selected from its predefined options prepared in EudraGMDP database by the applicant based on the operations actually ongoing in its own manufacturing site. Due to different terminology of manufacturing operations in Japan and the EU, MHLW bears no responsibility for the selection.

2-3. Information of a confidential nature

In regard to registration on EudraGMDP database, some manufacturers may keep their information as confidential to public users other than regulatory agency users on EudraGMDP database. In addition, even when the information is set to be open, the following information will be kept as confidential automatically.

i) The description of “Products” field in “Any restrictions or clarifying remarks related to the scope of this certificate” section
ii) Name, TEL/FAX number of the director of the division of MHLW in signatory section

However, the information above will be open to regulatory agency users of EudraGMDP database.

2-4. Validity period of the certification

The certification is valid for 3 years since the date of the last inspection described in the registered information on EudraGMDP database. When the certification is expired, the information registered on EudraGMDP database will be deleted.

Related Notifications and Notices

- "For Amendment of Issuing Certificates on Pharmaceuticals for Export", PFSB Notification No. 0628-19 dated June 28, 2013 issued by the Director General of Pharmaceutical and Food Safety Bureau (PFSB), MHLW (Japanese text only)

- "For Operations on Issuing Certificates on Pharmaceuticals for Export under Mutual Recognition Agreement", PFSB/CND Notification No. 0628-4 dated June 28, 2013 issued by the Director of Compliance and Narcotics Division (CND), Pharmaceutical and Food Safety Bureau (PFSB), MHLW (Japanese text only)

- "Points to be Considered on application of GMP certification under Mutual Recognition Agreement with European Union and Japan", PMDA Administrative Notice dated June 28, 2013 issued by Office of GMP/QMS Inspections; Office of Review Administration, PMDA. (Japanese text only)

- Annex: Outline of new application procedure for GMP certification (Japanese text only)