22 March 2012

Directorate D
DG Health and Consumers (SANCO)
European Commission

RE: Comments on the Public Consultation
(SANCO/D3/(2011)ddg1.d3.1438409)

The attached is Comments of Government of Japan on Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medical Products for Human Use: Concept Paper for Public Consultation.

Yours sincerely,

Akihiro Nakajima
First Secretary
(health, pharmaceuticals, and social affairs)
Mission of Japan to the European Union

Tel:32-2-500-7751
akihiro.nakajima@mofa.go.jp

Attached

Comments on:
Implementing Act on the Requirements for the Assessment of the Regulatory Framework Applicable to the Manufacturing of Active Substances of Medical Products for Human Use: Concept Paper for Public Consultation

Government of Japan

22 March 2012

1. General Remarks

(1) The Directive 2011/62/EU contains an inequitable treatment that requires non-EU countries to certify GMP conformity for their API sites through inspection in the issuance of a written confirmation and the equivalence assessment, although the EU does not establish compulsory GMP inspection for all the API sites within the EU countries.

(2) The Government of Japan (GOJ) considers this Directive as a discriminatory non-tariff measure.

2. Comments on item n°4.2 (Interface with existing mechanisms)

(1) Even though an authority of each country can certify conformity with its own GMP standard, it is difficult for the authority to certify conformity with GMP standard of another country. In addition, Japan has considerable performances about GMP inspection for the API sites. Moreover, there is Japan-EU MRA in the field of pharmaceuticals.

(2) Therefore, the EU should not impose such a burden on non-EU countries but should confirm the equivalency with other countries by its own responsibility. GOJ considers that there is no problem if the EU continues to accept the existing GMP certificates of conformity with Japanese GMP standard in accordance with the current system.