EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Director

Brussels, 14 JUIL. 2015
GROW D4/LS/bw/ARES(2015)3225846

Subject: EU-Japan Confidentiality Arrangement on Medical Devices

Dear Sirs,

On 28 October 2009, the European Commission's Directorate General Enterprise and Industry on the one side and the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the other side exchanged letters establishing a Confidentiality Arrangement to exchange regulatory information including advanced drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medical devices. This Arrangement was concluded for a period of five years.

In 2009, the European Commission transferred the responsibility related to the EU legislation on medical devices from Directorate General Enterprise and Industry to Directorate General Health and Consumers without affecting the Arrangement. In January 2015, two months after the expiration of the arrangement, this responsibility has been further transferred to the Directorate General Internal Market, Industry, Entrepreneurship and SME's.

Considering that all parties have assessed the effectiveness of the Arrangement and found it to be a useful tool for regulatory cooperation, the new arrangement proposed in the annex keeps the provisions of the expired arrangement and is concluded for a new period of five years with tacit renewal for subsequent periods of five years.

We look forward to continuing cooperative activities to further enhance our relationship in the best interest of public health.

Yours faithfully,

Carlo Pettinelli

Yuji Kanda
Director General
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices Agency

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: BREY 12/088 - Tel. direct line +32 229-63420 - Fax +32 229-66467 – e-mail: Laurent.Selles@ec.europa.eu

EUROPEAN COMMISSION
Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs

Consumer, Environmental and Health Technologies
Director

Brussels, 14 JUIL. 2015
GROW D4/LS/bw/ARES(2015)3225846

Subject: EU-Japan Confidentiality Arrangement on Medical Devices

The European Commission's Directorate General Internal Market, Industry, Entrepreneurship and SME's (DG GROWTH) on the one side and the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan on the other side, (collectively "the Participants"), have recognised the need to further improve their working relationship, including the need for increased cooperation in the field of regulations of medical devices as a means to better protect health and safety and to reduce technical barriers to trade affecting these products.

This exchange of letters should further enhance and strengthen the cooperation between the European and the Japanese authorities, notably in the framework of the International Medical Device Regulators Forum (IMDRF). We expect this cooperative activity to further enhance and strengthen communication between our respective organizations and further enhance public health promotion and protection in the European Union (EU) and Japan. In this context, the Participants see value in exchanging more regulatory information including advance drafts of legislation and/or regulatory guidance documents as well as information related to regulatory policies and practices in their respective regions.

Because this type of information may include information of a non-public nature, both sides should, to the extent permitted by their respective national and regional laws and regulations, keep the information exchanged confidential.

The information sharing based on this exchange of letters is intended, among other things, to help regulators on both sides to take informed decisions with regard to regulatory policies and practices in their respective regions. This cooperation should not compromise each Participant's ability to carry out its responsibilities and should not create any kind of legal obligation on the side of both Participants.

Yuji Kanda
Director General
Pharmaceutical and Food Safety Bureau
Ministry of Health, Labour and Welfare

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices Agency

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
Office: BREY 12/088 - Tel. direct line +32 229-63420 - Fax +32 229-66467 – e-mail: Laurent.Selles@ec.europa.eu

Therefore, DG GROWTH is pleased to cooperate with the MHLW and the PMDA to facilitate the sharing of documents and/or information related to ensuring the quality, safety and efficacy, as appropriate, of medical devices.

This cooperation activity will strengthen communication between public authorities involved in these activities and reinforce public health protection.

The language for the exchange of information will be English, and the type of information that may be shared includes, but is not limited to:

- Advanced drafts of pending laws, regulations, guidance documents, procedures and other technical documents available to the individual Participants related to medical devices.

- As far as known to the Participants, post-marketing data and information that could have an impact on public health, or information about impending regulatory actions.

- As far as known to the Participants, information on quality defects or product recalls of these products known by the MHWL and/or the PMDA to have been manufactured or distributed in the EU, and vice versa.

- As far as known to the Participants, data and information regarding medical device manufacturers and medical device Auditing Organisations which are gathered by the EU, the MHLW and/or the PMDA in the context of their regulatory activities as well as of international projects undertaken by both parties.

The Participants can limit the scope of the abovementioned information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individuals and of privacy, the public interests of the EU or Japan, or DG GROWTH's, MHLW's or PMDA's interest in the confidentiality of their proceedings. In some cases, exchange of information based on this exchange of letters may be subject to prior authorisation from the companies concerned.

The Participants note that it is an essential element of this exchange of letters on regulatory cooperation that confidential information emanated from one Participant will be treated as such by the other Participant.

On each occasion where there is a request for disclosure to third parties of non-public information received from DG GROWTH, the MHLW or the PMDA should consult with DG GROWTH. Likewise, on each occasion where there is a request for disclosure of non-public information received from the MHLW or the PMDA, DG GROWTH should consult with the MHLW or the PMDA.

The DG GROWTH affirms that it has the authority to maintain the confidentiality of non-public information, including confidential commercial information, provided to its officials or representatives by the MHLW and the PMDA, and will protect such information as information not to be disclosed under Article 4 of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents[1].

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32001R1049

Similarly, the MHLW and the PMDA should affirm that they have the authority to maintain the confidentiality of non-public information, including confidential commercial information, provided to their officials or representatives by DG GROWTH, and will protect such information as information not to be disclosed under Article 5 of Act on Access to Information Held by Administrative Organs (Act No.42 of 1999), which protects non-public information from further disclosure. The MHLW and the PMDA should recognise that DG GROWTH considers it crucial that this non-public information is protected from disclosure; otherwise, the relations between the Participants could be endangered. The MHLW and the PMDA should recognise that "confidential commercial information" includes information referred to in Regulation (EC) No 1049/2001 and in the Japanese Act on Access to Information Held by Administrative Organs (Act No.42 of 1999).

Each Participant will promptly inform the other of any changes to relevant laws, regulations, policies, or procedures that would affect the ability of the Participant to honour the mutual commitments set in this exchange of letters.

This letter, together with your letter on behalf of the MHLW and the PMDA, will constitute mutual intent for cooperation between the Participants, and the cooperative relationships proposed and defined in this exchange of letters will commence on the date of this letter.

This arrangement is applicable for a period of five years with tacit renewal for subsequent periods of five years.

We look forward to implementing this exchange of letters allowing for the sharing of non-public information in accordance with our respective national and regional laws and regulations, including Regulation (EC) No 1049/2001 and the Japanese Act on Access to Information Held by Administrative Organs (Act No.42 of 1999), and to continuing cooperative activities to further enhance the relationship between DG GROWTH and the MHLW and the PMDA, in the best interest of public health.

Yours sincerely,

Carlo Pettinelli