

15 March 2024  
EMA/116896/2024

## Records of data processing activity for the handling of data subject's requests

1.	Last update of this record, version number:	N/A, v01
2.	Reference number:	EMA-001-RoPA-01
3.	Name and contact details of controller:	European Medicines Agency  Internally: Depending on the subject matter and nature of the request, the applicable Head of Division, Advisory Function or Task Force is appointed as 'Internal Controller'  Contact: dataprotection@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 to handle and respond to the requests of data subjects looking to exercise the rights conferred upon them by Regulation (EU) 2018/1725 in the context of performing of the Agency tasks, including:

**Official address** Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

**Address for visits and deliveries** Refer to [www.ema.europa.eu/how-to-find-us](http://www.ema.europa.eu/how-to-find-us)

**Send us a question** Go to [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact) **Telephone** +31 (0)88 781 6000

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		<ul style="list-style-type: none"><li>• Performing the required checks as foreseen by law</li><li>• Performing the relevant administrative tasks required to respond to the data subject.</li></ul>
8.	Description of categories of persons whose data EMA processes and list of data categories	<p>EMA may process personal data directly collected from the data subjects when they submit their data subject request and when communicating with EMA. The Agency may also request an official identification document from data subjects in order to ensure the security of processing and minimize the risk of unauthorised disclosure of personal data. As data controller, EMA must be able to identify which data refer to the data subject and confirm the identity of the person in case of doubts.</p> <p>EMA may collect the following personal data from data subjects:</p> <ul style="list-style-type: none"><li>• First and last name</li><li>• Email address</li><li>• Copy of identification document (driver's license, passport, or any other official document that verifies your identity). For this purpose, EMA will only require certain information (e.g., issuing authority, first and last name, date of issue or expiry date). Other information on the identification document should be redacted where possible.</li><li>• Any other personal data that a data subject communicates to EMA (e.g. phone number, postal address)</li></ul> <p>If the request is done by an individual on behalf of the data subject, EMA may also process the abovementioned personal data of him/her.</p> <p>Article 12 EUDPR recognises that EMA may be able to demonstrate that it is not in a position to identify the data subject, including in pseudonymised data it holds. This may be the case if EMA does not have (or no longer has) access to additional information allowing attribution, is demonstrably unable to lawfully obtain such information and is demonstrably unable to reverse the pseudonymisation with the assistance of another controller. Consequently, except where the data subject (for exercising his or her rights) provides additional information enabling his or her identification, the</p>

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		<p>rights of data subjects enumerated in Article 12(2) or 14(2) EUDPR, respectively, shall not apply in this case.</p> <p>For instance, if the data subject can provide the pseudonym or pseudonyms under which data relating to him/her is stored, and proof that those pseudonyms pertain to him/her, EMA will try to identify him/her. In consequence, the data subject rights will apply in this case. Therefore, in order to give full effect to his/her rights, EMA will indicate how the data subject can obtain the pseudonyms relating to him/her, and how they can be used to demonstrate his/her identity. In this case, EMA may need to provide the identity and the contact details of the source of the pseudonymised data or of the pseudonymising controller.</p>
9.	Time limit for keeping the data	<p>The copy of the identification document will be kept until the data subject's identity or the identity of the person making the request on their behalf has been verified.</p> <p>The remaining personal data will be handled until the request has been concluded. Thereafter, it will be stored for a period of 5 years for audit and compliance purposes, after which all personal data will be deleted.</p>
10.	Recipients of the data	The data collected will be processed internally by staff within the EMA division(s), advisory function(s) and task force(s) responsible for addressing the request, in addition to the Data Protection Officer and the Legal Department when applicable.
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>The personal data is kept in an internal, secure electronic records management system designed and maintained to prevent accidental or unlawful destruction, loss, alteration or transfer of the data stored.</p> <p>Data may only be accessed by authorised EMA staff on a need-to-know basis.</p>
13.	For more information, including how to exercise	Details concerning the processing of your personal data are available on the Agency's website at:

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	your rights to access, rectification, object and data portability (where applicable), see the privacy statement:	<a href="https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement">https://www.ema.europa.eu/en/about-us/legal/general-privacy-statement</a> Here you may find the data protection notice regarding this specific data processing operation as well: <a href="https://www.ema.europa.eu/en/documents/other/records-data-processing-activity-handling-data-subjects-requests_en.pdf">https://www.ema.europa.eu/en/documents/other/records-data-processing-activity-handling-data-subjects-requests_en.pdf</a>
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**Commented [EO1]:** If a specific data protection notice is already published, the link should be added.

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