

MEMORANDUM OF UNDERSTANDING (MoU) BETWEEN THE SWEDISH MEDICAL PRODUCTS AGENCY (MPA) AND THE BRAZILIAN NATIONAL HEALTH SURVEILLANCE AGENCY (ANVISA)

RECOGNIZING that Sweden and Brazil wish to furthering cooperation on medical products between the two countries and other areas of health including sustainable development across multiple agencies.

RECALLING the agreement on cooperation in the field of trade and investment; science, innovation and high technology; bioenergy and biofuels; climate change and sustainable development; defence; and cultural exchange and education between Brazil and Sweden signed on 6th October 2009 which encourages the development and strengthen co-operation, to the benefit of the Brazilian and Swedish societies and

STATING the interest shown by both Parties to develop the bilateral cooperation and friendship between them on relevant themes for both institutions;

Hereby record their intention to increase bilateral cooperation and confidence between the parties to enhance their ability to protect and promote the health and safety of their respective populations with respect to products within the regulatory jurisdiction of ANVISA and the MPA.

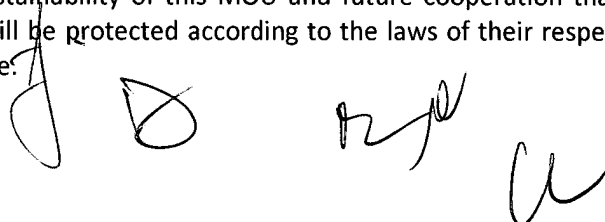
Further Agree to prioritize cooperation in the fields of rational use of medicines, sustainable development, antibiotic resistance, pharmacovigilance, medical devices and diagnostic kits, electronic submissions, pharmacopoeia and other areas of common interest.

The cooperation will be complementary to ongoing cooperation between the two countries and will cover the area of health including the aspects of sustainable development. The form of the cooperation could be carried out through the arrangement of bilateral meetings, coordination and consultation when required in order to promote exchange of information and experiences. Upon agreement, specific cooperation activities and projects may be undertaken.

ANVISA and MPA understand that some of the information it receives through the exchange of information between the Institutions may include non-public information exempt from public disclosure, such as confidential commercial information; trade secret information; personal privacy information; law enforcement information; or internal, pre-decisional information. Both institutions understands that this non-public information is shared in confidence Both institutions will advise the other of the non-public status of the information at the time that the information is shared.

Therefore, ANVISA and MPA certifies that it:

1. will protect the confidentiality of information in accordance with the laws of their respective countries as well as the policies and procedures permitted by those laws. ANVISA and MPA consider it crucial to the sustainability of this MOU and future cooperation that confidential information shared between them will be protected according to the laws of their respective countries from unauthorized use and disclosure.

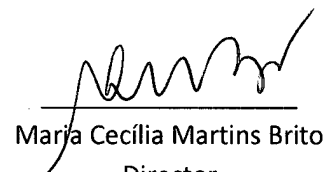


2. will inform the other Agency promptly of any effort made by judicial or legislative mandate to obtain non-public information provided under this MOU. If such judicial or legislative mandate orders disclosure of non-public information provided, the other Agency will take all appropriate legal measures in an effort to ensure that the information will be disclosed in a manner that protects the information from public disclosure; and
3. will promptly inform the other Agency of any changes in the law, or to any relevant policies or procedures, that would affect ANVISA's or MPA's ability to honor the commitments in this document.

Signed in BRASÍLIA on the 22 day of the month of JUNE of the year 2011.

For the National Health Surveillance Agency -
ANVISA


Dirceu Brás Aparecido Barbano
Director Chairman

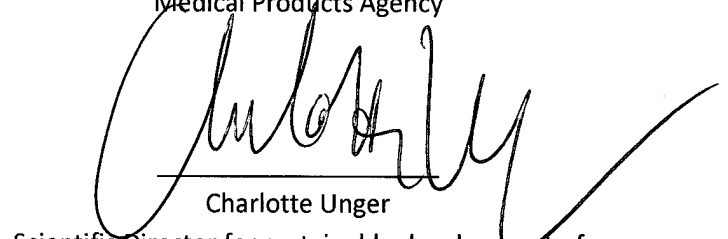

Maria Cecília Martins Brito
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For the Swedish Medical Products Agency


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