EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 June 2022
EMA/185307/2022

Records of data processing activity for the certification of medicinal products

1.	Last update of this record, version number:	23 June 2022, version 1
2.	Reference number:	H8
3.	Name and contact details of controller:	European Medicines Agency Internally: Head of H-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)	Not applicable
6.	Name and contact details of processor (where applicable)	Not applicable
7.	Purpose of the processing	Handling of personal data in the context of companies' requests for certification of medicinal products. This includes: • The collection and storage of personal data included in the application form for certificates of medicinal products (Link) submitted by companies in relation to requests for certification of medicinal products, and which are used for correspondence. • The collection and storage of personal data included in the permission letters (Link) submitted by marketing authorisation holders in relation to requests for certification of medicinal products, and which are used for correspondence.

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
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

		• Maintenance of internal records and the internal certificates database.
8.	Description of categories of persons whose data EMA processes and list of data categories	The types of data subjects processed are as follows: • Details of the contact person for correspondence with the certificate team: title, first name and surname, e-mail address, telephone number; • Name of the person signing the application form for certificates of medicinal products; • Supporting documentation (e.g. permission letter), where applicable.
9.	Time limit for keeping the data	Records which contain personal data shall be disposed of after 30 years from the date on which the certificate was issued.
10.	Recipients of the data	The data collected can be accessed by EMA staff. The data will be processed internally by staff within the EMA Divisions responsible for issuing certificates of medicinal products and related processes (e.g. invoicing, IT maintenance).
11.	Are there any transfers of personal data to third countries or international organisations? If so, to which ones and with which safeguards?	Not applicable
12.	General description of security measures, where possible.	The Agency has put in place appropriate technical and organisational measures (security policies and procedures) to protect personal data from accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to your personal data. The Agency takes all the necessary measures to ensure the maximum safety and security of personal data held. The data provided is held in a secured and protected database hosted by EMA, the operations of which abide by EMA's security policy. The database is not accessible from outside EMA. Within EMA, the database is managed using a user ID and password.
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/documents/other/european-medicines-agencys-data-protection-notice-certificates-medicinal-products_en.pdf Here you may find the data protection notice regarding this specific data processing operation as well.