EMA/463506/2019

Record of data processing activity regarding European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) Resource Database (public)

1.	Last update of this record, version number:	09/04/2020, version 2
2.	Reference number:	TDA3
3.	Name and contact details of controller:	European Medicines Agency (EMA) Head of the Data Analytics and Methods Task Force contact: encepp_secretariat@ema.europa.eu
4.	Name and contact details of Data Protection Officer (DPO):	Contact: dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	Not applicable
6.	Name and contact details of processor (where applicable)	Not applicable
7.	Purpose of the processing	The European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) is a network coordinated by the EMA. ENCePP promotes collaboration 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. Members of this network (the ENCePP partners) are public institutions and contract and research organisations (CROs) involved in research in pharmacoepidemiology and pharmacovigilance.

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		In support of ENCePP, EMA has established and maintains a Resource Database[1]. The purpose of this data processing activity 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. All information contained in this database is provided voluntary and maintained by the listed organisations, data providers or registry holders. It is the responsibility of each individual entity to enter the information and to keep its own information up to date in accordance with the Terms of Use. Participation to ENCePP is voluntary.
8.	Description of categories of persons whose data EMA processes and list of data categories	Names and contact details of representatives from research organisations, networks and data sources, including patient registries.
9.	Time limit for keeping the data	Personal data is kept by EMA until: • it is either updated by the data owner, or • it has not been updated within a reasonable amount of time following dispatch of the automated reminder, or • a request for removal is received. See also: Standard operating procedure ref. SOP/H/3363: Evaluation procedure – ENCePP database of research resources
10.	Recipients of the data	The database is 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.
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Not applicable.

[1] http://encepp.eu/encepp/resourcesDatabase.jsp

12.	General description of security measures, where possible.	The database is kept in a secure electronic environment designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored. Data may only be changed or deleted by authorised persons using a username and password. Authorisation is given at senior management level and based on business needs.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	Details concerning the processing of your personal data are available on the Agency's website at: https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement, where you may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.