22 May 2024
EMA/219343/2024

Records of data processing activity (public)

Name and reference number of processing operation: Risk Management Plans Publication Process

1.	Last update of this record, version number:	1.0
2.	Reference number:	EMA-H-012-RoPA
3.	Name and contact details of controller:	European Medicines Agency Contact: Datacontroller.HumanMedicines@ema.europa.eu
4.	Name and contact details of DPO:	dataprotection@ema.europa.eu
5.	Name and contact details of joint controller (where applicable)	N/A
6.	Name and contact details of processor (where applicable)	N/A
7.	Purpose of the 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;

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		• 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.
8.	Description of categories of persons whose data EMA processes and list of data categories	Full name of the QPPV. No other personal data will be present in the redacted RMP that will be published.
9.	Time limit for keeping the 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. 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) that it is always retain for pharmacovigilance purposes.
10.	Recipients of the data	Public domain. Redacted approved RMP for medicines authorised under the centralised procedure in the context of performing of the Agency tasks, will be published on EMA corporate website, product webpage.
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.	Publication of redacted approved RMP for medicines authorised under the centralised procedure are received by the EMA in a redacted version
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 Here you may find the data protection notice regarding this specific data processing operation as well.