Privacy Notice - Adverse events, product quality complaints and medical information enquiries

This Privacy Notice applies to processing personal data in relation to adverse events, product quality complaints or medical information enquiries. This notice is for individuals reporting or enquiring on their own behalf or on behalf of others.

Ipsen Pharma SAS together with the UK and Ireland local teams in Ipsen Ltd in the UK and Ipsen Pharmaceuticals Ltd in Ireland (together "Ipsen"), with our headquarters based at 65, quai Georges Gorse – 92100 Boulogne-Billancourt are the data controllers in relation to the activities in this privacy notice.

Data collected

We will collect and use the following types of personal data and special category data (sensitive data) for the purposes covered in this privacy notice:

- For adverse events, medical information enquiries or product quality complaints, we will collect basic contact information including name, email and/or postal address, telephone number, and for healthcare professionals, place of work.
- In order to process adverse event reports we may collect patient information including patient initials, age, date of birth, sex, weight, height, race, if pregnant and if breastfeeding, ethnicity, and occupational information if necessary.
- Where we need to, we may collect general health and lifestyle information, which might include the nature of any adverse events or product complaint, medical history, or use of medicines and other factors that are strictly relevant to the adverse event or product related situation.

Purpose and legal basis of data processing

The personal data we collect in relation to this privacy notice will be used only for the specific purpose of these activities. The specific purposes of this processing are there to:

- Monitor the safety of medical products and devices
- Meet our legal obligation to report adverse events to health authorities
- Respond to medical information queries about our products
- Monitor product quality complaints and potential of a market recall

The legal bases for processing the personal data we collect are to meet relevant legal obligations under GDPR Articles 6(1)(c) and in order to meet legitimate business interests under GDPR Article 6(1) (f).

Where we need to process health or other special category personal data in relation to adverse events and product quality complaints, we do so in line with GDPR Article 9 (2) (g) to meet our legal obligations in the Public Interest.

If you provide us with special category data (eg about health) when you submit a medical information enquiry, we will ask for consent to process that data under GDPR Article 9 (2) (a). We will also ask for consent for a member of the Ipsen Pharmacovigilance department to contact the treating Consultant or General Practitioner, where this is needed in relation to an adverse event or product quality complaint.

Data recipients

Information related to you will only be accessed by staff who have a relevant and tangible need to see your information. Information related to you may also be made available to other entities within the Ipsen group of companies for the purpose of meeting adverse event reporting requirements.

Ipsen works with ProPharma Group, as a data processor for Ipsen, to support the processing of safety reports and product quality complaints and responding to medical information enquiries. All medical information enquiries, adverse events and product quality complaints are logged on our MISTRAL database which is used to capture and respond to medical information enquiries and to log and process adverse events and product quality complaints. We also use a database called Trackwise to log and track product quality complaint investigations. These databases are accessed only by individuals who have been specially trained and permitted access.

Personal data may also be shared with healthcare professionals involved in reporting an adverse event.

Ipsen are required to report adverse event relevant information to Health Authorities across the world, some of whom have different levels of data protection. We limit the amount of personal data included in this reporting to a minimum. For patients, we would provide patient age / date and year of birth (where applicable), initials and gender as provided, but not the patient's name. Where adverse events are reported on behalf of patients, we may need to provide name, profession, initials, address, email and telephone number of the reporter as provided. The contact information is required to be able to follow-up with the reporter to gain high quality and complete information on adverse events.

Term of retention

We will only retain the personal data, in relation to this privacy notice, for as long as we reasonably need to achieve the purposes described above and as required under applicable laws. For information we process for adverse events, personal data is required to be kept for a minimum of 10 years after the product is withdrawn in the last country where the product is marketed. We expect to keep personal data in relation to product quality complaints for a minimum of five years after the enquiry. Personal data kept in relation to medical information enquiries is kept for a minimum of five years for healthcare professionals and one year for patients/consumers.

International transfers of data

Your personal data may be processed by service providers or companies affiliated with Ipsen in non-EU countries which do not ensure an adequate level of protection to personal data. To ensure that your personal data are protected, Ipsen will, where necessary, ensure that the recipient has certified its adherence to the Privacy Shield, enter into data transfer agreements which include the EU Commission's standard contractual clauses, or will adopt Binding Corporate Rules (BCRs) for transfers of personal data within the group of companies. Such contract or BCRs can be made available to you upon request.

Your rights

You may have the following rights regarding your information depending on the circumstances and applicable legislation:

Right	What does this mean?
1. The right of access	You have the right to obtain access to the information processed by Ipsen.
2. The right to rectification	You are entitled to have your information corrected if it is inaccurate or incomplete.
3. The right to erasure	This is also known as 'the right to be forgotten' and, in simple terms, enables you to request the deletion or removal of your information where there is no compelling reason for Ipsen to keep using it. This is not a general right to erasure; there are exceptions.
4. The right to restrict processing	You have rights to 'block' or suppress further use of your information in certain circumstances. When processing is restricted, Ipsen can still store your information, but may not use it further.
5. The right to data portability	You have rights to obtain and reuse your personal data in a structured, commonly used and machine-readable format in certain circumstances.
6. The right to object	You have the right to object to certain types of processing, in certain circumstances. If you object to the processing of your personal information, we will respect that choice to the extent this would not prejudice our ability to meet our legal obligations.

How to contact us

For more information on your rights, if you would like to exercise any of these rights, or if you are unhappy with how your information has been handled, please contact medinfo.uk-ie@ipsen.com.

If you have any questions or comments about this Privacy Notice, please feel free to email Ipsen's Data Privacy Officer at dataprivacy@ipsen.com.

If you are not satisfied with the response to your complaint or believe the processing of your information does not comply with data protection law, you can make a complaint to the relevant data supervisory authority, this is the Information Commissioner's Office for the UK and the Data Protection Commissioner for Ireland.