EMA/478558/2019

Records of data processing activity relating to the European Pharmacovigilance Issues Tracking Tool (public)

1.	Last update of this record, version number:	31 December 2019, version 1
2.	Reference number:	P7
3.	Name and contact details of controller:	European Medicines Agency Internally Head of Inspections, Human Medicines Pharmacovigilance and Committees Contact: datacontroller.analytics@ema.europa.eu
4.	Name and contact details of DPO:	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 Pharmacovigilance Issues Tracking Tool (**EPITT**) is a tool that facilitates the coordination of the monitoring of medicinal products which have been authorised within the Union to ensure their safe and effective use. More specifically, EPITT facilitates the tracking and rapid exchange of pharmacovigilance issues on the basis of Rapid Alerts (RA), safety signals[1], Emerging Safety Issues (ESI)[2] and Non Urgent Safety Information (NUI) as well as recommendations from the Pharmacovigilance Risk Assessment Committee (PRAC)[3]. The purpose of processing such data within EPITT is to maintain an accurate trail of who is the responsible person to contact related to a pharmacovigilance issue and who has edited records.

[1] As per the legal requirement laid down in Article 21(5) of the Commission Implementing Regulation EU (No) 520/2012
[2] See chapter IX.C.2. Emerging safety issues; Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management (Rev 1); https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-gvp-module-ix-signal-management-rev-1_en.pdf
[3] https://www.ema.europa.eu/en/committees/pharmacovigilance-risk-assessment-committee-prac

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8.	Description of categories of persons whose data EMA processes and list of data categories	The following categories of data subjects are subject to this processing operation: • Contact points at National Competent Authorities (**NCAs**) located within a Member State of the Union or the Agency as the identifier of an issue; • Authorised users who create records within EPITT; • Authorised users who modify records within EPITT. The following categories of personal data are collected for this processing operation: • Forename • Surname • Email address • Telephone number To administer access and user rights, the following information is maintained outside of EPITT for the purpose: • Authorised EPITT usernames; • Application forms to grant/withdraw user access submitted on behalf of PRAC members including the name, email address, phone number and signature of the PRAC member/deputy or the NCA EPITT contact point.
9.	Time limit for keeping the data	Information on safety issues, i.e., information about general descriptions of the potential problem with a medicine or a class of medicines under investigation, including references to case report numbers of adverse reaction reports held in EudraVigilance or safety issues described in the scientific literature, is maintained for an indefinite period in EPITT, necessary to monitor issues over time and to establish a knowledge base. This is to provide for a scientific knowledge base in relation to the safety monitoring of medicines in the EU, to facilitate archiving of safety issue notifications and to track records for data access and administration purposes.
10.	Recipients of the data	EPITT is accessible to authorised staff of the Agency and NCAs in Member States of the Union. Authorised staff of the Agency can administrate user information for the purpose of access management and for determining user rights.
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 Agency has appropriate technical and organisational measures in place, including organisational policies, to safeguard the security of personal data and ensure the confidentiality, integrity and availability of the relevant systems, services and the personal data processed within them. In particular, • The database and administrative information are kept in a secure electronic environment designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored.

		• Access is granted to authorised persons only using a username and password. • Authorisation to administrate user information and access rights is given at senior management level.
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.