



**PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

PS/W 7/2012
13 April 2012

**Confidentiality Commitment from the Pharmaceutical Inspection Co-operation
Scheme not to disclose non-public information shared by
the European Medicines Agency**


The Pharmaceutical Inspection Co-operation Scheme (hereinafter referred to as “PIC/S”), an Association under the Swiss Code of Civil Law (Art. 60 ff), undertakes, under applicable laws and within the scope of its activities, to protect non-public information, including commercial confidential information, provided to its officials, representatives, Participating Authorities or Partners in confidence by the European Medicines Agency (hereinafter referred to as “EMA”) in the frame of the “Co-operation between the Pharmaceutical Inspection Co-operation Scheme and the European Medicines Agency” of 28 December 2010 and any of its annexes, addendum or amendments, including the Addendum No. 1 to the Co-operation between the PIC/S and the EMA of 8 May 2012 regarding the Harmonisation of PIC/S and GMDP IWG Consultation Procedure (hereinafter collectively referred to as the “Co-operation between PIC/S and the EMA”), and will protect such information from disclosure.

PIC/S understands that some of the information it receives from EMA may include non-public information exempt of public disclosure under the laws and regulations of the European Union, such as confidential information; trade secrets information; personal privacy information; law enforcement information; or internal, pre-decisional information. PIC/S understands that this non-public information is shared in confidence and that EMA considers it critical that PIC/S, including its Participating Authorities and Partners, maintains the confidentiality of the information. Disclosure of this information by PIC/S could seriously jeopardise any further confidential scientific and regulatory interactions between PIC/S and EMA.

Therefore, the PIC/S undertakes that it:

1. will protect from disclosure such non-public information provided to PIC/S, including its Participating Authorities and Partners, in confidence by EMA in the context of the Co-operation between PIC/S and the EMA;
2. will not disclose, or use for any other purpose than that provided for in the Co-operation between PIC/S and the EMA, such EMA-provided non-public information without prior agreement from the EMA, or written authorisation from the individual who is the subject of the personal privacy information, or a written statement from EMA that the information no longer has non-public status;
3. will inform EMA promptly of any effort made by judicial or legislative mandate to obtain EMA-provided non-public information from PIC/S. If such judicial or legislative mandate orders disclosure of EMA-provided non-public information, PIC/S 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
4. will promptly inform EMA of any change to the laws applicable to PIC/S, or to any relevant policies or procedures that would affect PIC/S' ability to honour the commitments in this document.

Date and signature:

	
Ms. Helena Baião Chairperson	30 May 2012
FOR THE PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME (PIC/S)	