



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/250671/2022

Confidentiality Undertaking for network Product Owner and Subject Matter Experts (SMEs) in European Medicines Agency's agile way-of-working

I, the undersigned, (title) (name) (surname)

In view of the following definitions:

- a) "EMA" means the European Medicines Agency;
- b) "EMA's Activities" encompass any meeting (including ceremonies, coaching, meeting preparation and follow-up, associated discussions or any other related activity) of the European Medicines Agency's Product Team or Value Stream;
- c) "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 involvement in EMA's Activities;
- d) "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's Activities. Furthermore, any records or notes made by me relating to Confidential Information or Confidential Documents shall be treated as the Confidential Documents.

hereby confirm that I understand that I participate in the EMA's Activities and thereby have the responsibility to:

- i. comply, as a minimum, with all applicable legislation and EMA's [requirements](#) on the handling, processing and protection of Confidential Information and/or Confidential Documents;
- ii. use the Confidential Information and/or Confidential Documents solely for the purpose for which the access to them has been granted to me;
- iii. maintain confidentiality of the issues discussed within the Product Team or Value Stream and other confidential information made available to me as a member of the Product Team (e.g. information related to other Product Teams or Value Streams discussed during considerations on interdependencies);
- iv. treat all Confidential Information and Confidential Documents as strictly confidential as long as the information or document has not been made public or is not in the public domain;

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- v. 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;
- vi. not to disclose (or authorise any other person to disclose) to any third party¹ any Confidential Information or Confidential Document;
- vii. dispose of Confidential Documents as confidential material in accordance with the EMA's confidential waste disposal procedure as soon as I have no further use for them;
- viii. immediately report any incident regarding the loss, unauthorised access or misuse of the Confidential Information and/or Confidential Documents to:
 - AF-LD-DISCLOSURES@ema.europa.eu and
 - SecurityReportingAlerts@ema.europa.eu

This confidentiality undertaking shall not be limited in time, and 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 otherwise than as a result of a breach of any of the above undertaking.

Date and signature:

¹ 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.
