EUROPEAN COMMISSION
**DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY**

**Acting Director-General**

EUROPEAN MEDICINES AGENCY

EMA/512920/2015

Dear Dr Marie-Paule Kieny,

**Subject: Working Arrangement to exchange non-public information on medicinal products between DG SANTE/EMA and WHO**

As you are aware, the pharmaceutical legislation in the European Union, has since 1993, provided for collaboration between the European Commission and the European Medicines Agency and WHO on many aspects of medicines regulation including pharmacovigilance, and, since 2004, provision of scientific opinions on medicinal products for human use that are intended exclusively for markets outside of the EU. We also share a long history of scientific and technical collaboration between our respective organisations at a multilateral level, most notably in the context of the International Conference on Harmonisation (ICH) and the International Pharmaceutical Regulators Forum (IPRF).

In view of further strengthening our collaboration, the Arrangement in Annex will enable to increase the exchange of regulatory information for the purpose of accelerating access of patients and animals to new and innovative medicines; saving resources due to reduced duplication of assessment and improving performance and safety as a result of the involvement of the best regulatory expertise from both sides.

We would be grateful if you could confirm this Arrangement and look forward to continuing cooperative activities to further enhance our relationship in the best interests of public health.

L. Miko
European Commission
Health and Food Safety Directorate General
Acting Director General

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EMA/512919/2015

Dear Dr Marie-Paule Kieny,

The World Health Organization (WHO) on the one side and European Commission's Directorate General Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) on the other side (each a "Participant" and collectively "the Participants") have recognized a need for a working arrangement to enable the exchange of specific scientific and technical information and documents related to the safety, quality, efficacy and post-authorization follow-up of medicinal/pharmaceutical products for human use that come within their respective responsibilities.

This cooperation activity will strengthen communication between the respective organisations and will reinforce global public health protection.

In this context, DG SANTE together with the EMA and WHO see value in establishing an working arrangement to exchange regulatory and other similar information, which may include confidential medicinal or pharmaceutical product information; commercial information; or internal operational information.

This type of information may include information of a non-public confidential and/or proprietary nature ("non-public information"). Both sides therefore accept to keep exchanged information confidential, to the extent permitted by their respective applicable legislation and/or organisations' policies, and as set forth in this arrangement.

Therefore, DG SANTE, the EMA and WHO are pleased to cooperate with each other to facilitate the sharing of documents and/or information related to ensuring the safety, quality, and efficacy of medicinal/pharmaceutical products for human use, authorised or under review in the European Union (EU) or prequalified or under review by WHO.

The Participants are willing to provide each other access to documents and/or information as aforesaid (collectively "information") exclusively for use in the performance of their respective duties with regard to medicinal/pharmaceutical products for human use as well as for the protection of public health ("the Purpose").

The information that the Participants may wish to share includes, by way of example:

- 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.

- 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.

- Inspections concerning specific products, manufacturing facilities and clinical research activities and related reports.

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This arrangement covers medicinal/pharmaceutical products for human use under the respective responsibilities of the Participants as follows:

In the EU, "medicinal products for human use" is defined in Directive 2001/83/EC [1] and the arrangement covers medicinal products which fall within the scope of EMA's activities as defined in Regulation (EC) No. 726/2004[2].

For WHO 'pharmaceutical products', means those defined in the WHO Technical Report Series No.953, 2009 Annex 3 and WHO Technical Report Series No.978, 2010 Annex 6, meaning those subject to evaluation by WHO according to the Procedure for prequalification of pharmaceutical products and vaccines.

The Participants affirm they have the authority to ensure that all persons considered as "within the respective organizations" of the Participants are bound by similar obligations of confidentiality and restrictions on use as contained in this arrangement.

Information exchanged hereunder may be shared by a receiving Participant with persons within its organisation who have a need to know for the Purpose and are bound by similar obligations of confidentiality and restrictions on use as contained herein.

For DG SANTE and EMA "persons within its organisation" include DG SANTE staff members 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, the EMA may share information received from WHO with representatives of Member States Regulatory Authorities of European Economic Area with whom EMA has entered into a cooperation agreement which covers the exchange of confidential information. EMA accepts to ensure that the above representatives of Member States Regulatory Authorities of EEA are made aware of the confidentiality and restrictions on use regime set forth in this arrangement and agree to comply therewith.

For WHO, "persons within its organization", includes WHO staff members, persons on secondment to WHO, consultants, collaborating experts and advisers.

This arrangement does not affect the Participants' right to limit the scope of information to be exchanged hereunder, should its dissemination or exchange undermine specific interests or violate legal obligations, including those imposed on the Participants by applicable legislation and/or organisations' policies, including in respect of commercial, industrial or professional secrecy, the public interests or the protection of a Participant's interests in the confidentiality of its proceedings. In some cases, exchange of information under this arrangement may be subject to prior authorisation from third parties concerned, including the person and/or organisation from which the information emanated.

The Participants agree that it is an essential element of this arrangement that non-public information emanating from the other Participant is treated as confidential, and is used only for the Purpose.

On each occasion where there is a request for disclosure to third parties of information received from DG SANTE or the EMA, WHO will consult with DG SANTE or the EMA. Likewise, on each occasion where there is a request for disclosure to third parties of information received from WHO, DG SANTE or the EMA will consult with WHO. In cases where a Participant considers that disclosure to third parties may violate its specific interests or legal obligations, the other Participant affirms it has the authority to and agrees not to disclose the information in question in order to protect this working arrangement and therefore the international relations between the Participants[3].

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[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency

[3] in cases where the request is addressed to DG SANTE / EMA, subject to the rules laid down under Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents. .

This arrangement is applicable for a period of five years with tacit renewal for subsequent periods of five years. Notwithstanding the termination of this arrangement for whatever reason, the obligations of confidentiality and restrictions on use in respect of non-public information exchanged hereunder shall survive such termination, unless and until such information becomes public through no fault of the recipient.

Nothing in this arrangement shall be interpreted as a waiver of any privileges or immunities accorded to WHO by its constituent documents or international law.

DG SANTE and the EMA would be grateful if WHO would acknowledge receipt of this letter and confirm that this letter and your reply constitute the arrangement set out above between our services.

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 look forward to furthering cooperation on the basis of this arrangement allowing for the sharing of non-public information and to further enhance the relationship between WHO, DG SANTE and the EMA in the best interests of global public health.

Ladislav Miko
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A. Pott
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