



EMA/331101/2020

Record of data processing activity (public)

Name and reference number of processing operation: **Validation of proof of establishment when natural persons apply for orphan designation or a transfer of an orphan designation**

1.	Last update of this record, version number:	18 June 2020, version 1
2.	Reference number:	H2
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of Human Medicines Division 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 personal data processing is to verify, in the case of natural persons applying for orphan designation of a medicinal product (or a transfer thereof), that they are established within the EEA, i.e. that they are citizens of at least one of the Members States of EEA (such as all European Union Member States, as well as Iceland, Liechtenstein and Norway).
8.	Description of categories of persons whose data EMA processes and list of data categories	Natural persons applying for orphan designation of a medicinal product or a transfer of an orphan designation of a medicinal product List of data processed: <ul style="list-style-type: none">• Copy of identification document provided as proof of citizenship (e.g. passport);• Name, email address, telephone number



9.	Time limit for keeping the data	Once the proof of establishment has been received by EMA, proof of citizenship is verified by EMA within the time needed for validation of the application. At the end of the validation process all the personal data are deleted from EMA's systems.
10.	Recipients of the data	Personal data processed in this activity are only accessible to EMA staff members. None of the data processed will be published or shared outside of the EMA.
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.	All data is stored within secure systems of EMA with password protection.
13.	For more information, including how to exercise your rights to access, rectification, object and data portability (where applicable), see the Privacy Statement.	https://www.ema.europa.eu/en/documents/other/privacy-statement-validation-proof-establishment-when-natural-persons-apply-orphan-designation_en.pdf