European Commission | EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | ANVISA Agência Nacional de Vigilância Sanitária

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

The Agencia Nacional de Vigilancia Sanitaria (ANVISA), 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 (each a "Participant" and collectively "the Participants"), have recognised the need for a working arrangement (this "Arrangement") to enable further increased cooperation as a means to better protect health and facilitate access to safe and high quality medical/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"). Both sides therefore accept to keep the exchanged information confidential, to the extent permitted by their respective applicable legislation and/or organisation's 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 medical/medicinal products for human and veterinary use, authorised or under review both in Brazil and in the Union, exclusively for use in the performance of their respective duties with regard to medical/medicinal products, as well as for the protection of public health ("the Purpose").

In this context, medical products in Brazil refer to medicines for human use, including vaccines and pharmaceutical ingredients, and medical devices. In the European Union, medicinal products refer to "medicinal products for human use" as defined in Directive 2001/83/EC and "medicinal products for veterinary use" as defined in Directive 2001/82/EC, 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, while medical products refer to medical devices as defined in Regulation (EU) 2017/745 on medical devices and in vitro diagnostic medical devices as defined in Regulation (EU) 2017/746 on in vitro diagnostic medical devices.

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 medical/medicinal products for safety, efficacy and quality, such as licensing and approvals, authorization of clinical trials, audits of manufacturers and conformity assessment bodies, product labelling, and the development of policies and guidance;

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 medical/medicinal products; and,

3. Compliance and enforcement activities with regard to medical/medicinal products, such as inspections, 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 for the Purpose and 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.

For ANVISA, "persons within their organisation" include ANVISA agents, contractors, experts or expert committees 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 that are applicable to ANVISA.

For DG SANTE and EMA, "persons within their organisation" 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 at assessments of conformity assessment bodies and in other DG SANTE or EMA activities. DG SANTE and EMA may, therefore, share information received from ANVISA with representatives of national competent authorities in the European Economic Area (EEA) with whom DG SANTE or EMA has entered into a cooperation agreement that covers the exchange of confidential information. DG SANTE and 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 and/or organisation's 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.

The 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 and the recipient 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 present and the following paragraph.

In case personal data would be transferred under this Arrangement, the personal data may be transmitted by ANVISA in accordance with Law 13.709/2018[1] and other applicable laws and policies. 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.[2]

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 ANVISA, if and insofar as that information is covered by the exceptions provided for in Article 4 of Regulation (EC) No 1049/2001[3] as interpreted by the Court of Justice of the European Union. DG SANTE and the EMA understand that ANVISA 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, ANVISA 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. ANVISA 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.

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[1] Law 13.709/2018 of 14 August 2018, the Brazilian General Law on Personal Data Protection, on the processing of personal data, including in digital media, by natural persons or legal persons under public or private law, with the purpose of protecting the fundamental rights of freedom and privacy and the free development of the personality of the natural person. The general rules contained in this Law are of national interest and must be observed by the Union, States, Federal District and Municipalities.

[2] 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).

[3] 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.

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

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.

Similarly, in case of future changes in the organisation chart of ANVISA regarding assignment of responsibilities between different branches, this confidentiality arrangement will continue to be applicable to the branch of ANVISA which has within its remit responsibility for medical products.

Notwithstanding the termination of this Arrangement for whatever reason, the participants understand that the obligations of confidentiality and restrictions on use in respect of non-public information exchanged hereunder will survive such termination, unless and until such information becomes public through no fault of the recipient.

This arrangement is signed with two original copies in English and Portuguese languages, both equally authentic. In the event of any divergence, the English text shall prevail. 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 under international or domestic law and does not entail any financial obligations.

Signed on behalf of DG SANTE

[redacted]

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European Commission
Directorate-General for Health and Food Safety
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Date

Signed on behalf of EMA

Emer Cooke Digitally signed by Emer Cooke Date: 2021.03.01 16:76:04 +01'00'

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Date

Signed on behalf of ANVISA

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