European Commission | EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | PIC/S

Working Arrangement between
DG SANTE/EMA and PIC/S
for the exchange of non-public information
on medicinal products

The Pharmaceutical Inspection Co-operation Scheme (PIC/S), an Association under the Swiss Code of Civil Law (Art. 60 ff), on the one side, and the European Commission's Directorate-General for 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 confidentiality arrangement (this "Arrangement") to enable further increased co-operation as a means to better protect public and animal health and facilitate access to safe, effective and high quality medicinal products.

In this context, the Participants see value in establishing the present Arrangement to exchange regulatory and other similar information, which may include, inter alia, information of a non-public confidential and/or proprietary nature ("non-public information"). The non-public information to be exchanged will notably be in the field of Good Distribution and Manufacturing Practice (GMDP) standards of medicinal products for human use or veterinary medicinal products and will be exchanged in the framework of the "Co-operation between the Directorate General for Health and Food Safety and the Pharmaceutical Inspection Co-operation Scheme" of 19th July 2022 and the "Co-operation between the European Medicines Agency and the Pharmaceutical Inspection Co-operation Scheme" of 28 December 2010. 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.

The Participants may wish to share certain specific scientific and technical information and documents (collectively "information") related to ensuring the safety, efficacy and quality of health/medicinal products , exclusively for use in the performance of their respective duties with regard to medicinal products, as well as for the protection of public and animal health ("the Purpose").

In this context, in the European Union, "medicinal products" refers to "medicinal products for human use" as defined in Directive 2001/83/EC[1] and "veterinary medicinal products" as defined in Regulation (EU) 2019/6[2] authorised either through the centralised procedure or nationally, which fall within the scope of EMA's activities as defined in Regulation (EC) No 726/2004. In PIC/S, "medicinal product" means: "(a) any pharmaceutical, medicine or similar product intended for human or veterinary use which is subject to control by health legislation, and (b) any active pharmaceutical ingredient (API) or excipient which the manufacturer uses in the manufacture of a product referred to in sub-paragraph (a) above." (paragraph 5 of PIC Scheme, PIC/S 1/95 (Rev. 6)).

The scope of this Arrangement may include, but is not limited to, the exchange of information in the following areas:

1. Activities related to the regulation of health/medicinal products for safety, efficacy and quality, such as licensing, authorization of clinical trials, product labelling, and the development of policies and guidance;

[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 (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

2. Activities related to compliance monitoring such as the collection, monitoring and analysis of adverse reactions or incident data as well as benefit-risk assessments, and policy development to regulate marketed health products; and,

3. Compliance and enforcement activities with regard to health/medicinal products, such as inspections, audit reports, compliance verification, recalls, investigations and enforcement measures and risk assessment.

For the purposes of this Arrangement, non-public information may be shared by a receiving Participant with persons within their respective organisations on a need to know basis and who are bound by obligations of confidentiality and professional secrecy, as defined in their respective laws and policies and in accordance with the restrictions on use as contained in this Arrangement.

For PIC/S, "persons within their organisation" includes PIC/S employees, agents, contractors, experts or expert committees[3] who a) require the information solely for work purposes in respect of this Arrangement, b) will only use that information for purposes contemplated by this Arrangement; and c) will have a legally enforceable obligation, such as, but not limited to, an employment contract, an agency agreement, confidentiality contract or other document that permits those persons to use the information for the purposes of this Arrangement and requires them to protect the confidentiality of the information in accordance with the laws and policies that are applicable to PIC/S. PIC/S understands that this non-public information is shared in confidence and that DG SANTE/EMA considers it critical that PIC/S, including its Participating Authorities and Associated Partner Organisations, maintains the confidentiality of the information.

For DG SANTE and EMA, "persons within their organisation" includes DG SANTE staff members and EMA staff members, national experts on secondment, members or experts participating at their scientific committees, working parties, working groups and expert groups and in other DG SANTE and EMA activities. EMA may, therefore, share information received from PIC/S with representatives of national competent authorities in the EEA with whom EMA has entered into a co-operation 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.

This Arrangement does not affect each Participant's right to limit the scope of the above 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 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. 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.

This Arrangement is not intended to contain data that is personal and the Participants intend to make all reasonable efforts to ensure that personal data is not shared or exchanged with each other. If one Participant discovers that personal data has been provided or received inadvertently, the Participant intends to immediately inform the other Participant. The recipient Participant intends to take immediate and appropriate measures to permanently destroy the record(s) containing personal data in accordance with applicable laws and the providing Participant intends to provide an updated record with personal data removed. In case information on legal persons identifies a natural person, both Participants intend to consider such information as personal data and treat it according to the above paragraphs.

[3] PIC/S may share information received from DG SANTE or the EMA with representatives of Participating Authorities who have signed a declaration of confidentiality with PIC/S, which covers the exchange and protection of confidential information. PIC/S agrees to ensure that the above representatives of Participating Authorities are made aware of the confidentiality and restrictions on use regime set forth in this Arrangement and agree to comply therewith.

In case personal data would be transferred under this Arrangement, the personal data may be transmitted by PIC/S in accordance with the applicable laws and policies pertaining to PIC/S. Similarly, in case personal data would be transferred by DG SANTE or EMA under this Arrangement, such transfers shall be carried out in compliance with Regulation (EU) 2018/1725.[4]

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.

DG SANTE and EMA confirm that they have the authority to protect non-public information, including commercially confidential information provided by PIC/S, if and insofar as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001[5] as interpreted by the Court of Justice of the European Union. DG SANTE and the EMA understand that PIC/S 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 international relations between the Participants.

Similarly, PIC/S confirms that it has the authority to protect non-public information, including confidential information, provided by DG SANTE or the EMA, as information not to be publicly disclosed. PIC/S understands that DG SANTE and 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, PIC/S 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 PIC/S, DG SANTE or the EMA will consult with PIC/S.

In case of future changes in the organisation chart of the European Commission regarding assignment of responsibilities among Directorates-General, this confidentiality arrangement will continue to be applicable to the Directorate(s)-General of the European Commission, which has/have within its/their remit responsibility for medicinal products for human or veterinary use.

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.

The Participants may amend this Arrangement at any time upon their mutual written consent. Either Participant may terminate this Arrangement by giving the other Participants thirty (30) days written notice of its intent to terminate.

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 is not legally binding.

[4] 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.
Pursuant to the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[5] 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.

Signed on behalf of DG SANTE:

Qualified electronic signature by:
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Date

Signed on behalf of EMA

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Signed on behalf of PIC/S

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