The Director

Prof. Dr Guido Rasi
Executive Director
European Medicines Agency

Dr Anne Bucher
Director General
European Commission
Directorate General Health & Food Safety

RZ/PH/2019-02000L
SK/EPo

Strasbourg, 25 March 2019

ACCEPTANCE OF WORKING ARRANGEMENT BY EDQM (ANSWER TO COVER NOTE)

Dear Dr Bucher, dear Prof Rasi,

I refer to your letter dated 22 March 2019, setting out a working arrangement between the European Commission's Directorate General Health and Food Safety (DG SANTE) and the European Medicines Agency (EMA) on one side and the European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe on the other side.

I am pleased to confirm that your letter together with this reply will constitute the working arrangement between our respective organisations regarding the exchange of information and documents as aforesaid.

EDQM welcomes this cooperation with DG SANTE and EMA, which will further strengthen and reinforce public health protection.

Yours sincerely,

[redacted]

Dr Susanne Keitel
Director

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European Commission

Directorate-General for Health and Food Safety (DG SANTE)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/188400/2019

Dear Dr Keitel,

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

As you are aware, in the framework of the International Conference on Harmonisation (nowadays, the International Council for Harmonisation)[1], a consensus was reached in 2000 to provide a harmonised format and terminology for a Common Technical Document through which a homogeneous organisation and presentation of a marketing authorisation application dossier for human medicinal products could be achieved. Accordingly, the pharmaceutical legislation in the European Union has since 2003 provided for collaboration between the European Commission and the European Medicines Agency (EMA) and the Council of Europe, European Directorate for the Quality of Medicines and HealthCare (EDQM) on several aspects related to the requirements governing the regulation of medicinal products in the European Union.

The cooperation between the European Commission, the EMA and the EDQM has its legal basis in the EU pharmaceutical legislation, notably in Directives 2001/82/EC and 2001/83/EC (as amended) of the European Parliament and of the Council on the Community code relating to medicinal products for veterinary and human use respectively and this cooperation is important in the context of globalisation in order to achieve common objectives in the most efficient manner while maintaining a high level of health and safety.

EDQM, the European Commission and EMA share the same goals of protecting public health and ensuring the quality of medicinal products, as well as a long history of scientific and technical collaboration between our respective organisations. The EDQM staff has participated regularly in, and provided expertise to several EMA committees, working parties and working groups over the years, while at the same time the European Commission and EMA staff have participated in, and provided expertise to the European Pharmacopoeia Commission, its expert groups, several advisory groups of the European network of Official Medicines Control Laboratories, the steering committee of the Certification of Suitability to the Monographs of the European Pharmacopoeia Procedure, as well as the steering committee of the Biological Standardisation Programme.

To further strengthen our collaboration, the appended Arrangement will facilitate the exchange of regulatory information, save resources and improve performance as a result of involvement of regulatory expertise from both sides, while applying applicable legislation relating to the protection of personal data and non-public information (including commercially confidential information).

[1] https://www.ich.org/home.html.

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We would be grateful if you could acknowledge receipt of this letter and confirm your agreement whereby this letter and your reply constitute the Arrangement set out in the appendix. We look forward to continuing our cooperation in the best interests of global public health.

Anne Bucher
European Commission
Directorate General Health and Food Safety
Director General

Guido Rasi
European Medicines Agency
Executive Director

European Commission
Directorate-General for Health and Food Safety (DG SANTE)

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/188401/2019

Dear Dr Keitel,

The European Directorate for the Quality of Medicines and HealthCare (EDQM) of the Council of Europe 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 recognised the need for a working arrangement (this "Arrangement") to enable the exchange of specific scientific and technical information and documents related to the safety, quality and efficacy of medicinal products that come within their respective responsibilities.

In this context, the Participants see value in establishing the present Arrangement to exchange regulatory and other similar information, which may include non-public information exempt from public disclosure, such as commercially confidential information, personal data, or pre-decisional information.

The Participants may wish to share certain specific scientific and technical information and documents (collectively "information") exclusively for use in the performance of their respective duties with regard to medicinal products ("the Purpose").

This type of information may include information of a non-public nature ("non-public information") in the cases in which such information may be lawfully shared under the conditions, if any, set out in the applicable legislation and in compliance with this working arrangement. Both sides therefore accept to keep the exchanged information confidential, to the extent permitted by their respective applicable legislation and/or organisations' policies, and as set forth in this Arrangement.

Such information may include, but is not limited to:

- Inspections concerning specific medicinal products and their active substances, manufacturing facilities and clinical research activities and related reports
- Post-approval surveillance and activities of the European network of Official Medicines Control Laboratories (OMCL), including the Sampling and Testing Programme of Centrally Authorised Products
- Draft Pharmacopoeia monographs, draft Herbal Medicinal Products monographs, drafts of EMA guidelines and Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) guidelines as well as summary reports of working groups
- EMA assessment reports and EDQM assessment reports related to certification of suitability to the monographs of the European Pharmacopoeia.

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.

This Arrangement covers medicinal products, including their active substances, for either human or veterinary use, governed by the European Union (EU) legislation and the Convention on the Elaboration of a European Pharmacopoeia, as follows:

In the EU, "medicinal products for human use" as defined in Directive 2001/83/EC[1] and "medicinal products for veterinary use" as defined in Directive 2001/82/EC[2], authorised either through the

[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] Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products.

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centralised procedure or nationally, which fall within the scope of EMA's activities as defined in Regulation (EC) No 726/2004[3].

For the Council of Europe, the definition of "medicinal products for human or for veterinary use" is laid down in the Standard Terms: Introduction and Guidance for Use (version 2.1.3)[4] published by the EDQM.

The Convention on the Elaboration of a European Pharmacopoeia (Ph.Eur.) entered into force in May 1974 and was ratified by all of the EU Member States, in addition to a number of non-EU European countries. The Ph. Eur. aims to harmonise specifications for medicinal substances in their original state or in the form of pharmaceutical preparations and is legally binding in States which are signatories to the Convention on the Elaboration of a European Pharmacopoeia.

The arrangement covers all quality-related issues including counterfeiting/falsification of medicines and/or substances for pharmaceutical use as defined by EU legislation, where these substances are used.

For the purposes of this arrangement, information exchanged may be shared with persons within their respective organisations who are bound by obligations of confidentiality and professional secrecy, as defined in their respective laws and in accordance with the restrictions on use as contained in this Arrangement.

Information exchanged hereunder may be shared by a receiving Participant with persons within their organisation who have a need to know basis for the Purpose and are bound by similar obligations of confidentiality and professional secrecy, as defined in their respective laws and in accordance with the restrictions on use as contained herein.

For DG SANTE and EMA, "persons within their organisation" who are bound by obligations of confidentiality and professional secrecy include DG SANTE staff members and EMA staff members, national experts on secondment, members or experts participating at its scientific committees, working parties, working groups and expert groups and in other EMA activities. EMA may, therefore, share information received from EDQM with representatives of national competent authorities in the EEA with whom EMA has entered into a cooperation agreement that covers the exchange of confidential information. EMA accepts to ensure that the above representatives of national competent authorities in the EEA are made aware of the confidentiality and restrictions on use regime set forth in this arrangement and agree to comply therewith. Provision should be made to ensure that the exchange of information foreseen under this Arrangement should not extend to persons who work in the pharmaceutical industry.

For EDQM, "persons within its organisation" who are bound by obligations of confidentiality and professional secrecy include EDQM staff members and persons on secondment to EDQM, members or experts participating in its scientific Commissions, committees, working parties and expert groups and EDQM activities, but only when they belong to a national competent authority or an OMCL in the States which are signatories to the Convention on the Elaboration of a European Pharmacopoeia. In this regard, provision should be made to ensure that the exchange of information foreseen under this Arrangement should not extend to members or experts who do not work for a national competent authority or an OMCL in the States which are signatories to the Convention on the Elaboration of a European Pharmacopoeia, in particular, to persons who work in the pharmaceutical industry.

This Arrangement does not affect each Participant's 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, protection of personal data 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 or relates to.

[3] 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.

[4] https://www.edqm.eu/sites/default/files/standard_terms_introduction_and_guidance_for_use.pdf.

In case personal data would be transferred by DG SANTE or EMA to EDQM under this Arrangement, such transfers shall be carried out in compliance with Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data[5]. Similarly, EDQM will ensure that it will process personal data, as required, in accordance with the Secretary General's Regulation of 17 April 1989 outlining a data protection system for personal data files in the Council of Europe.

In situations where the exchange of information may affect the rights of third parties, in particular commercial interests of a legal or natural 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 in accordance with their respective applicable laws.

DG SANTE and the EMA affirm that they have the authority to protect from disclosure such non-public information, including commercially confidential information provided to DG SANTE and/or EMA in confidence by EDQM, if and insofar as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001[6]. DG SANTE and the EMA understand that the EDQM 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 parties.

Similarly, EDQM affirms that it has the authority to protect non-public information, including commercially confidential information, provided by the DG SANTE or the EMA, and that such information should be protected from disclosure in accordance with the terms and conditions of this Arrangement. EDQM 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 parties. EDQM will apply its own policy in accordance with Resolution [Res(2001)6] on access to Council of Europe documents on classification of documents to any documents submitted by the EMA or DG SANTE.

On each occasion where there is a request for disclosure to third parties of information received from DG SANTE or the EMA, EDQM 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 EDQM, DG SANTE or the EMA will consult with EDQM.

This Arrangement is applicable for a period of five years with tacit renewal for subsequent periods of five years. In case of future changes in the organisation chart of the European Commission regarding assignment of responsibilities between different Directorates-General, this confidentiality arrangement will continue to be applicable to the Directorate-General of the Commission which has within its remit responsibility for medicinal products. 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.

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.

[redacted]

Anne Bucher
European Commission
Directorate General Health and Food Safety
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[redacted]

Guido Rasi
European Medicines Agency
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[5] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

[6] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.