EMA/119597/2024
4 March 2024

European Medicines Agency's Data Protection Notice

For Scientific Explorer

This Data Protection Notice explains the most essential details of the processing of personal data by the European Medicines Agency (hereinafter "EMA" or "Agency") in the context of "Scientific Explorer".

Scientific Explorer is an Artificial Intelligence (AI) enabled tool for medicines regulators of the European Medicines Regulatory Network (EMRN) that facilitates easy, focused and precise searches within regulatory procedure documents and structured data from the Interactive Regulatory Information System (IRIS). Scientific Explorer is only available to EMRN regulators registered in IRIS.
Through Scientific Explorer EMRN regulators can access more efficiently the information already available to them in IRIS, in the context of the relevant regulatory process.
Scientific Explorer has been developed under the Research and Development Value Stream following EMA software development delivery practices.
Scientific Explorer enables:

- The identification and extraction of selected (non-personal) information from unstructured scientific documents submitted or produced in the context of EMA scientific advice procedures using Natural Language Processing techniques, referred to as AI extractions (see more below). The unstructured scientific documents processed are:
  - scientific advice letters on medicinal products for human use,
  - protocol assistance advice letters on medicinal products for human use,
  - qualification advice letters and opinions for novel methodologies,
  - clarification letters on the above procedures, and
  - briefing documents associated with these procedures (between 01/08/2018 and 25/10/2022 briefing documents were appended to the Final Advice Letters).
- The possibility of combining the AI extractions above with structured data from the scientific advice procedures applications forms contained in the procedure management system IRIS and free text of in procedure documents to maximise the users' search capabilities.
- The ability to interrogate or "chat" with selected parts of the search results (excluding personal information) via a chat function user interface.

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- Ready access to the source document to verify search findings.
- The generation of summary statistics and reports on the searches performed to support the continuous improvement of the scientific quality and efficiency of the Agency's work.

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 Head of the Human Medicines Division is appointed as 'Internal Controller' to ensure the lawful conduct of this processing operation.

You may contact the Internal Controller via the following email address: Datacontroller.HumanMedicines@ema.europa.eu

1.2. Who is the data processor?

The Agency may engage third parties to process data on behalf of the Agency and, in particular, to carry out the following activities:

- Infrastructure (cloud services) support:

    a. Microsoft Azure components used to manage information (read/create/update/delete/index activities)

    b. Microsoft Azure OpenAI (MS OpenAI) used to extract information from documents and interrogate results.

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

    Microsoft Ireland Operations Limited
    One Microsoft Place
    South County Business Park
    Leopardstown, Dublin, 18
    Ireland
    EU Data Protection Officer's contact: DPOffice@Microsoft.com Telephone: (+353 1 7063117)

Maintenance third-line support of Scientific Explorer solution

    The contact details of the data processor(s) for this activity are the following:
    CapGemini Nederland B.V.
    Reykjavikplein 1, 3543 AK Utrecht
    The Netherlands
    Data Protection Officer contact: ema.nl@capgemini.com

2. Purpose of this data processing

EMA provides scientific advice to support the timely and sound development of high-quality, effective and safe medicines, for the benefit of patients. It is important that due account is taken of previous advice procedures from the EMA to support consistency and quality of the output. Scientific advice procedures are managed through the IRIS case management system.

The purpose of data processing in Scientific Explorer is to support and improve the retrieval of relevant information concerning applicable regulatory precedents.

The scientific advice related documentation and associated structured data (explained above) are required to support medicines regulators in the EMRN to perform their tasks.
More specifically, the processing of personal data enables authorized users of the Scientific Explorer to identify or search for staff of EMA or medicines regulators associated with a particular procedure in procedural (structured) data coming only from IRIS. There are no AI extractions relating to personal data.

In the context of the scientific advice procedures, and enabling the development of new medicines, this is essential to:

- Discuss the corresponding scientific advice precedents with the applicable coordinators (if they are current members of the Scientific Advice Working Party (SAWP)), or with assessors or experts of the EMRN where there are related scientific advices (e.g. same product or class, indication, qualification methods),
- Deepen understanding regarding these previous procedures and
- Involve the current SAWP members, or the respective EMRN medicines regulators in ongoing or upcoming advice procedures.

Use of AI in Scientific Explorer is limited to:

- Extracting unstructured scientific and non-personal data (AI extractions) from scientific advice documents, and
- Chat with the selected parts of the search results; together these comprise the 2 scenarios of use of AI in scientific explorer.

Scientific Explorer is using the same type of large language models (Microsoft OpenAI) in EMA's secure cloud environment. All data are processed in servers within the EU region and no EMA data is stored or used to retrain new models, nor to train the AI algorithm being used in Scientific Explorer. Scientific Explorer does not use the public ChatGPT function. Data are not combined with other external data sources.

2.1. Personal data concerned

In this processing operation, we process personal data from IRIS and regulatory procedure documents. Such data may include the following data subjects and personal data categories:

- Personal data from IRIS (structured data):
  - First and last name of EMA Assistant, Scientific Officer, Scientific Coordinators.
- Personal data in scientific documents produced in the context of EMA scientific advice procedures (unstructured data):
  - Final advice, protocol assistance and qualification letters: first and last name of EMA Scientific Officer and two to four Scientific Coordinators.
  - Clarification letters: first name and last name of applicant contact person; first name, last name and signature of Head of Scientific Advice Office.

There are no personal data expected to be included in scientific documents submitted by applicants in the context of EMA's scientific advice procedures, e.g. briefing documents (unstructured data). In exceptional cases, the briefing document may contain personal data from the applicant (e.g. first name, last name, work email address, work phone number).

The data subjects are further defined as follows:

- EMA assistant: an EMA employee responsible for assisting the scientific advice procedure;
- Scientific officer: an EMA employee responsible for managing the scientific advice procedure;
- Scientific coordinator, EMRN medicines regulator coordinator, or (co-)rapporteur: an employee responsible for drafting the scientific advice letter;
- Head of Scientific Advice Office: EMA employee managing the Scientific Advice Office;
- Applicant contact person: point of contact for the scientific advice submission.

2.2. Legal basis of the processing

The operation of Scientific Explorer is necessary for the performance of the Agency tasks carried out in the public interest (in accordance with Article 5(1)(a) of Regulation (EU) 2018/1725).

The legal basis for undertaking Scientific Advice procedures by EMA is provided for in Regulation (EC) No 726/2004, more specifically Articles 56(3) and 57(1).

Scientific advice is a core EMA activity in supporting other EMA functions including the following:

- **Protecting Public Health:** The core legal basis for this objective is Regulation (EC) No 726/2004, which lays down procedures for the authorisation and supervision of medicinal products for human and veterinary use. This regulation emphasises the importance of ensuring a high level of protection of human and animal health.
- **Facilitating Development and Access to Medicines:** The EMA's role in supporting the development of medicines is outlined in various regulations, including those concerning orphan medicinal products (Regulation (EC) No 141/2000) and paediatric medicines (Regulation (EC) No 1901/2006). These regulations aim to encourage the development of treatments for rare diseases and for the paediatric population.

- **Promoting Harmonization:** Directive 2001/83/EC on the Community code relating to medicinal products for human use aims to harmonize the regulation of medicines within the EU. This directive establishes standards for the quality, safety, and efficacy of medicinal products.
- **Science-Based Decision Making:** The EMA's commitment to science-based decisions is embedded in its founding regulations, which emphasize the role of scientific assessment and expert advice in the evaluation of medicines.
- **International Collaboration:** The EMA cooperates with international partners under the framework of various global initiatives and agreements, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). These collaborations are supported by the EU's broader legislative framework, which encourages international cooperation in the field of medicinal products.
- **Transparency and Engagement:** Transparency and public engagement are integral parts of the EMA's operations, as mandated by Regulation (EC) No 726/2004. This regulation requires the EMA to ensure transparency in its scientific assessment and decision-making processes.
- **Fostering Innovation:** The EMA's role in promoting innovation is supported by various EU initiatives and legislation, including the framework for advanced therapies (Regulation (EC) No 1394/2007) and initiatives for small and medium-sized enterprises (SMEs).

In this regard, please note that you have the **right to object** against the processing as explained in below.

2.3. Transfer of personal data outside of EU

To implement Scientific Explorer, EMA uses IRIS Microsoft Cloud services as well as Microsoft Azure services, including OpenAI. All services store and manage data within EU. For further information please refer to the following DPNs:

- Interactive Regulatory Information System (IRIS)
- Use of Microsoft Applications: OneDrive, Outlook 365, Teams and SharePoint

3. How long do we keep your data?

Personal data are kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data were collected or for which they are further processed. Outputs of scientific advice procedures (the documents and data referred to above) contain scientific and regulatory precedents material to potential future scientific advice and marketing authorisation procedures in same or related indication or products. Personal data will be kept for as long as the activities described in the section "Purpose of this data processing" remain relevant.

Data are only processed by MS OpenAI and not stored.

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

The use of Scientific Explorer is restricted to the use by medicines regulators of the EMRN. All data referred to above are only accessible to authorised and authenticated users at EMA, including the technical maintenance and support teams acting as processors of EMA and staff of medicines regulators of the EMRN who are authorised to have access in support of their professional tasks. Access control is the same as for IRIS with access managed via EMA's Identity and Access Management.

5. Your data protection rights

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

Right to object – You have the right to object at any time to this processing on grounds related to your particular situation. If you do so, EMA may only continue processing your personal data if it demonstrates overriding legitimate grounds to do so or if this is necessary for the establishment, exercise or defence of legal claims.

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 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 Data Protection Notice or the general EMA Privacy Statement, please contact the **Internal Controller** at Datacontroller.HumanMedicines@ema.europa.eu or the **EMA Data Protection Officer** at dataprotection@ema.europa.eu.

You also have the right to lodge a complaint with the **European Data Protection Supervisor (EDPS)** at any time at the following address:

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