Sundhedsstyrelsen
Danish Health and Medicines Authority

Agência Nacional
de Vigilância Sanitária

Memorandum of Understanding between

The Danish Health and Medicines Authority, The Kingdom of Denmark

And

The Brazilian Health Surveillance Agency, Brazil

On

Cooperation in the field of health products and drug administration

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Article 1 – Purpose of the MoU

With this Memorandum of Understanding (MoU), the Danish Health and Medicines Authority (DHMA) and The Brazilian Health Surveillance Agency (ANVISA), hereinafter referred to as the Parties, wish to encourage bilateral cooperation and facilitate the mutual exchange of information and expertise on matters pertaining to health products and drug administration.

Both Parties shall encourage exchanges and cooperation on the basis of equality, mutual benefit and reciprocity.

Article 2 – Forms of Cooperation

Through the following activities, the Parties will conduct close cooperation in the field of health products and drug administration:

- Exchange of information, including information on best practice
- Exchange visits of staff and professionals from both parties
- Other cooperation in the area of health products and drug administration to be agreed upon by both parties

Article 3 – Sharing of information in relation to medical devices and medicinal products for human use

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

Both Parties agree on the exchange of inspection reports done by one Party which are of significant public health interest to the other Party. Both Parties will not publicly disclose inspection reports provided by the other Party without its written authorization.

Other information that may be shared between the Parties includes, but is not limited to:

- Post-authorization pharmacovigilance data held by one Party, which raises safety concern about a product manufactured or distributed in the territory of the other Party.
- Information on quality defect or product recalls held by one Party in relation to medicinal products and medical devices distributed or manufactured in the territory of the other Party.
- Information contained in marketing authorization applications and applications to vary a marketing authorization received by one Party, which are of significant public health interest to the other Party.

The Parties, their officials or representatives may limit the scope of the above information, at their absolute discretion, particularly if its dissemination or exchange may harm the commercial interest of a third party, breach a duty of confidence or privacy attaching to the information, disclose a trade secret, be contrary to the Party's public interest or be contrary to legislation with respect to freedom of information.

Article 4 – Cost related to activities under the MoU

The cost related to activities under the MoU is borne by the parties individually.

Cooperation activities under the MoU are to be coordinated between the Parties on a regular basis, after mutual consultations and in accordance with the requirements of each Party.

Cooperation activities under the MoU will be subject to the availability of the appropriate funds and other resources, as well as to the applicable national laws and legal provisions of each Party.

Article 5 – Single Point of Contact

Each Party shall designate a Single Point of Contact (SPOC). The SPOC shall serve as the principal coordinator of information and activities between the Parties.

Article 6 – Entry into force

This MoU will enter into force upon its signature by both Parties, and will remain in force until further notice. This MoU may be modified in writing with the consent of both Parties and may be terminated, on a six months' written notice, by either Party.

This MoU may be amended at any time by mutual written consent of the Parties.

Signed in duplicate, in Copenhagen, on 22 May 2014 in Portuguese and English, both texts having equal validity. In the case of divergent interpretations, the English text will prevail.

Representative from the
Danish Health and Medicines
Authority

Representative from the
The Brazilian Health Surveillance
Agency