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swissmedic

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Berne, 10 July 2015

Dear Mr. Miko, dear Mr. Pott,

I have the honor to acknowledge receipt of your letter of 9 July 2015, which reads as follows:

"The Swiss Federal Department of Home Affairs (FDHA) and Swissmedic, the Swiss Agency for Therapeutic Products (Swissmedic) as executing Agency, on the one side and the European Commission's Directorate General Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) on the other side (collectively "the Participants") have recognised the need to further improve their relationship including the need for increased co-operation as a means to better protect health and to address technical barriers to trade in goods.

There is already considerable experience in the field of regulatory and administrative cooperation between the participants in the pharmaceutical sector. To date, this has been in the context of the Agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessment (OJ L 114 30.4.2002, p.369), the EMA – Swissmedic arrangement for shared non-public information regarding the influenza A (H1N1) pandemic dated 12 February 2010, and informal collaboration in the framework of the International Conference on Harmonisation (ICH).

In this context, DG SANTE together with the EMA and Swissmedic on behalf of the FDHA see value in establishing an administrative arrangement to exchange more regulatory information for the purpose of accelerating access of patients and animals to new and innovative medicines; resource savings due to reduced duplication of assessment and improved performance and safety as a result of the involvement of the best regulatory expertise from both sides. This co-operation does not intend to compromise each Participant's ability to carry out its responsibilities neither does it intend to result in creating rights or obligations under international law on the part of the Participants.

This arrangement covers medicinal products for either human or animal use regulated by the Participants' legislation. Therefore, DG SANTE and the EMA are pleased to cooperate with

Swissmedic to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal products for human and veterinary use, authorised or under review both in Switzerland and in the European Union (EU).

In the EU, "medicinal products for human use" and "medicinal products for veterinary use are defined in Article 2(1) of REGULATION (EC) No 726/2004 in conjunction with Directive 2001/83/EC and Directive 2001/82/EEC. The arrangement covers Medicinal products for human or veterinary use which come within the scope of EMA's activities

In Switzerland, medicinal products for human use and medicinal products for veterinary use are defined in Article 4 (a) of the Swiss Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA).

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

The type of information that the Participants may wish to share includes, but is not limited to:

1. *Legislation and guidance documents available under the rules and regulations governing medicinal products in the EU and in Switzerland. This also includes position papers, notes for guidance and any other guidance documents either in draft, finalised or released for consultation.*

2. *Post-authorisation pharmacovigilance data, particularly those of an urgent nature related to EU or non-EU originating adverse drug reactions as well as safety concerns arising from periodic safety update reports and post-authorisation obligations and commitments.*

3. *Information contained in applications for scientific advice, orphan medicine designation, marketing authorisation or post-authorisation activities of significant public health interest, and applications for agreement of paediatric investigation plans.*

4. *Pharmacovigilance and Good Clinical Practices (GCP) inspection reports and information that come within the scope of the participants' activities.*

The Participants acknowledge that this arrangement does not affect the Participants' right to limit the scope of the above information should its dissemination or exchange undermine specific interests, including commercial, industrial or professional secrecy, the protection of the individual and of privacy, the public interests of the EU and Switzerland or the protection of the Participants' interests in the confidentiality of their proceedings.
When the above information contains personal data, those personal data may only be transmitted by DG SANTE and EMA in accordance with the provisions of Regulation (EC) No 45/2001 and Commission Decision 2000/518/EC, similarly, by Swissmedic in accordance with the provisions of the Federal Act on Data Protection, the Freedom of Information Act as well as the Therapeutic Products Act.
In situations where the exchange of information may affect the rights of third parties, in particular commercial interests of a natural or legal person, including intellectual property, both sides declare to decide on a case by case analysis in accordance with their respective laws in order to

ensure that such information is treated to the extent permitted by their respective laws. In some cases, exchange of information under this arrangement may be subject to prior authorisation from the concerned third party.
For the purposes of this arrangement information may be shared with persons within the respective organisations who are bound by obligations of confidentiality, as defined in their respective laws.
For DG SANTE and the EMA "persons within its organisation" include DG SANTE and EMA staff members, national experts on secondment, experts participating in EMA activities and members or experts participating at its scientific committees, working parties and expert groups. By analogy DG SANTE and EMA may share information received from Swissmedic with representatives of EU Member States Regulatory Authorities provided that they are required to ensure similar obligations of confidentiality.
For Swissmedic, "persons within its organisation", include Swissmedic staff members and experts participating in Swissmedic's medicines expert committees.
DG SANTE and the EMA affirm that they have the authority to protect non-public or confidential information, including confidential commercial information provided by Swissmedic, and that such information should be protected from disclosure under Article 4.2, first indent, Article 4.1(b) and/or Article 4.1(a) of Regulation (EC) No 1049/2001. DG SANTE and the EMA understand that Swissmedic considers it crucial that this non-public information be protected from disclosure to any person not identified in this arrangement; otherwise, it could endanger the privacy and integrity of individuals, the commercial interests of the entities concerned and/or the international relations between the Participants.

Similarly, Swissmedic affirms that it has the authority to protect non-public or confidential information, including confidential commercial information, provided by DG SANTE or the EMA, and that such information should be protected from disclosure under current Swiss data protection and freedom of information legislation (Article 9 of the Federal Act on Data Protection; Article 7 and Article 9 of the Freedom of Information Act) and under the secrecy and data confidentiality provisions of the Therapeutic Products Act (Article 61 and Article 62). Swissmedic understands that DG SANTE and the EMA consider it crucial that this non-public information be protected from disclosure to any person not identified in this arrangement; otherwise, it could endanger the privacy and integrity of individuals, the commercial interests of the entities concerned and/or the international relations between the Participants.

On each occasion where there is a request for disclosure to third parties of non-public information received from DG SANTE or the EMA, Swissmedic is expected to consult with DG SANTE or the EMA. Likewise, on each occasion where there is a request for disclosure of non-public information received from Swissmedic, DG SANTE or the EMA is expected to consult with Swissmedic.

This arrangement is intended to apply for a period of five years with tacit renewal for subsequent periods of five years. The Participants may withdraw at any time from the arrangement. Information about the intention to withdraw should be given to the other Participant at least one month in advance.
It is understood that the requirements regarding confidentiality should continue to apply to any information shared prior to the withdrawal.

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This co-operation does not intend to compromise each Participant's ability to carry out its responsibilities neither does it intend to result in creating rights or obligations under international law on the part of the Participants.

We would be grateful if you could confirm this exchange of letters and look forward to furthering cooperation in the field of sharing of information and to other activities to further enhance the relationship between Swissmedic, DG SANTE, and the EMA in the best interests of public health."

I have the honour to inform you that the foregoing corresponds to the intentions of Swissmedic on behalf of the FDHA and that your letter, together with the present letter in reply constitutes a not legally binding arrangement between the Participants, coming into effect on the date of the present reply.

I avail myself of this opportunity to renew to you the assurances of my highest consideration.

Yours sincerely,

Swissmedic, Swiss Agency
for Therapeutic Products
Executive director

Jürg H. Schnetzer