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European Medicines Agency's Data Protection Notice

For the processing of personal data contained in the Agency's historical records selected for permanent preservation and opening to the public

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of the depositing of its historical archives in the Historical Archives of the European Union (HAEU) at the European University Institute (EUI) in Florence.

This includes:

- The appraisal and selection of EMA historical records that will be deposited at the EUI, including the assessment of personal data contained in them.
- The preparation and description of the historical records to be transferred, including the anonymization (redaction) of personal data in the digital copies thereof.
- The transfer and storage of the original records to the HAEU in Florence, together with the redacted digital copies.

1. Who is responsible for processing your data?

1.1. Who is the data controller?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Administration and Corporate Management Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address:
DataController.Administration@ema.europa.eu

1.2. Who is the data processor?

The European University Institute (EUI) acts as a processor of EMA as regards the processing of personal data contained in the historical archives deposited at EUI.

The contact details of the data processor(s) are the following: Data_Protection_Officer@EUI.eu

2. Purpose of this data processing

The purpose of this data processing activity is to make available to the public, whenever possible, the established EMA historical archives (following the 30 years rule), to promote their consultation and to stimulate research into the history of European integration and the European institutions.

2.1. *Personal data concerned*

In this processing operation we process data that was collected at the time of the creation of the records selected for permanent preservation. Such data may include, for example, the following: Names, job titles, personal or professional addresses, marital and family status, other types of personal data included in documents submitted to the Agency by its stakeholders.

2.2. *Legal basis of the processing*

In addition, the activities explained in this DPN are necessary for compliance with Council Regulation (EEC, EURATOM) No 354/83 concerning the opening to the public of the historical archives of the European Economic Community and the European Atomic Energy Community. In particular, the processing of data is necessary for the performance of tasks carried out in the public interest in relation to:

- The establishment and opening to the public of EMA's historical archives after the expiry of a period of 30 years starting from the date of the creation of the documents
- The transfer of historical records to the HAEU to promote their consultation and to stimulate research into the history of European integration and the European institutions.

In this regard, please note that you have the **right to object** against the processing as explained in Section 5 below.

3. How long do we keep your data?

The personal data decided to be retained as part of the historical archives is kept permanently because of its historical value. Other types of data which are decided not to be retained as part of the historical archives are only processed during the appraisal process and deleted/redacted from the historical archives as part of that process.

4. Who has access to your information and to whom is it disclosed?

The data collected will be processed internally by staff within the EMA Division responsible for the historical archives' services.

Historical records will be published on the HAEU website, accessible upon registration with an account.

5. Your data protection rights

As data subject (i.e. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.

- **Right to access** – You have the right to access your personal data. You have the right to request and obtain a copy of the personal data processed by EMA.
- **Right to rectification** – You have the right to obtain - without undue delay - the rectification or completion of your personal if it is incorrect or incomplete.
- **Right to erasure** – You have the right to require EMA to delete or stop processing your data, for example where the data is no longer necessary for the purposes of processing. In certain cases your data may be kept to the extent it is necessary, for example, to comply with a legal obligation of the Agency or if it is necessary for reasons of public interest in the area of public health.
- **Right to restrict processing** – In a few, codified cases, you have the right to obtain the restriction of the processing, meaning that your data will only be stored, but not actively processed for a limited period of time. For more information about this right and its limitations, see the EMA General Privacy Statement, hosted at www.ema.europa.eu/en/about-us/legal/privacy-statement.
- **Right to object** – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725. For anything that is not specifically provided for in this Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

5. Recourse

In case you have any questions regarding the processing of your personal data, or you think that the processing is unlawful or it is not in compliance with this Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at ArchiveServices@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en