EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2020
EMA/331929/2019

European Medicines Agency's Privacy Statement for EudraVigilance

The European Medicines Agency (hereafter referred to as "the Agency"), in collaboration with Union Member States and the Commission, has set up and maintains the EudraVigilance[1],[2],[3] database and data processing network to collate and analyse information on suspected adverse reactions regarding investigational medicinal products (IMPs) studied in clinical trials and medicinal products authorised in the Union. This is to allow national Competent Authorities (NCAs), the Agency and the Commission to access and share that information simultaneously. Whilst EudraVigilance is operated by the Agency, its content originates from NCAs, marketing authorisation holders (MAHs) and sponsors of clinical trials.

This Privacy Statement explains the most essential details of the processing of personal data by the Agency, which includes:

- the area of **pharmacovigilance**[4] and information on suspected adverse drug reactions (ADRs) from patients, health care professionals and other sources, which is reported to EudraVigilance by NCAs and MAHs, who perform an assessment to ensure the continuous safety of medicines[5];
- the area of **clinical trials**[6] and information on suspected unexpected serious adverse reactions (SUSARs) reported by sponsors to EudraVigilance thus allowing NCAs to evaluate whether an IMP poses an unknown risk to the trial subject and to take measures to protect the safety of trial subjects, if necessary[7].

[1] Pharmacovigilance: Overview
[1] Title IX, Chapter 3 of Directiv
e 2001/83/EC, Title II, Chapter 3 of Regulation (EC) 726/2004 and Chapters III, IV and V of the Commission Implementing Regulation (EU) 520/2012
[2] Clinical trials in human medicines
[2] Article 17 of Directive 2001/20/EC; Communication from the Commission —

[4] Pharmacovigilance: Overview
[5] Title IX, Chapter 3 of Directive 2001/83/EC, Title II, Chapter 3 of Regulation (EC) 726/2004 and Chapters III, IV and V of the Commission Implementing Regulation (EU) 520/2012
[6] Clinical trials in human medicines
[7] Article 17 of Directive 2001/20/EC; Communication from the Commission — Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ('CT-3')(2011/C 172/01)

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

1. Who is responsible for your data?

1.1. Who is the data controller?

The Agency is jointly responsible with NCAs, MAHs and sponsors of clinical trials in Union Member States to comply with your data protection rights and freedoms. On behalf of the Agency, the Head of the Inspections, Human Medicines Pharmacovigilance & Committees Division is appointed as a 'Data Controller' to ensure the proper implementation of the processing operation.

The contact details of the Agency's Data Controller are provided in section 7.

1.2. Who is the data processor?

The Agency may engage third parties to provide support for the:

- monitoring of a number of substances and selected medical literature to identify suspected adverse reactions with medicines authorised in the European Union (EU), and for entering the relevant information into EudraVigilance[8],
- management of duplicated ADR reports submitted to EudraVigilance[9],
- assurance of data quality in EudraVigilance.

The contact details of the data processor(s) are the following:

Kinapse Ltd – E-mail: info@kinapse.com

2. Purpose of this data processing

The purpose of the EudraVigilance data processing activities can be summarised as follows:

a. Area of pharmacovigilance:

- collecting and recording of ADR information reported by patients[10], healthcare professionals or other sources;
- structuring and storage of ADR information in the internationally agreed format of Individual Case Safety Reports (ICSRs)[11];
- use of ADR information for signal detection and safety monitoring of medicines[12].

b. Area of clinical trials:

- collecting and recording of SUSAR information reported by sponsors of clinical trials;
- structuring and storage of ADR information in the internationally agreed format of Individual Case Safety Reports (ICSRs);
- use of SUSAR information by NCAs to evaluate whether an IMP poses an unknown risk to the trial subject and to take measures to protect the safety of subjects, if necessary.

[8] Monitoring of medical literature and entry of adverse reaction reports into EudraVigilance
[9] Guideline on good pharmacovigilance practices (GVP) Module VI Addendum I – Duplicate management of suspected adverse reaction reports (EMA/405655/2016)
[10] Did you know? You can report side effects yourself
[11] E2B(R3) Individual Case Safety Report (ICSR) Specification and Related Files
[12] Signal management

3. What personal data do we process and how?

3.1. Personal Data concerned

Personal data refer to any information relating to an identified or identifiable natural person ("data subject"). An identifiable natural person is one who can be identified, directly or indirectly, in particular by an identifier such as name, an identification number or others[13].

The content of ICSRs is defined by legislation[14] with the minimum reporting criteria further set out in good pharmacovigilance practice guidance (GVP) Module VI[15]. Examples of personal data that can be processed by NCAs, MAHs and sponsors of clinical trials for the reporting of suspected adverse reactions are name, address or phone number of a healthcare professional/investigator, a patient's email address (name.surname@xxxx.com) or details regarding an identified or identifiable patient's health or personal characteristics (e.g., age, gender). NCAs, MAHs and sponsors of clinical trials pseudonymise such information before submission to EudraVigilance, while ensuring that reports still contain sufficient information to allow for the safety monitoring and assessment of medicines. Pseudonymisation means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person[16].

NCAs, MAHs and sponsors of clinical trials assign a unique identifier to each ICSR so they can follow-up reports and when submitted to EudraVigilance, the ICSRs can be adequately processed and duplicates detected and managed. Rules are in place prohibiting re-identification of data subjects with the exception where NCAs, MAHs or sponsors of clinical trials need to follow-up with the initial reporter of the suspected adverse reaction(s).

GVP Module VI[17] also sets out the obligations as regards the monitoring of public sources such as medical literature, internet or digital media including social media. This may involve the processing of personal data as part of ADR reports originating from such public sources, which are important to support the monitoring of the safety and the risk-benefit balance of medicinal products, particularly in relation to the detection of new safety signals or emerging safety issues.

3.2. Legal Basis

EudraVigilance related personal data processing operations are expressly provided for in the pharmaceutical legislation[18] and in relevant national provisions and are necessary for the performance of tasks carried out in the public interest. They refer the purpose of the protection of health by setting standards of quality and safety for medicinal products. In particular, the processing of data is provided for under:

[13] Definition in accordance with Article 3(1) of 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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC)
[14] Article 28 of the Commission Implementing Regulation (EU) 520/2012
[15] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[16] Article 3(6) of Regulation (EU) 2018/1725.
[17] Guideline on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)
[18] EudraLex - Volume 1 - Pharmaceutical legislation for medicinal products for human use

- Title II, Chapter 3 of Regulation (EC) 726/2004[19] as regards the pharmacovigilance obligations for centrally authorised medicinal products;
- Title IX, Chapter 3 of Directive 2001/83/EC[20] and the obligations for the recording, reporting and assessment of pharmacovigilance data relating to non-centrally authorised medicinal products;
- Article 17 of Directive 2001/20/EC[21] and the requirements for the recording and reporting of SUSARs relating to IMPs studied in clinical trials supplemented by further guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ("CT-3")[22];
- Chapter IV[23] of the Commission Implementing Regulation (EC) No 520/2012, which sets out the rules on the format and content for the submission of reports of suspected adverse reactions and Chapter V[24] lays down the principles for the transmission of reports of suspected adverse reactions including the content of such reports;
- Chapter III[25] of the Commission Implementing Regulation (EC) No 520/2012, which defines the minimum requirements for the monitoring of data in the EudraVigilance database with further details on the signal management process provided for in GVP Module IX[26].

3.3. Transfer of personal data outside of EU

Reports of suspected adverse reactions submitted to EudraVigilance may be shared with regulatory authorities and international organisations of third countries based on mutual cooperation agreements or confidentiality arrangements. Please see also section 6.

4. How long do we keep your data?

Pseudonymised reports of suspected adverse reactions are maintained for an indefinite period in EudraVigilance. This is to provide for a large and coherent data pool covering a wide range of medicinal products and ADRs, which is necessary to ensure that statistical methods and algorithms for signal detection and data analysis operate consistently and a full and complete scientific evaluation across different medicinal products and therapeutic areas is provided for.

[19] Title II "Authorisation and supervision of medicinal products for human use", Chapter 3 "Pharmacovigilance" of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
[20] Title IX "Pharmacovigilance", Chapter 3 "Recording, reporting and assessment of pharmacovigilance data" of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2 DIRECTIVE 2001/83/EC on the Community code relating to medicinal products for human use.
[21] Directive 2001/20/EC OF the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
[22] Detailed guidance on the collection, verification and presentation of adverse event/reaction reports arising from clinical trials on medicinal products for human use ("CT-3")
[23] CHAPTER IV "Use of terminology, formats and standards" Commission Implementing Regulation (EU) 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
[24] CHAPTER V "Transmission of reports of suspected adverse reactions" Commission Implementing Regulation (EU) 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
[25] CHAPTER III "Minimum requirements for the monitoring of data in the Eudravigilance database", Commission Implementing Regulation (EU) 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council.
[26] Guideline on good pharmacovigilance practices (GVP) Module IX – Signal management (Rev 1).

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

The provisions of access to EudraVigilance data and the actors, to whom access should be granted, are set out in the pharmaceutical legislation[27]. The EudraVigilance Access Policy[28] further details the different levels of access provided to these actors taking into account the need to protect personal data as well as their pharmacovigilance obligations or interests. These actors refer to NCAs in Union Member States, the European Commission, the Agency, healthcare professionals, the public, MAHs, academia, the WHO and medicines and regulatory authorities in third countries.

Information on spontaneous reports from patients and healthcare professionals held in EudraVigilance can be accessed publicly as follows: adrreports.eu.

In accordance with Article 17(3)(a) of Directive 2001/20/EC, access to SUSARs reported to EudraVigilance is provided to NCAs in Union Member States, the Agency and the Commission.

6. What are your rights under personal data protection?

As data subjects, you have a number of rights, which are further outlined below.

In the context of the right to access and the right to rectification, you should note that there may be instances where a requestor contacts the Agency as regards their personal data being processed in EudraVigilance but it may not be possible for the Agency to confirm whether personal data concerning the requestor are being processed. This is based on the principle that generally personal data in ADR/SUSAR reports are pseudonymised before being submitted by an NCA, a MAH or a sponsor to EudraVigilance (as outlined in section 3.1). In such instances, the Agency will refer the requestor to the NCA, MAH or sponsor that submitted the ADR/SUSAR report to EudraVigilance, who may in turn refer them to their healthcare professional/investigator where the report was received from the healthcare professional/investigator.

- **Right to be informed** – This Privacy Statement is aimed at informing data subjects how the Agency collects and uses their personal data.
- **Right to access** – Data subjects have the right to access their personal data. You have the right to request and obtain a copy of the personal data held by the Agency, based on the principles set out above.
- **Right to rectification** – Data subjects have the right to obtain without undue delay the rectification of inaccurate personal data concerning him or her, based on the principles set out above.
- **Right to erasure** – Data subjects have generally the right to require the Agency to delete or stop processing their data, for example where the data is no longer necessary for the purposes of processing. However, such right is not applicable to the extent that processing is necessary for compliance with a legal obligation, which requires processing by Union or Member State law to which the controller is subject, or if it is necessary for reasons of public interest in the area of public health.
  In cases where the right to erasure is requested and granted to a data subject, data may be kept if it has undergone an appropriate process of anonymisation.

[27] Article 24(2) of Regulation (EC) No 726/2004
[28] European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use (EudraVigilance Access Policy) (EMA/759287/2009 Revision 3*)

- **Right to object** – Data subjects have the right to object at any time to the processing of data relating to them on grounds related to their particular situation. Exceptions apply in certain cases, for example, where the data controller has overriding legitimate grounds for the processing or when processing is necessary for the performance of a task carried out for reasons of public interest.

The rights of the data subject can be exercised in accordance with the provisions of Regulation (EU) 2018/1725[29].

Data subjects also have the right to lodge a complaint with the European Data Protection Supervisor (EDPS) at any time at the following address: edps@edps.europa.eu.

For anything that is not specifically provided for in this privacy notice, please refer to the contents of the general EMA Privacy Statement: www.ema.europa.eu/en/about-us/legal/privacy-statement

7. 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, you may contact the Data Controller on the following email address: P-SUP@ema.europa.eu.

In addition, you may submit a question or complaint to 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

[29] 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, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC)