



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2022
EMA/13742/2019 Rev.2
Administration and Corporate Management

European Medicines Agency's Data Protection Notice

For the processing of personal data in the context of public procurement procedures

This Data Protection Notice explains the essential details about how personal data of candidates and tenderers for EMA's public procurement procedures are processed by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of these procedures. In relation to this data processing activity this document also provides information about the rights of the individuals concerned (i.e. the data subjects) to access and to rectify their personal data which is processed.

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 controller of this processing is the relevant Head of Division indicated in the 'Invitation to tender letter' and appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

2. Purpose of this data processing?

Upon receipt of your pre-qualification questionnaire for restricted tender procedures or your request to participate in the case of other two-step tender procedures or your tender by EMA, your personal data is collected and processed for the purpose of:

- the management and administration of the respective procurement award procedure by EMA;
- additionally, and only with regard to the personal data of awarded tenderer(s), the preparation of the contract.

2.1. Personal data concerned

We process data directly submitted by you in the course of the tender procedure (e.g., in the pre-qualification questionnaire, in your request to participate, in your tender and in other documents submitted as part of the procedure). Personal data collected and further processed will concern the candidate or tenderer, its staff, and any subcontractors. Information can relate to the following data:

- Name (title, first name, surname) and function;



- Contact details (company and department, postal address, country of residence, business telephone number, mobile telephone number, fax number, e-mail address, website address);
- Bank account details (account number, name of the account holder, name and address of the bank, IBAN and BIC codes);
- Passport/ID number (natural persons) or company registration number (legal persons), VAT number and/or membership in a trade or professional organisation;
- Information for the evaluation of selection criteria: financial and economic capacity (bank statements or professional risk indemnity insurance or balance sheet or statement of turnover), expertise, technical and language skills, educational background, professional experience including details on current and past employment;
- Certificates for social security contributions and taxes paid, extracts from judicial records;
- Other personal data contained in CVs (e.g. gender, place and date of birth, nationality);
- Other personal data contained in the proposal or tender;
- Information submitted as evidence that the candidate or tenderer is not in any of the situations of exclusion referred to in Article 136 of the general Financial Regulation (referenced below) and further stipulated in the declaration on honour.

The collected personal data and all related information are stored securely by EMA and on servers of EMA with appropriate levels of security.

2.2. Providing your personal data

The candidate or tenderer, i.e., the data subject, agrees that all data provided in the course of the public procurement procedure will be processed for the purpose(s) stated above in Section 2. The provision of personal data in the context of procurement procedures is in principle not mandatory, however failure to provide certain information may imply the exclusion from the evaluation and award procedure.

2.3. Legal basis of the processing

EMA processes your personal data in accordance with [Regulation \(EU\) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation \(EC\) No 45/2001 and Decision No 1247/2002/EC](#).

The legal basis for the processing operations on personal data is a legal obligation (Article 5(1)(b) of Regulation EU 2018/1725), meaning that this data processing is necessary for our compliance with a legal obligation to which we are subject to. More specifically, we process your data to comply with the requirements of [Regulation \(EU, Euratom\) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations \(EU\) No 1296/2013, \(EU\) No 1301/2013, \(EU\) No 1303/2013, \(EU\) No 1304/2013, \(EU\) No 1309/2013, \(EU\) No 1316/2013, \(EU\) No 223/2014, \(EU\) No 283/2014, and Decision No 541/2014/EU and repealing Regulation \(EU, Euratom\) No 966/2012](#) ("Financial Regulation") in particular Articles 160-179 for procurement procedures.

2.4. Transfer of personal data outside of EU

Your personal data is not transferred outside of the EU.

3. How long do we keep your data?

Original signed contracts which include specifications of the call for tender and winning tender submissions are archived for seven years from the expiry of the resulting contract. The remaining documentation (including proposals/tenders of unsuccessful candidates/tenderers) is destroyed five years after the award decision.

List of names for Curricula Vitae are destroyed following finalisation of the procurement procedure in question. The Curricula Vitae are kept for five years after signature of the award decision in question.

Extracts from judicial records are kept for two years after signature of the award decision in question.

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

For the purpose(s) indicated above (Section 2), access to your personal data is given to authorised staff members dealing with procurement procedures which may include the Head of Division, Department or Service for the relevant procurement procedure, procurement officers, staff dealing with financial matters and the Accounting Officer, appointed members of evaluation committees, external experts or project managers responsible for contract implementation, members of the Agency's Advisory Committee on Procurement and Contracts, staff in the Legal Department.

Authorised staff members from external bodies in charge of a monitoring, auditing or inspection task in accordance with European Union legislation (such as the European Court of Auditors, the Internal Audit service of the European Commission, the European Anti-Fraud Office (OLAF) as well as the EU Ombudsman or the European Data Protection Supervisor) may also have access to relevant personal data for audit control and other monitoring purposes.

Data of economic operators who are in one of the exclusion situations referred to in Article 136 of the Financial Regulation may be included in the Early Detection and Exclusion System (EDES) and communicated to the designated persons of the European Commission, other EU institutions, agencies, authorities and bodies mentioned in Articles 142 and 143 of the Financial Regulation. This refers as well to the persons with powers of representation, decision-making or control over the said economic operators.

In case of litigation, including for contractual liability claims, data may be shared with the competent courts (e.g., General Court of the European Union, Courts of Amsterdam, the Kingdom of the Netherlands).

Pursuant to the publication requirements laid down in the Financial Regulation, limited personal data is made public as concerns the outcome of procurement procedures. This information concerns the name, address and amount awarded for which successful tenderers are awarded a contract. The data is published in supplement S of the Official Journal of the European Union as well as on the EMA corporate website:

<https://www.ema.europa.eu/en/about-us/procurement/procurement-archive>

5. Your data protection rights

As data subject (i.e., the individual whose personal data is processed), you have several 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.

If the exercise of one of the abovementioned rights (especially the right to erasure) concerns information that is necessary for the management, administration or evaluation of tenders, executing your request may lead to the rejection from the evaluation and award procedure.

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 Data Protection and Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

6. 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 Privacy Statement or the general EMA Privacy Statement, please contact the Data Controller.

The contact details of the Data Controller are indicated in the 'Invitation to tender letter'.

Data subjects may lodge a complaint with the **EMA Data Protection Officer**: dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor**:

- Email: edps@edps.europa.eu
- Website: www.edps.europa.eu
- Further contact information: www.edps.europa.eu/about-edps/contact_en