EMA/463507/2019

Record of data processing activity regarding the European Union electronic Register of Post-Authorisation Studies (EU PAS Register) (public)

1.	Last update of this record, version number:	16/03/2020, version 2
2.	Reference number:	TDA4
3.	Name and contact details of controller:	European Medicines Agency Head of 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 EU PAS Register®[1] is a publicly available database to provide a register of non-interventional post-authorisation studies (PAS) in support of the save and effective use of medicinal products authorised in the Union. Article 26(1)(h) of Regulation (EU) No 726/2004 requires the Agency, in collaboration with the Member States and the Commission, to set up and maintain a European medicines web-portal for the dissemination of information on medicinal products authorised in the Union. By means of that portal, the Agency shall make public protocols and public abstracts of results of the post-authorisation safety studies[2].

[1] (http://www.encepp.eu/encepp_studies/indexRegister.shtml)
[2] Post-authorisation studies referred to in Articles 107n and 107p of Directive 2001/83/EC

8.	Description of categories of persons whose data EMA processes and list of data categories	The EU PAS Register database processes information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available. The EU PAS Register also processes names and contact details of primary lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study. Documents uploaded to the database may contain pseudonymised personal data (e.g. study reports). Documents uploaded to the database, in particular relating to 'ENCePP Seal' studies, which may contain names and contact details of researchers and other individuals involved in the study (e.g. declaration of interest, checklists, declaration on compliance with the ENCePP Code of Conduct, composition of steering group/observers).
9.	Time limit for keeping the data	Information on the study objectives, the main methodological aspects and associated key documents, including study protocols and study results where available as well as general contact details of lead investigators conducting the study and contact persons for scientific or public enquiries relating to a particular study is maintained for an indefinite period in the EU PAS Register. This is to provide for an important resource for scientific research thus providing a large and coherent data pool covering a wide range of medicinal products and studies conducted in Europe.
10.	Recipients of the data	The data is available to the general public.
11.	Are there any transfers of personal data to third countries or international organisations?	Not applicable.
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 staff 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.