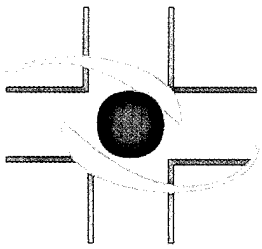

CONFIDENTIALITY ARRANGEMENT

between

the UNITED KINGDOM of GREAT BRITAIN and NORTHERN IRELAND MEDICINES and HEALTHCARE PRODUCTS REGULATORY AGENCY

and

the AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA of BRAZIL

Introduction:

1. The Medicines and Healthcare products Regulatory Agency of the United Kingdom of Great Britain and Northern Ireland (UK) (the MHRA) and the Agência Nacional de Vigilância Sanitária (the ANVISA), are the regulatory authorities (collectively, the Participants) with responsibility in their respective countries for the authorisation, granting, renewal, variation, suspension, and revocation of licences, certificates, or other regulatory mechanisms relating to those medicinal products and medical devices for human use which are clinically investigated, marketed, supplied, manufactured, or assembled in the UK and Brazil respectively.

2. The MHRA acknowledges that the ANVISA is authorized, subject to relevant data protection requirements, to exchange information and documentation relating to medicinal products and medical devices in accordance with the domestic laws under which it is constituted.

3. The Participants consider that from time to time circumstances will arise where sharing information held by one regulatory authority will assist the other regulatory authority 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 which are under clinical investigation, authorised for marketing, or under review for marketing authorisation in both the UK and Brazil.

4. The MHRA will co-operate with the ANVISA to facilitate the sharing between the ANVISA and the MHRA of otherwise non-public documents and information for the purposes of assisting the MHRA in carrying out its functions. This arrangement sets out a co-operation and framework understanding of the information which the ANVISA and the MHRA may share with each other and the basis upon which they may share it. Non-public documents or information means any document or information not in the public domain that is held by a Participant and is treated as confidential by that Participant in accordance with the domestic laws applicable to the Participant.

5. In this Confidentiality Arrangement, the term "medicinal products for human use" excludes all medicinal products subject to evaluation or authorised by the European Medicines Agency (EMA) under the centralised procedure as well as medicinal products authorised at national level by European Union Member States that are subject to official European Union arbitration and referrals.

Information that may be shared between the MHRA and the ANVISA:

6. The type of information that may be shared between the regulatory authorities includes, but is not limited to:

    I. Post-authorisation pharmacovigilance data held by one Participant which raises safety concerns about a product manufactured or distributed in the territory of the other authority.

    II. Information on quality defect or product recalls held by one Participant in relation to medicinal products and medical devices which are distributed or have been manufactured in the territory of the other Participant.

    III. Information contained in marketing authorisation applications and applications to vary a marketing authorisation received by one Participant which are of significant public health interest to the other Participant to which they are disclosed.

    IV. Information contained in reports on inspections done by one Participant which are of significant public health interest to the other Participant to which they are disclosed.

7. The Participants, their officials or representatives, may in their absolute discretion limit the scope of the above information, particularly if its dissemination or exchange may harm the commercial interests of a third party, breach a duty of confidence or privacy attaching to the information, disclose a trade secret, or be contrary to the public interest or the interests of the Participant. In some cases, exchange of information under this

arrangement may be subject to prior consent from the companies or individuals concerned.

The basis on which this information is shared between the ANVISA and the MHRA:

8. The Participants recognise that it is an essential element of this arrangement that confidential information emanating from one Participant to the other will continue to be treated as such by the receiving Participant, and that so far as practicable and to the extent permitted by its respective laws, the receiving Participant will keep the information exchanged confidential.

9. The MHRA acknowledges that some of the information it will receive from the ANVISA may include non-public information exempt from public disclosure under the relevant laws and regulations of Brazil, such as confidential information, commercially sensitive information, trade secrets, personal information, law enforcement information, or internal pre-decisional information. The MHRA understands that this non-public information is shared in confidence with it, and that the ANVISA considers it critical that the MHRA maintain the confidentiality of this information. The MHRA understands that the ANVISA will advise the MHRA of the non-public status of the information at the time that the information is shared.

10. The MHRA understands that the ANVISA affirms that the ANVISA has the authority to protect such non-public information provided to it (including its officials and representatives) by the MHRA, and that it will protect such information as information not to be disclosed by it under the Brazilian Official Information Act. The MHRA considers it crucial that such non-public information should not be disclosed without the consent of the MHRA and that disclosure made without such consent could endanger the international relations between the Participants and seriously jeopardise any further scientific and regulatory interactions between the ANVISA and the MHRA.

11. The MHRA understands that the ANVISA is of the view that the disclosure by the MHRA of any non public information provided to it (including its officials and representatives) by the ANVISA could seriously jeopardise any further scientific and regulatory interactions between the ANVISA and the MHRA and would prejudice the international relations between the MHRA and the ANVISA. The MHRA understands that the ANVISA considers that it is crucial that this non-public information is protected from disclosure and that the condition of sharing this non-public information with the MHRA is that it be held in strict confidence by the MHRA.

12. The MHRA affirms that it has the authority to protect non-public information, including confidential commercial information, provided to its officials or representatives by the ANVISA and will take all practicable steps to protect any such non-public information from disclosure unless the owner of the information has provided written authorisation to make the

information public or, unless in relation to the information requested, the ANVISA informs the MHRA that it no longer considers the information to be non-public or that it no longer considers that disclosure of the non-public information will harm international relations between the MHRA and the ANVISA or if the non-public information is required to be released under Brazilian law.

13. Within 5 working days of receiving from the MHRA a third party request for disclosure, the ANVISA will inform the MHRA as to whether the ANVISA remains of the view that the requested disclosure should not be made and that if made it will breach a confidence and/or endanger international relations between the Participants.

14. On each occasion where the MHRA receives a request from a third party for disclosure to that third party of non-public information received from the ANVISA, the MHRA will consult with the ANVISA on that requested disclosure and understands that the ANVISA will respond to MHRA as per paragraph 13.

15. On each occasion when the ANVISA receives a request from a third party for disclosure to that third party of non-public information received from the MHRA, the MHRA understands that the ANVISA will consult with the MHRA on that requested disclosure, and the MHRA will provide the ANVISA with its position on whether or not that non-public information should be disclosed within 5 working days of receiving from the ANVISA any third party request for disclosure.

16. The Participants recognise that there may be occasions when the Participant with whom confidential information is shared may as a result of receiving that information need to take measures to protect public health which may necessitate sharing some or all of such confidential information with certain other agencies. In those circumstances the Participants will only decide to share the information in consultation with the other Participant.

17. Both the MHRA and the ANVISA recognise that if requests for information in their possession (including otherwise non-public information received from the other Participant) are demanded by judicial, parliamentary order or other order issued under statute, the Participant will have to surrender the information to the court, legislature, or person concerned. If such an order is received for otherwise non-public information received from the other Participant, the Participant under order to produce the information will inform the requestor immediately and will take all measures open to it to ensure that the information will be disclosed in a manner that protects the information from public disclosure.

Duration, change, and termination of Arrangement:

18. This arrangement will come into effect on signature. It is intended to replace any previous similar arrangement between the Participants and will continue in effect until terminated by either Participant on 30 days written notice to the other Participant or if mutually decided by the Participants at any time.

19. The Participants may amend this Arrangement at any time by mutual decision in writing.

Professor Kent Woods
Chief Executive
Medicines and Healthcare products Regulatory Agency
26 November 2012