

**CO-OPERATION ARRANGEMENT BETWEEN
THE DIRECTORATE GENERAL FOR HEALTH AND FOOD SAFETY (DG
SANTE)**

AND

THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)

1. Objective of this Co-operation Arrangement

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Commission's Directorate-General for Health and Food Safety (DG SANTE) recognising that they share a common goal to protect public and animal Health and Safety, have agreed to enter into this working arrangement to cooperate in areas of common interest.

The co-operation will notably be on Good Manufacturing and Distribution Practice (GMDP) standards and their implementation processes for medicinal products for human or veterinary use with a view to make best use of available resources and avoid duplication of activities. DG SANTE has very close relations and interactions as part of the EU Regulatory Network with the European Medicines Agency (EMA) that has its own co-operation agreement with PIC/S. Also the Heads of Medicines Agencies of the European Economic Area (HMA) has signed a letter of agreement with PIC/S. The co-operation under this arrangement will be complementary to those co-operations.

2. Co-operation activities

The co-operation focuses notably on the following activities:

2.1 Participation in each other's meetings:

A representative of DG SANTE may participate in PIC/S Committee meetings in the capacity of PIC/S Associated Partner, subject to the rules of participation of each such meeting.

As regards the participation of a representative of PIC/S in the meetings of the GMP/GDP Inspectors Working Group (GMDP IWG), reference is made to the co-operation agreement between the EMA and PIC/S and should follow that agreement.

Appropriate arrangements can be made on a case-by-case basis to provide for the participation of DG SANTE and PIC/S in meetings, seminars and conferences during which matters of common interest will be discussed, in conformity with their rules applicable to such participation.

2.2 Training, including the possibility of participation at each other's training events, providing material and speakers for training and if possible hosting of training events. The focus of the training will in particular be on auditor training on the European Economic Area (EEA) joint audit programme (JAP), PIC/S accession or PIC/s Joint Re-Assessment Programme (JRP), and GMDP training for inspectors.

2.3 Developing and maintaining harmonised Good Manufacturing and Distribution Practice (GMDP) standards and quality systems of National Competent Authorities of the

EEA (NCAs) in collaboration with the EMA and the GMDP IWG whilst striving for international harmonised standards and systems through PIC/S.

2.4 Auditing of GMDP competent authorities, including:

- Sharing of audit reports related notably to JAP, PIC/S accession and JRP, Mutual Recognition Agreements (MRA) between the European Union (EU) and a non-EU country or Active Pharmaceutical Ingredient (API) listing by the European Commission under the Falsified Medicines Directive (Directive 2011/62/EU);
- Coordination of audits, including joint audits JAP, PIC/S accession and JRP, MRA or API listing by the European Commission.

2.5 Assistance to the competent authorities of the candidate countries to the EEA or DG SANTE's strategic partners in the PIC/S pre-accession and accession procedures.

3. Confidentiality arrangement

Information shared or exchanged hereunder will only be used for the performance by DG SANTE and PIC/S of their respective duties with regard to pharmaceutical products as well as for the protection of public and animal health.

Information provided by either side to the other side under this co-operation arrangement may include non-public confidential and/or classified information, which is covered by a separate Confidentiality Arrangement between DG SANTE and the EMA on the one hand and PIC/S on the other.

4. General provisions

Each side will be solely responsible for the manner in which it carries out its part of the activities under this co-operation. Thus, a side will not be responsible for any loss, accident, damage or injury suffered or caused by the other side, or that other side's staff or sub-contractors in connection with, or as a result of, the collaboration under this co-operation arrangement.

Nothing in this co-operation arrangement should be considered as precluding co-operation in other areas that may arise and as mutually agreed, such as in the area of blood, tissues and cells.

The use of one side's name, emblem and/or logo by the other side is subject to the former side's prior approval in writing.

In case of future changes in the organisation chart of the European Commission regarding assignment of responsibilities among Directorates-General, this co-operation 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.

This co-operation arrangement becomes applicable upon its signature by both sides and will have an initial term of three years, tacitly renewable for additional terms of three years each. The sides may amend this co-operation arrangement at any time upon their mutual written consent.

Either side may terminate this co-operation arrangement at any time, by giving the other side 30 days advance written notice to that effect (subject always, however, to the orderly

conclusion of any ongoing activities). Notwithstanding the termination of this co-operation arrangement for whatever reason, the obligations of confidentiality and restrictions on use in respect of confidential information exchanged hereunder shall survive such termination, unless and until such information becomes public through no fault of the recipient.

This co-operation arrangement does not constitute any legal obligation or financial liability on either side nor does it intend to result in creating rights or obligations under international law on the part of the sides. This co-operation arrangement is not legally binding.

Qualified electronic signature by:

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Date: 2022-07-19 09:19:33 +02:00

Agreed and signed on behalf of
the Directorate General Health
and Food Safety

Digitally signed by

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Date: 2022.06.30 08:37:19
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Agreed and signed on behalf of the
Pharmaceutical Inspection Co-operation
Scheme