European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE

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ANVISA

Memorandum of Understanding between the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM) and the Brazilian Health Regulatory Agency (ANVISA)

Considering that the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM) and the Brazilian Health Regulatory Agency (ANVISA), hereinafter jointly referred to as "the Partners", share the common goal of protecting public health by ensuring the quality and safety of Substances for Pharmaceutical Use;

Recalling that Brazil is an observer to the Council of the Europe and officially recognizes the European Pharmacopeia as a standard;

Recognizing that they share a common goal to protect public health and safety by assessing the quality of substances for pharmaceutical use that are used in the production or preparation of pharmaceutical products;

Taking into account that EDQM assesses and concludes the suitability of monographs for substances covered by the European Pharmacopoeia through the procedure called "Certification of Suitability to the monographs of the European Pharmacopoeia" (CEP);

Bearing in mind that the CEP procedure also checks compliance of manufacturing and/or distribution sites with both Good Manufacturing Practices (GMP) for active substances and of CEPs granted with the submitted information, regardless of geographical origin of the manufacturer;

Recalling that ANVISA assesses the closed and open portions of the Drug Master File (DMF) as part of the DMF review process and the medicine authorization submission;

Recognizing the importance of international reliance, transparency, trust and good regulatory practices to share information related to Good Manufacturing Practices for substances for pharmaceutical use in helping reduce duplication of work and the improvement of quality assessment reports of the Drug Master File (DMF) while ensuring high standards of safety and quality;

The Partners have decided to collaborate as follows:

Paragraph 1 – Forms of Cooperation

Cooperation between the Partners will take the following forms:

a) Confidence building activities for the use of CEP as part of the reviewing process, the exchange of regulatory frameworks, regulations policies, guidance documents, procedures and other documents relating to the assessment of medicinal products;

b) Information on Good Manufacturing Practices (GMP) for substances, which includes letters of suspension or actions taken on CEPs issued by EDQM, and inspections reports;

c) Information on the quality of substances for pharmaceutical substances, which includes assessment reports;

d) Information on Information Technology (IT), e.g., information management systems, database system, and other related computer applications that support the assessment of substances and/ or reports of dossiers;

e) Any other form of collaboration that may be jointly agreed upon by the Partners.

Paragraph 2 – Confidence Building Activities

The Partners agree to exercise confidence building activities in order to consider the incorporation of CEPs into ANVISA´s evaluation of medicinal products. Confidence building activities will be included in a specific Work Plan and may comprise, among others jointly defined upon by the Partners:

a) Exchange of information on EDQM´s and ANVISA´s review practices;

b) Exchange visits of staff and experts from both Partners, as well as technical workshops, on-site visits, exchange programs of European Pharmacopoeia, laboratory activities, joint comparison exercises of suitability of CEP;

c) Design of a roadmap to a phased approach to the use of CEPs by ANVISA;

d) Other activities that the Partners consider beneficial to confidence building for the use of CEPs in ANVISA´s review process.

Paragraph 3 – Sharing of Information

The Partners consider that from time to time circumstances will arise where sharing of information held by one Partner will assist the other Partner in carrying out its regulatory functions to ensure the safety, quality and efficacy of medicinal products for human use.

a) Information to be shared by EDQM includes:

- information on actions taken on CEPs, or applications for CEPs in the context of the EDQM inspection program, which includes details of the reasons for GMP non-compliance for the companies inspected by EDQM;

- information on actions taken on CEPs or applications for CEPs, as a consequence of a failure from the holder or intended holder to meet the requirements of the Certification procedure;

- upon request from ANVISA, information on inspections of manufacturers of pharmaceutical substances carried out by EDQM, typically inspection reports;

- upon request from ANVISA, quality assessment reports for CEP applications;

b) Information to be shared by ANVISA includes:

- upon request from EDQM, information on inspections of manufacturers of pharmaceutical substances carried out by ANVISA, typically inspection reports, performed on national territory and internationally regarding active substances. It is understood that these reports are written in Portuguese.

Paragraph 4 – Confidentiality

The participants acknowledge that the information exchanged under this MoU may be confidential and not in the public domain in the territory of the Partner that originated the information. At the moment of exchanging the information, the originating Partner will inform the receiving Partner of the confidentiality of such information. In this case each Participant understands that confidential information will be shared in accordance with the applicable laws, policies and procedures of each territory. Each Partner will make its best efforts to avoid:

a) public disclosure of confidential information exchanged under this MoU; and

c) any other disclosure of information for purposes that are not established by this MoU.

Paragraph 5 – Final Considerations

The Partners note that this Agreement:

a) does not affect the authority of the two organizations to carry out their regulatory responsibilities;

b) does not create any obligation to share information and that each Partner may decline to provide information to the other Partner.

Any disputes or disagreements with respect to the interpretation or implementation of the present Agreement will be resolved amicably by good faith negotiations between the Partners.

This Agreement is to commence on the date that Partners exchange signed copies of this letter, both in two original versions, in the English and Portuguese languages. In case of doubt between the Partners, the English version prevails.

Date: 17/4/17

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