



EUROPEAN COMMISSION

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

Consumer, Environmental and Health Technologies
Director

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

Subject: EU - Japan Confidentiality Arrangement on Cosmetics

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 cosmetic products. This Arrangement was concluded for a period of five years.

In 2010 the European Commission transferred the responsibility related to the EU legislation on cosmetic products 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 annex is maintaining 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



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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 in particular for increased cooperation in the field of regulation of cosmetic products including those Japanese quasi-drugs defined as cosmetics in the EU as a means to better protect health and safety and to reduce technical barriers to trade affecting these products.

There is already some degree of cooperation between the authorities, notably in the framework of the International Cooperation on Cosmetic Regulation" ("ICCR").

However there has been an expectation from the both sides of the Participants to complement this multilateral forum by bilateral policy and regulatory cooperation.

In this context, the Participants see value in exchanging letters in order to exchange more regulatory information including advanced drafts of legislation and/or regulatory guidance documents as well as information related to the supervision of cosmetic products. 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 potential benefits of this exercise are expected to include aligned regulatory approaches to identical issues and improved in-market control. This cooperation shall 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.

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 safety of cosmetic products.

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

Tatsuya Kondo
Chief Executive
Pharmaceuticals and Medical Devices Agency

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 cosmetics.
- 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 MHLW and/or the PMDA to have been manufactured or distributed in the EU, and vice versa.

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 the PMDA's interests 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 should 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 documents¹.

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 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

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

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 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