



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 May 2024
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European Medicines Agency's Data Protection Notice For the Risk Management Plans Publication Process

This Data Protection Notice 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 Risk Management Plans (hereinafter 'RMP') publication process.

1. Who is responsible for processing your data?

1.1. Who is the data controller?

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

You may contact the Internal Controller via the following email address:
Datacontroller.HumanMedicines@ema.europa.eu

2. Purpose of this data processing

The purpose of this data processing activity is the publication of approved RMP for medicines authorised under the centralised procedure in the context of performing of the Agency's tasks. The RMP will be published in redacted form. This publication process includes:

- Sending to Applicants and Marketing Authorisation Holders (MAHs) the request to provide a redacted version of the approved RMP, free from personal data and commercial confidential information;
- The Agency receives RMP documents via secure communication (e.g. EudraLink, eCTD submission). Applicants provide the EMA with the documents in track changes with the proposed redactions, as well as the clean redacted documents. Track changes versions of the RMP are submitted with the sole purpose of identifying changes (i.e. deletions and insertions) to Rapporteur/s and EMA staff in order to facilitate the assessment of the submission/s;
- Contacting the Applicant/MAH if any personal data or commercial confidential information is still present in the received redacted RMP, requesting an updated document;
- Saving the RMP documents in the EMA document management system;
- Publishing the redacted RMP on the EMA corporate website, on the same page as the product's EPAR and Product Information.



2.1. Personal data concerned

In this processing operation we process data received from the Applicants and Marketing Authorisation holders when they submit the redacted RMP.

- Personal data in the version of the RMP with track changes with suggestions for redaction, as per the [‘Anonymisation of personal data and assessment of commercially confidential information during the preparation and redaction of risk management plans \(body and Annexes 4 and 6\)’](#)
- Full name of the QPPV. No other personal data will be present in the redacted RMP that will be published.

3. Legal basis of the processing

The processing of personal data for the publication of RMPs is necessary for compliance with a legal obligation to which the controller is subject, pursuant to Article 5(1)(b) of Regulation 2018/1725. In particular, the legal obligations are provided for as follows:

- Art. 26 Regulation. (EC) 1235/2010 ‘The Agency shall, in collaboration with the Member States and the Commission, 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 at least the following... a summary of the risk management plans for medicinal products authorised in accordance with this Regulation’;
- and Article 106 Dir. 2010/84/EU ‘Each Member State shall set up and maintain a national medicines web-portal which shall be linked to the European medicines web-portal established in accordance with Article 26 of Regulation (EC) No 726/2004. By means of the national medicines web-portals, the Member States shall make publicly available at least the following: (a) public assessment reports, together with a summary thereof; (b) summaries of product characteristics and package leaflets; (c) summaries of risk management plans for medicinal products authorised in accordance with this Directive; (d) the list of medicinal products referred to in Article 23 of Regulation (EC) No 726/2004; (e) information on the different ways of reporting suspected adverse reactions to medicinal products to national competent authorities by healthcare professionals and patients, including the web-based structured forms referred to in Article 25 of Regulation (EC) No 726/2004’.

4. How long do we keep your data?

Data and documents relating to individual authorised medicinal products are retained as long as the product is authorised and for at least 10 years after the marketing authorisation has expired, as per Article 16 of the Commission Implementing Regulation (EU) No 520/2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council. RMPs are published in a redacted version, the only personal data that remain included in the published RMPs is the name of the qualified person for pharmacovigilance (QPPV), which will be retained for the abovementioned period.

5. Who has access to your information and to whom is it disclosed?

The data collected will be processed internally by staff within the EMA Divisions responsible for RMP publication, namely Human Division and Stakeholders and Communication Division.

Redacted RMPs will be published on the EMA corporate website.

6. Your data protection rights

As data subject (e.g. the individual whose personal data is processed), you have a number of rights:

- **Right to be informed** – This Data Protection Notice provides information on how EMA collects and uses your personal data. Requests for other information regarding the processing may also be directed to the Internal Controller.
- **Right to access** – You have the right to access your personal data. You have the right 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 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 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.

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 Data Protection Notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

7. 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 Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at Datacontroller.HumanMedicines@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@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
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en