



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

29 July 2024
EMA/318484/2021 – ver.2

Records of data processing activity (public) for the Union Product Database (UPD)

1.	Last update of this record, version number:	29 July 2024, version 2
2.	Reference number:	V02
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Veterinary Medicines Division Contact: datacontroller.veterinary@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	The contact points of joint controllers are the following: European Medicines Agency: datacontroller.veterinary@ema.europa.eu Member States: Annex I of the Joint Controllership Arrangement
6.	Name and contact details of processor (where applicable)	N/a
7.	Purpose of the processing	The purpose of this data processing activity is to collect and maintain information on veterinary medicinal products authorised in the Union as mandated by Regulation (EU) 2019/6. In this context, the Qualified Person responsible for Pharmacovigilance (QPPV) personal data are processed while creating new veterinary medicinal product entries and maintaining the QPPV information via variations not requiring assessment, as well as providing an audit trail and traceability of actions and changes to the datasets performed by registered users in the restricted areas of the Union Product Database (UPD).

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8.	Description of categories of persons whose data EMA processes and list of data categories	<ul style="list-style-type: none"> • First name and last name of QQPVs; • Location (address) where the QQPVs operate; • Email address of QPPV • Name, surname and email address of registered users.
9.	Time limit for keeping the data	Information on veterinary medicinal products and, as such, personal data related to QPPVs as well as data history, which relates to the audit trail and traceability of data changes performed by registered users are kept for 30 years in the Union Product database, upon which the retention of the data will be subject to review and may be extended if justified based on the purposes of the processing.
10.	Recipients of the data	<p>The provisions on access to the UPD and the actors to whom access should be granted are set out in Article 56 of Regulation (EU) 2019/6. The Union Product Database Access Policy further details the different levels of access provided to these actors, taking into account the need to protect personal data as well as their obligations or interests. As far as the handling of the personal data, these actors refer to [the European Commission (EC) (as one of the users),] national competent authorities (NCAs) within the EU Member States and the European Medicines Agency (EMA), including contractors and external service providers working for them on UPD-related matters.</p> <p>History of actions and changes to the data sets performed by the registered users in the restricted areas of the UPD can only be accessed by the EMA administrators (technical staff).</p> <p>Reports on the history of changes to the data sets already existing in the UPD can be obtained by NCAs, EC and EMA, and by marketing authorisation holders only for their veterinary medicinal products.</p>
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	N/A
12.	General description of security measures, where possible.	<p>Access is granted only to restricted users based on Article 56 of Regulation (EU) 2019/6, see Union Product Database Access Policy, which details the different levels of access provided to these users taking into account the need to protect personal data as well as their obligations or interests.</p> <p>Access is regulated by username and password.</p>

13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	<p>Details concerning the processing of your personal data are available on the Agency's website at:</p> <p>https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement</p> <p>Here you may find the EMA General Privacy Statement as well as the privacy statements on specific data processing operations.</p>
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