Press Release

Exemption of the EU’s regulatory control applicable to APIs exported from Japan to the European Union

6 June 2013

[Summary]
Japan is listed as one of the third countries with a regulatory framework applicable to Active Pharmaceutical Ingredients (APIs) for medicinal products for human use and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that of the European Union (EU). This enables manufactures in Japan to export APIs to the EU without obtaining a written GMP confirmation of Japanese authorities.

Having regard to the amendment of the Directive 2001/83/EC adopted by the European Parliament on 8 June 2011, the EU will enforce new regulation on APIs imported to the EU on and after 2 July 2013. Under the new regulation, each drug regulatory agency of exporting country will be required to confirm whether a manufacturing site is controlled based on an equivalent standard to the EU GMP requirements and issue a written GMP confirmation for every export, in order to ensure that the quality of APIs imported to the EU is equivalent to that of the EU. On the other hand, if a third country accepts an assessment by the EU and is recognized that the country’s pharmaceutical regulatory framework and the respective control and enforcement activities applicable to APIs are at the same level of the EU, the EU will include the country in the list of third countries which have exemption of a written GMP confirmation.
On 6 December 2013, the Ministry of Health, Labour and Welfare (MHLW) applied so that Japan could be included in the list. And then, the Japanese authorities and manufacturing sites had received the on-site assessment by the EU assessment team (The on-site assessment was conducted from 15 April 2013 to 22 April 2013). According to the notice published in the Official Journal of the European Union dated 4 June 2013, Japan is included in the list of third countries ensuring a level of protection of public health equivalent to that of the EU. This enables manufactures in Japan will export APIs to the EU without obtaining a written GMP confirmation of Japanese authorities.

References:
The Official Journal of the European Union dated 4 June 2013

MHLW Press Release: “Exemption of the EU’s regulatory control applicable to APIs exported from Japan to the European Union” dated 6 June 2013 (Japanese version)