Privacy Notice – Safety information, product quality complaints and medical information enquiries

This Privacy Notice applies to processing personal data in relation to safety information, 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 with its headquarters based at 65, quai Georges Gorse – 92100 Boulogne-Billancourt together with the UK and Ireland local teams in Ipsen Ltd in the UK and Ipsen Pharmaceuticals Ltd in Ireland (together "Ipsen") are the data controllers in relation to this privacy notice.

Personal data collected

We may receive information directly from an individual about themselves or from someone who notifies us of an issue related to another person, or from someone making a medical information enquiry on their own behalf. The lists below include the types of personal data we will process:

Where the notifier or person enquiring is a HCP, we may process (as relevant):

- Name and contact details (e.g. email, telephone number) along with any relevant details about speciality or place of work if needed

Where the notifier or person enquiring is a Patient or a member of the public we may process (as relevant):

- Name and contact details, as needed to follow up with you
- Contact details of any HCP who can provide further information
- Patient's identification data (e.g. initials, age, date of birth, sex, weight, height)
- Patient's health data: treatments administered, test results, nature of the adverse reaction(s), personal or family history, associated diseases or events, risk factors, information on the method of prescribing and use of the medicinal products and on the therapeutic conduct of the prescriber or health professionals involved in the management of the disease or adverse reaction
- Patient's family situation (e.g. information relating to ancestry and descent, conception, progress and outcome of pregnancy)
- Patient's habits and behaviours (e.g. addiction, assistance, physical exercise, diet and exercise, dietary behaviour)

In addition, if you call Ipsen's customer care line your call may be recorded.

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:

- Enable the prevention, monitoring, evaluation and management of adverse events or safety issues related to medical products
- Meet our legal obligation to report adverse events/safety issues to health authorities
- Respond to medical information queries about our products
- Monitor product quality complaints and potential of a market recall
- Manage and improve the service we provide through our customer care line

When we use personal data in relation to reporting adverse events/safety issues or product quality complaints, the legal basis for this is to meet our legal obligations under health legislation.

When we process personal data in relation to medical enquiries, the legal basis for this processing is legitimate interests as a pharmaceutical company.

The legal bases for processing the personal data we collect are to meet relevant legal obligations and in order to meet legitimate business interests.

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. If you provide special category data about someone's health to us as part of a medical information enquiry you undertake to obtain from the individual the consent to process that data.

We will also ask for consent for a member of the Ipsen team to contact the treating Consultant or General Practitioner, where this is needed in relation to an adverse event/safety issue or product quality complaint.

Data recipients

Information related to you will only be accessed by authorised employees at Ipsen.

Only Ipsen's authorised employees should have access to the personal data processed, within the limits of their responsibilities:

- Ipsen Pharmacovigilance Teams, the collaborators and agents involved in the process of managing Pharmacovigilance
- Ipsen Medical Information Teams, the collaborators and agents involved in the process of managing the medical information requested by you
- Personnel of the audit department to verify compliance with regulatory requirements
- Authorised personnel in charge of managing complaints

The following may also be recipients of data as necessary for the performance of their duties:

- Data Processors (Pharmacovigilance and Medical Information service providers) who process data on behalf of Ipsen. This includes the ProPharma Group, who are a data processor for Ipsen, to support the processing of safety reports and product quality complaints and responding to medical information enquiries. A list of any other processors used can be provided on request.
- HCPs involved in the follow-up of the patient and HCPs or other professionals who can provide additional 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 are required to report adverse event relevant information to Health Authorities, bodies responsible for the evaluation of a medicinal product, or parties whose medicines, devices or products could be implicated 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/safety issues 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.

Security

To prevent unauthorised access, maintain data accuracy, and ensure the correct use of information, Ipsen and its third-party service providers have put in place appropriate physical, electronic, and managerial procedures to safeguard and secure the information we collect.

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-UK or 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 entered into data transfer agreements which include appropriate standard contractual clauses, or other approved transfer agreements.

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.

If you would like to exercise any of these rights you can contact us as follows:

- If you are not a patient, please send your request by completing this **form**.
- If you are a patient, please send any rights requests to dataprivacy@ipsen.com

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

If you are a patient, please be aware that your identity will be revealed to the Data Protection Officer if you email 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 supervisory authority, this is the Information Commissioner's Office for the UK and the Data Protection Commissioner for Ireland.

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