# Pharmacovigilance Privacy Notice

**Last updated: April 2023**

**Chugai Pharma Europe Ltd** and **Chugai Pharma UK** (together referred to as "we", "us" or "our" or "**Chugai**") respect your right to privacy and treat all your personal data in accordance with Chugai's Privacy Policy and applicable privacy and data protection laws. This Privacy Notice explains who we are, how we collect, share and use personal information about you and how you can exercise your privacy rights.

If you have any questions or concerns about our use of your personal information, please contact us using the contact details provided at the '**Contact Us'** section of this Privacy Notice.

Read this Privacy Notice carefully to ensure you don't miss any information that may be relevant to you.

***Note to non-patient reporters***

*As Chugai doesn't have access to the full identity of the patient, please inform them of the existence of this mention and suggest that they refer to it on our corporate website at https://www.chugai.eu/.*

**Scope of this Privacy Notice**

This Pharmacovigilance Privacy Notice applies to personal data being collected and processed in relation to Chugai's pharmacovigilance management and maintenance activities, in order to fulfil its legal tasks and obligations.

Reports may be received by phone, fax, e-mail or post, as well as through any online media or communication channel.

For general information about data processing at Chugai, please refer the Privacy section in the footer of this website.

**Who is the Data Controller?**

In collecting and processing this personal data **Chugai Pharma Europe Ltd. together with Chugai Pharma UK Ltd, where they have the relationship with you,** are the controllers of your personal data. When we say "Chugai", "we", "us" or "our", we are referring to the controller.

The registered company address and contract details for each company are shared in the **'Contact Us'** section below.

**What type of information we have?**

We collect and process the following information:

- Reporter details: When you report an adverse reaction, we process your full identity (surname, first name) as well as your contact details.
- Patient details: For each case of pharmacovigilance that we receive, we collect the following data relating to the patient (whether or not they are a notifier): initials or identification number (code), identifying information (age, year or date of birth, sex, weight, height), health data such as the treatments administered, test results, nature of adverse reactions or incidents, personal or family history, diseases or associated events, risk factors, information on ancestry and descent, data on working life, lifestyle habits and behaviours, lifestyle.

Only adequate, relevant, and limited data in relation to the analysis of the pharmacovigilance case shall be collected and processed.

**How we get the information and why we have it?**

Most of the personal information we process is provided to us directly by you for one of the following reasons:

- Your data may be collected directly from you, when you report an adverse reaction, and we are in direct contact with you.

We also receive personal information indirectly, from the following sources in the following scenarios:

- Your data is collected from the notifier (reporter) if you are a patient (who has presented the adverse reaction) or a healthcare professional who can provide additional information. The notifier may include, but is not limited to, our commercial and licensing partners, service providers, healthcare professionals or relatives to you.
- Finally, we are required to collect adverse reactions that may be published in the literature or mentioned on a website or online application that is our responsibility (blog, discussion forum, comment on a mobile application, etc).

*In the absence of reporter details, the data shall be deemed to be collected from the data subject*

**Our Lawful Basis**

Pharmacovigilance information is very important for public health and will be used for the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. Any personal data provided to Chugai related to adverse events or other activities related to pharmacovigilance will be used solely for these purposes.

Under the UK General Data Protection Regulation (GDPR), the lawful bases we rely on for processing this information are:

- Compliance with a legal pharmacovigilance obligation (GVP) to which Chugai is subject to.
- The processing of special categories of data, such as health data and data relating to sex life or sexual orientation, is necessary for reasons of public interest in the field of public health.

The collection and processing of your data is of a regulatory nature and of major public health interest. However, the non-provision of your data will not have a significant impact on you on the part of Chugai and as a patient, it will not have an impact on your medical care or your relationship with your healthcare professional.

**What we do with the information we have?**

We use the information that you have given us, in order to manage pharmacovigilance activities (adverse reaction, special situation), including the management of contacts by Chugai with the notifier, with the person to be questioned to obtain further details on the reported adverse reaction or the health professional who attended the person who presented the adverse reaction.

**Data Sharing and Transfer**

Your data is accessible to Chugai and to the Chugai group companies and affiliates in charge of pharmacovigilance, to business partners and to service providers to health professionals able to provide useful additional information, to third-party laboratories from which a medicinal product would be concerned, as well as to health authorities worldwide. The reports contain details about the incident but will only contain limited and relevant personal data.

Certain data may also be transmitted to Chugai departments in charge of medical information

or quality assurance if your pharmacovigilance notification is associated with a request for medical information or a quality claim.

It is possible that in the exchange of data within the Chugai group, business partners and service providers, your personal data may be transferred to countries that do not provide the same level of protection as your own. In this case, contracts containing the EU Standard Contractual Clauses according to EU Commission decisions will be ensured and shall constitute appropriate and suitable safeguards to ensure compliance with GDPR.

**Retention Period**

As information related to pharmacovigilance (reports about adverse events) are important for public health reasons, reports are kept for minimum of 10 years after the marketing authorisation for the product concerned has ceased to exist or longer if required by local legislation.

**Security**

Chugai takes precautions to ensure that personal data collected for pharmacovigilance purposes is protected and that the processing is in accordance with applicable data protection rules, consistent with generally accepted industry standards, including technical, administrative, and physical safeguards to protect the personal data submitted to us from loss, misuse and unauthorised access, disclosure, alteration and destruction.

**Your data protection rights**

Under data protection law, you have rights including:

- **Your right of access** - You have the right to ask us for copies of your personal information.
- **Your right to rectification** - You have the right to ask us to rectify information you think is inaccurate. You also have the right to ask us to complete information you think is incomplete.
- **Your right to restriction of processing** - You have the right to ask us to restrict the processing of your information in certain circumstances.

The corresponding data processing cannot be the subject of a request for erasure or opposition as pharmacovigilance is a legal requirement for Chugai.

Patients who are not themselves the originators of the notification can exercise their rights with Chugai directly or through the notifier as well as through the health professional of their choice.

You are not required to pay any charge for exercising your rights. If you make a request, we have one month to respond to you.

Please contact us using our contact details in the section below if you wish to make a request.

**Your Right to Complain**

You also have the right to make a complaint at any time to the relevant supervisory authority for data protection issues. We would, however, appreciate the chance to deal with your concerns before you approach the supervisory authority, so please contact us in the first instance.

If you are unhappy with how we have used your data, you can also complain to the ICO using the below contact points:

- **Post:** Information Commissioner's Office

  Wycliffe House

  Water Lane

  Wilmslow

Cheshire

SK9 5AF

- **Helpline number:** 0303 123 1113
- **Webform:** https://ico.org.uk/make-a-complaint/

**Contact us**

Chugai Pharma Europe Ltd and Chugai Pharma UK Ltd have appointed a data protection officer (DPO) who can respond to any enquiries about our use of your personal data. If you have any questions about this policy, including any requests to exercise your legal rights, please contact the UK DPO using the details set out below:

- **Registered Office and Post Address for both companies:** Mulliner House, Flanders Road, Turnham Green, London, W4 1NN, United Kingdom
- **e-mail:** dataprotection@chugai-pharm.co.uk
- **Phone:** +44 (0)208 987 5600

**Updates to this Privacy Notice**

We keep this Privacy Notice under regular review, and we will place any updates on this website in response to changing legal, technical or business developments. We encourage you to periodically review this page for the latest information on our privacy practices.