



Confidentiality undertaking for observers

I, (title)..... (Name)..... (Surname).....

In view of the following definitions:

“EMA Activities” encompass any meeting (including meeting preparation and follow-up, associated discussion or any other related activity) of the European Medicines Agency’s Management Board, Committees, Working Parties, Expert Groups, or any other such meeting; work as an expert on assessments; work as an expert on guidance development.

“Confidential Information” means all information, facts, data and any other matters of which I acquire knowledge, either directly or indirectly, as a result of my EMA Activities.

“Confidential Documents” mean all drafts, preparatory information, documents and any other material, together with any information contained therein, to which I have access, either directly or indirectly, as a result of my participation in EMA Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as Confidential Documents.

understand that I may be invited to participate either directly or indirectly in certain EMA activities and hereby undertake:

1. to treat all Confidential Information and Confidential Documents under conditions of strict confidentiality.
2. not to disclose (or authorise any other person to disclose) in any way to any third partyⁱ any Confidential Information or Confidential Document.
3. not to use (or authorise any other person to use) any Confidential Information or Confidential Document other than for the purposes of my work in connection with EMA activities.
4. to dispose of Confidential Documents as confidential material as soon as I have no further use for them.

This undertaking shall not be limited in time, but shall not apply to any document or information that I can reasonably prove was known to me before the date of this undertaking or which becomes public knowledge other than as a result of a breach of any of the above undertakings.

Date and signature:

ⁱ Third party does not include employees of the National Competent Authorities who either have employment contracts that provide confidentiality obligations or are encompassed by confidentiality obligations under national legislation on professional secrecy.

