



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

9 April 2020  
EMA/85959/2020

## European Medicines Agency's Privacy Statement

### For the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resource Database

This Privacy Statement 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 coordination of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) network.

## 1. Who is responsible for your data?

The European Medicines Agency ("EMA") is ultimately responsible to comply with your data protection rights and freedoms. On behalf of EMA, the Head of Data Analytics and Methods Task Force is appointed as a 'Data Controller' to ensure the lawful conduct of this processing operation.

Contact details: [encepp\\_secretariat@ema.europa.eu](mailto:encepp_secretariat@ema.europa.eu).

## 2. What is the purpose of this data processing?

The ENCePP is a network coordinated by the EMA in which participation is voluntary. It promotes collaborations with the objective to improve pharmacoepidemiological research and post-authorisation safety surveillance of medicinal products in Europe through access to a robust network of resources. In support of the ENCePP network, EMA has established and maintains a **Resource Database**<sup>1</sup>, which purpose is to make available a resource for researchers and potential study funders seeking to identify organisations they would consider appropriate for conducting specific pharmacoepidemiological and pharmacovigilance projects.

### 2.1. Personal Data concerned

All information contained in this database (i.e. names and contact details of representatives from research organisations, networks and data sources, including patient registries) is provided and maintained by the listed organisations / data providers which voluntarily register their data sources in the Resource Database by filling-in the form online. It is therefore their responsibility to keep this information up to date in accordance with the Terms of Use. Information may be edited at any time by the entities concerned.

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<sup>1</sup> <http://encepp.eu/encepp/resourcesDatabase.jsp>



Registration in the Resource Database implies a commitment to review and update the entries regularly, and, as a minimum, at least every twelve (12) months.

## 2.2. Legal Basis

When providing data, the provider consents to the processing of that data in accordance with this Privacy Statement. They have the right to withdraw their consent at any time. In this case, the ENCePP secretariat needs to be informed at [encepp\\_secretariat@ema.europa.eu](mailto:encepp_secretariat@ema.europa.eu) so that the data can be deleted from the database and therefore from the ENCePP website. Please note that such withdrawal does not affect the lawfulness of processing carried out by EMA before the withdrawal of your consent.

## 3. How long do we keep your data?

Personal data is kept by EMA until:

- it is either updated by the data owner, or
- a request for removal is received.

See also: Standard operating procedure SOP/H/3363 on Handling of ENCePP study seal applications.<sup>2</sup>

## 4. Who has access to the data and to whom is it disclosed?

The data registered on a voluntary basis is made available to the general public. It serves as a resource for researchers and potential study funders seeking to identify organisations they would consider appropriate for conducting specific pharmacovigilance projects.

## 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 Privacy Statement provides information on how EMA collects and uses your personal data.
- **Right to access** – You have the right to access your personal data and 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 withdraw consent** – You have the right to withdraw your consent to the processing of your personal data. However, this will not affect the lawfulness of any processing carried out before consent is withdrawn. Please note that if you withdraw your consent, the Agency may not be able to provide certain services to you. EMA will advise you if this is the case at the time you withdraw your consent
- **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

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<sup>2</sup> [https://www.ema.europa.eu/en/documents/sop/standard-operating-procedure-handling-european-network-centres-pharmacoepidemiology\\_en.pdf](https://www.ema.europa.eu/en/documents/sop/standard-operating-procedure-handling-european-network-centres-pharmacoepidemiology_en.pdf)

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](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).

- **Right to portability** - Where the processing is carried out based on your consent and in automated means you have the right to receive your personal data (which was provided to the EMA directly by you) in a machine-readable format. You may also ask the EMA to directly transfer such data to another controller.

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 privacy notice, please refer to the contents of the general EMA Privacy Statement: [www.ema.europa.eu/en/about-us/legal/privacy-statement](http://www.ema.europa.eu/en/about-us/legal/privacy-statement).

## 6. 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 Privacy Statement or the general EMA Privacy Statement, please contact [encepp\\_secretariat@ema.europa.eu](mailto:encepp_secretariat@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](mailto:edps@edps.europa.eu)
- Website: [www.edps.europa.eu](http://www.edps.europa.eu)
- Further contact information: [www.edps.europa.eu/about-edps/contact\\_en](http://www.edps.europa.eu/about-edps/contact_en)