Confidentiality Agreement
between
the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe
and
the Brazilian Health Surveillance Agency (ANVISA)

The European Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM) and the Brazilian Health Surveillance Agency (ANVISA), hereinafter referred to as "the Partners", share the common goal of protecting public health and safety by ensuring the quality and safety of Substances for Pharmaceutical Use, i.e. Active Pharmaceutical Ingredients (API) and Excipients that are used in the production or preparation of medicinal products.

The Partners will co-operate as follows to facilitate the sharing of information related to the quality and manufacture of substances for pharmaceutical use and in particular Active Pharmaceutical Ingredients (APIs) of common interest, including non-public and proprietary information.

The information to be shared by EDQM includes:

- information on negative actions taken on Certificates of suitability to the monographs of the European Pharmacopoeia (CEPs), or applications for CEPs in the context of the EDQM inspection programme, which includes details of the reasons for GMP non-compliance for the companies inspected by EDQM;

- information on negative 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 inspections reports).

The 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. It is understood that these reports are written in Portuguese and will not be translated.

Partners understand that some of the information they receive from each other may include non-public information exempt from public disclosure under the applicable laws and regulations, including each Partner's internal rules, such as confidential commercial information, trade secret information, personal privacy information, law enforcement information or internal operational information. Both Partners understand that this non-public information is shared in confidence, and that it is critical that the confidentiality of the information is maintained.

Both Partners shall inform each other of the non-public status of the information at the time that the information is shared. They shall guarantee confidentiality in accordance with the applicable laws and regulations, including their own internal rules.

EDQM and ANVISA note that this Agreement relating to the exchange of information:

1. does not affect the authority of the two organisations to carry out their regulatory responsibilities;

2. 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 shall be resolved amicably by good faith negotiations between the Partners.

This Agreement is to commence on the date that EDQM and ANVISA exchange signed copies of this letter.

This confidentiality agreement is signed in 2 original versions, in the English and Portuguese languages. In case of doubt between the Partners, the English version prevails.

Date: 3/9/12

Dr. Susanne Keitel
Director
European Directorate for the Quality of Medicines and HealthCare of the Council of Europe
7 Allée Kastner
CS 30026
F - 67081 Strasbourg

Date: .....

Dirceu Brás Aparecido Barbano
Director Chairman
ANVISA
Setor de Indústria e Abastecimento (SIA)
Trecho 5, Área Especial 57 / Lote 200
BR - Brasília (DF) 71205-050