

CRITICAL MEDICINES ALLIANCE

PRIVACY STATEMENT

Processing operation		Critical Medicines Alliance
Data Controller		European Commission, European Health Emergency Preparedness and Response Authority, Unit 3 – Medical Counter-Measures
Record reference		DPR-EC-24950

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1. INTRODUCTION

The European Commission (hereafter ‘the Commission’) is committed to protect your personal data and to respect your privacy. The Commission collects and further processes personal data pursuant to [Regulation \(EU\) 2018/1725](#) of the European Parliament and of the Council of 23 October 2018 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 (repealing Regulation (EC) No 45/2001).

This privacy statement explains the reason for the processing of your personal data, the way we collect, handle and ensure protection of all personal data provided, how that information is used and what rights you have in relation to your personal data. It also specifies the contact details of the responsible Data Controller with whom you may exercise your rights, the Data Protection Officer and the European Data Protection Supervisor.

The information in relation to processing operation ‘Critical Medicines Alliance’ undertaken by the European Commission, European Health Emergency Preparedness and Response Authority, Unit 3 – Medical Counter-Measures (hereinafter “HERA, Unit 3” or the “Data Controller”) is presented below.

2. WHY AND HOW DO WE PROCESS YOUR DATA?

Purpose of the processing operation: HERA, Unit 3 collects and uses your personal information to set up and operate the Critical Medicines Alliance.

The Critical Medicines Alliance is a consultative mechanism which brings together all relevant stakeholders to identify the challenges, the priorities for action as well as the possible policy solutions to the shortages of critical medicines in the EU.

The Alliance provides the Commission and other EU decision makers with advice on the most appropriate actions and instruments to tackle medicines shortages, drawing on a set of available tools. The Alliances' recommendations are detailed in a multi-year set of actions ('Strategic Plan'), prepared by the Steering Board and endorsed by the Forum, containing milestones and corresponding deadlines. This document aims at guiding the Commission, the Member States and industry in the implementations of the recommendations, should they be chosen by respective parties.

The Forum is open to all Member Organisations. It meets at least once a year to discuss high level policy issues related to the Alliance (for instance, the Forum is consulted before the adoption of the Strategic Plan by the Steering Board). It involves high-level representatives from within its Membership.

The Steering Board is composed of four representatives of the Member States, four representatives of the industry, two representatives of patients/consumers/healthcare professionals, one representative of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), one representative of the EMA, and all chairs of the Working Groups. It is in charge of:

- preparing the Forum;
- preparing and adopting the Strategic Plan;
- ensuring consistency and integration of the work of the different working groups and with the other existing structures;
- maintaining a roadmap of the implementation of the actions proposed by the Alliance, based on the working groups' input;
- supporting the European Commission in facilitating, communicating, and monitoring the work of the Alliance, as well as validating its outputs.

Working Groups may be set up by the Commission at the Steering Board's request to focus on specific topics. They are open for participation to Member Organisations with appropriate activities and expertise in relation to the working groups' area of work. They provide input for the Steering Board to draft the Strategic Plan.

The European Commission provides the Alliance's Secretariat; assesses the fulfilment of eligibility criteria by applicant organisations; acts as a facilitator of the Forum and organises its meetings; chairs the Steering Board, organises its work, and provides its secretariat; sets up and defines membership of the Working Groups.

More precisely, personal data are collected and processed for the following purposes:

- 1.1.** For the purpose of the treatment of requests to become a Member Organisation of the Alliance: The Data Controller processes the personal data (title, given name and family name, contact details, name of the organisation, position or function in the organisation) of the person and backup person filling out the registration form on behalf of the applicant organisation so that the organisation can be contacted on matters related to its participation in the Alliance.
- 1.2.** For the purpose of validating compliance with the conditions for membership of the Alliance: The Data Controller processes the personal data (title, given name and family name, contact details, name of the organisation, position or function in the organisation) of the person authorising the Alliance Declaration and their confirmation that they are duly authorised by the applicant organisation.
- 1.3.** For the purpose of operation of the Alliance Forum, Steering Board, and Working Groups, the Data Controller processes the personal data (title, given name and family name, contact details, name of the organisation, position or function in the organisation) of the person and backup person who filled out the registration form on behalf of the Alliance Member Organisation.

Your personal data will not be used for an automated decision-making including profiling.

3. ON WHAT LEGAL GROUNDS DO WE PROCESS YOUR PERSONAL DATA?

We process your personal data, because processing is necessary for the performance of a task carried out in the public interest. The Union law for such necessary processing under Article 5(1)(a) of Regulation (EU) 2018/1725 is Article 173 of the Treaty on the Functioning of the European Union. The Communication from the Commission “Addressing medicine shortages in the EU” (COM(2023) 672 final), based in particular on Article 173 TFEU, states that “the Commission intends to set up a “Critical Medicines Alliance” by early 2024. This would allow national authorities, industry, civil society representatives, the Commission and EU agencies to come together to develop coordinated action at the EU level against the shortages of medicines.”

4. WHICH PERSONAL DATA DO WE COLLECT AND FURTHER PROCESS?

In order to carry out this processing operation HERA, Unit 3 collects the following categories of personal data:

- Title (Mr/Mrs/Ms/Mx/Dr/Prof.)
- Given name and Family name
- Contact details (e-mail address and phone number)
- Affiliation (name of the organisation)
- Position or function in the organisation

The provision of personal data is not mandatory.

5. HOW LONG DO WE KEEP YOUR PERSONAL DATA?

The Data Controller only keeps your personal data for the time necessary to fulfil the purpose of collection or further processing, namely for the duration of the member participation in the Alliance. In case the Alliance is permanently discontinued, contact data will be kept for a maximum of 5 years.

6. HOW DO WE PROTECT AND SAFEGUARD YOUR PERSONAL DATA?

All personal data in electronic format (e-mails, documents, databases, uploaded batches of data, etc.) are stored either on the servers of the European Commission. All processing operations are carried out pursuant to the Commission Decision (EU, Euratom) 2017/46 of 10 January 2017 on the security of communication and information systems in the European Commission.

In order to protect your personal data, the Commission has put in place a number of technical and organisational measures. Technical measures include appropriate actions to address online security, risk of data loss, alteration of data or unauthorised access, taking into consideration the risk presented by the processing and the nature of the personal data being processed. Organisational measures include restricting access to the personal data solely to authorised persons with a legitimate need to know for the purposes of this processing operation.

7. WHO HAS ACCESS TO YOUR PERSONAL DATA AND TO WHOM IS IT DISCLOSED?

Access to your personal data is provided to the Commission staff responsible for carrying out this processing operation and to authorised staff according to the “need to know” principle. Such staff abide by statutory, and when required, additional confidentiality agreements.

The information we collect will not be given to any other third party, except to the extent and for the purpose we may be required to do so by law.

8. WHAT ARE YOUR RIGHTS AND HOW CAN YOU EXERCISE THEM?

You have specific rights as a ‘data subject’ under Chapter III (Articles 14-25) of Regulation (EU) 2018/1725, in particular the right to access, your personal data and to rectify them in case your personal data are inaccurate or incomplete. Where applicable, you have the right to erase your personal data, to restrict the processing of your personal data, to object to the processing, and the right to data portability.

You have the right to object to the processing of your personal data, which is lawfully carried out pursuant to Article 5(1)(a), on grounds relating to your particular situation.

You can exercise your rights by contacting HERA, Unit 3, or in case of conflict the Data Protection Officer. If necessary, you can also address the European Data Protection Supervisor. Their contact information is given under Heading 9 below.

Where you wish to exercise your rights in the context of one or several specific processing operations, please provide their description (i.e. their Record reference(s) as specified under Heading 10 below) in your request.

9. CONTACT INFORMATION

9.1. The Data Controller

If you would like to exercise your rights under Regulation (EU) 2018/1725, or if you have comments, questions or concerns, or if you would like to submit a complaint regarding the collection and use of your personal data, please feel free to contact the Data Controller:

European Commission

Health Emergency Preparedness and Response Authority (HERA)

Unit 03 – Medical Counter-Measures

Rue de la Loi 15 / Wetstraat 15, 1000 Brussels, Belgium

E-Mail address: HERA-CRITICAL-MEDICINES-ALLIANCE@ec.europa.eu

9.2. The Data Protection Officer (DPO) of the Commission

You may contact the Data Protection Officer (DATA-PROTECTION-OFFICER@ec.europa.eu) with regard to issues related to the processing of your personal data under Regulation (EU) 2018/1725.

9.3. The European Data Protection Supervisor (EDPS)

You have the right to have recourse (i.e. you can lodge a complaint) to the European Data Protection Supervisor (edps@edps.europa.eu) if you consider that your rights under Regulation (EU) 2018/1725 have been infringed as a result of the processing of your personal data by the Data Controller.

10. WHERE TO FIND MORE DETAILED INFORMATION?

The Commission DPO publishes the register of all processing operations on personal data by the Commission, which have been documented and notified to him. You may access the register via the following link: <http://ec.europa.eu/dpo-register>

This processing operation has been included in the DPO's public register with the following Record reference: DPR-EC-24950.