PRIVACY NOTICE FOR PHARMACOVIGILANCE AND PRODUCT QUALITY ACTIVITIES

Last updated: April 2025

1. What does this notice cover?

This notice describes how the United Kingdom and European affiliates of Lupin Limited/India which act as Marketing Authorization Holders and/or Distributors for medical products ("**Lupin**" **we**", "**us**" or "**our**") uses and discloses your personal data as Controller for activities that are related to pharmacovigilance if you are a patient. If you are a healthcare professional ("**HCP**"), details of how Lupin processes your personal data in a pharmacovigilance context are included in this notice.

This notice also describes your data protection rights, including a right to object to some of the processing which Lupin carries out. More information about your rights, and how to exercise them, is set out in the "*Your choices and rights*" section.

This notice applies to data received by Lupin employees and by contractors who provide services to Lupin on its behalf. The data processing described in this notice may be limited as required by applicable law.

We also may provide you with additional information when we collect personal data, where we feel it would be helpful to provide relevant and timely information.

Lupin Limited has designated Hormosan Pharma GmbH and Lupin Europe GmbH, Hanauer Landstraße 139-141, 60314 Frankfurt, Germany, as its representative under applicable medical regulations for Pharmacovigilance in the European Union; and Lupin Healthcare (UK) Limited in the United Kingdom.

2. What personal data we collect from You

For the provision of the services and our pharmacovigilance obligations Lupin may process the following categories of data about you where permissible:

- Contact information, such as your name, phone number, email address and home address
- Patient/Case ID and other personal details, such as your date of birth, age, gender, weight, height citizenship, nationality, marital status or relationship to a person and picture
- Records of communications, where permissible
- Other legal information like job title, professional qualifications (if you are a healthcare professional)
- Information on the relationship between a patient and their healthcare professional
- Health information (physical or mental), such as medical history including medical diagnostic results and medication received, accident and injury reports, disability status or health risk factors, health impact of the adverse event or product quality issue being reported
- Racial or ethnic origin
- Biometric and/or genetic information

We collect this information from you directly when you contact us via letter, fax, telephone, email and in person or from a third person in relation to your care.

For example, data is collected through forms that you expressly fill up; from correspondence with you; or through meetings, calls or other communications that may take place.

3. What personal data we collect from other sources

We may also collect the same categories of personal data referenced above indirectly where you have initially reported it to one of our third party medical service information providers, who then pass that information on to us.

We may also collect adverse event reports from the relevant medical regulatory authority in your jurisdiction if you have made a report directly to that authority. The authority will upload your report information to their database, and this is subsequently downloaded by Lupin and stored in Lupin's pharmacovigilance database so we are able to monitor any adverse effects of our medicines. Reports or complaints received via these means will be pseudonymised so will not include your full name or contact information.

Regulatory authorities' Defective Medicine Reporting Centres may also forward reports or complaints on to Lupin. Reports or complaints received via these means could include your contact information and public health authority number.

4. Why we collect, use and store this personal data

We collect, use and store your personal data for the reasons set out below:

- **Where necessary for Lupin's legitimate interests, as listed below, and where our interests are not overridden by your data protection rights:**
    - Respond to enquiries for information, products or services
    - Reporting, assessing and processing of adverse events, product quality complaints and management of complaints, to the extent not required by a legal obligation (below)
    - Cross-collaboration with our clinical teams in the event of a complex safety review, in which case the data will be pseudonymised to prevent your direct identification and will be subject to appropriate safeguards. The subsequent conduct of such pseudonymised research would be the responsibility of Lupin's clinical team.

Where we process personal data on this basis, then – as required by data protection law – we have carried out a balancing test to document our interests, to consider what the impact of the processing will be on individuals and to determine whether individuals' interests outweigh our interests in the processing taking place. You can obtain more information about this balancing test by using the contact details at the end of the notice.

- **Where necessary to comply with a legal obligation such as:**
    - Monitor and guarantee product safety and quality, including response to product quality complaints raised by you regarding Lupin products
    - Administration and legal maintenance of product registries (where required under applicable laws)
    - Management of adverse events, including investigating the adverse event and contacting you for further information on the adverse event that you have suffered
    - Provision of reports to authorities with respect to the safety of a Lupin product, in accordance with the applicable laws
    - Responding to court orders, subpoenas or other legal processes with which Lupin is required to comply;
    - Complying with legal, regulatory and other requirements under EU or Member State laws.

- **With your consent:**
    - Where you have provided us with your express consent to process your data for a particular purpose.

We may provide you with more specific notices for some of the processing described above and, if we require your consent, will ask for this at the time we collect your personal data.

In addition, where the abovementioned purposes imply Lupin processing your health data, and/or other special categories of personal data, Lupin hereby declares and guarantees that the processing purpose additionally relies in a valid condition for the processing of special categories of data.

Where we collect personal data to administer our contract with you or to comply with our legal obligations, this is mandatory and we will not be able to comply with our purposes without this information.

5. How we share your personal data

Personal data may be shared with government authorities and/or law enforcement officials if required for the purposes above and if required for the protection of our legitimate interests.

We have offices and operations in a number of international locations, and we share information between our group companies as part of our pharmacovigilance activities and for business and administrative purposes. Hormosan Pharma GmbH, Lupin Europe GmbH (and if you are in the UK, also Lupin Healthcare (UK) Limited) are joint controllers for these purposes, with responsibilities allocated as follows:

- Where you are located in the UK, Lupin Healthcare (UK) Limited will process personal data in connection with the maintenance of product registries, liaising with UK medical regulatory authorities in the event of urgent requests, responding to enquiries for patient information, and UK product complaints. To the extent adverse events are reported to Lupin Healthcare (UK) Limited, these will be sent to Lupin's German entities who will upload the pseudonymized report to Lupin's pharmacovigilance database (with administrative support from other Lupin entities) and report into the relevant medical regulatory authorities on Lupin Healthcare (UK) Limited's behalf. Lupin's German entities will also be involved in oversight of UK product complants.

- Where you are located in the EU, all of these activities are undertaken by Hormosan Pharma GmbH / Lupin Europe GmbH, and adverse event and product complaint reports are made directly to Hormosan Pharma GmbH / Lupin Europe GmbH. Lupin Healthcare (UK) Limited does not have a role in the processing of EU adverse event and product complaint reports.

Please see the "**Contact us**" details below for the relevant point of contact for data protection queries and complaints.

Your information may be shared with our internal staff for pharmacovigilance and administrative purposes, including our staff located in India, as outlined above. Please visit https://www.lupin.com/contact-us/global-offices/ to see a list of the locations within our corporate group. For this purpose, your personal data will be pseudonymized.

In addition, Lupin may also share your personal data with the following third-party recipients:

Recipient	**Purpose**
National and/or international regulatory, enforcements, public body or courts where we are required to do so by applicable law or regulation or at their request.	To comply with the applicable laws or regulation and react at their request.
Co-marketing and distribution partners (Marketing Authorization Holder of the product or connected Marketing Authorization Holder)	To allow them to comply with the applicable laws or regulation and react at their request.
Competent health authorities	To comply with the applicable pharmacovigilance laws.
Third-party buyers or assignees	To facilitate the sale and assignment of Lupin, where applicable.

Personal data may also be shared with third party service providers, who will process it on our behalf and in accordance with our instructions. These third parties may include medical service information/contact centre providers and IT service providers, such as hosting and/or cloud providers. Third parties that process personal data on our behalf are deemed Data Processors under the applicable data protection regulations. Lupin is expressly obliged under the applicable data protection law to enter into a contract or Data Processing Agreement ("**DPA**") with its Data Processors. This DPA ensures access by Data Processors to Lupin data remains compliant with the applicable law. Lupin therefore guarantees to enter into a DPA with any and all Data Processors that exist and that may exist in the future. Data Processors are further prohibited from using the personal data for any purpose other than to perform the services as instructed by Lupin.

6. Location of your personal data

Your personal data may be shared with recipients and Data Processors located in the following countries: EEA, UK, USA, India. To the extent personal data is shared from the UK to the EEA, this relies on the UK government's adequacy regulation in respect of the EEA countries. To the extent personal data is shared from the EEA to the UK, this relies on the EU Commission's adequacy decision in respect of the UK.

In the event that your personal data is transferred outside of the UK or the EEA to a third party that is located in a country which is not subject to an adequacy decision by the EU Commission, an adequacy regulation by the UK government, or considered adequate as determined by applicable data protection laws, we will take steps to ensure your personal information is adequately protected (e.g. by way EU Commission approved Standard Contractual Clauses, the UK International Data Transfer Agreement or Addendum or by relying on alternative data transfer mechanisms as available under applicable data protection laws). A copy of the relevant mechanism that is employed to guarantee the safety of your personal data can be obtained for your review on request by using the contact details below.

7. Your Choices and Rights

You have the right to **request Lupin for:**

- A copy of your personal data (right of access);
- Correct your personal data (right of rectification);
- Delete your personal data (right of erasure);
- Restrict the processing of your personal data;
- Obtain your personal data in a structured, machine-readable format (right to data portability); and
- Under certain circumstances (e.g., where we don't have to process the data to meet a contractual or other legal requirement), object to the processing of your personal data (right of objection).

In addition, where we have asked for your consent, you may **withdraw consent** at any time. If you ask to withdraw your consent to Lupin processing your data, this will not affect any processing which has already taken place at that time.

These **rights may be limited**, for example if fulfilling your request would reveal personal data about another person, or if you ask us to delete information which we are required by law or have compelling legitimate interests to keep.

We also inform you that you have the **right to lodge a complaint against Lupin** before a competent data protection authority.

8. How long we retain your personal data

Lupin will retain and process personal data relating to you in accordance with our customary pharmacovigilance retention periods.

Pharmacovigilance personal data will generally be kept for as long as is reasonably necessary taking into consideration our need to answer queries or resolve problems, any other purpose outlined above or to comply with legal requirements under applicable law(s), in particular by national legislation on medicinal products, e.g. Medical Products Act (AMG). In particular, pharmocavigilance safety data is required to be kept for until at least 10 years after the last registration has expired worldwide for the relevant product, and thereafter will be retained in Lupin's validated safety database in accordance with applicable law.

A copy of the relevant retention periods affecting your personal data can be obtained for your review on request by using the contact details below.

9. Updates to this privacy notice

We reserve the right to update this privacy notice at any time, and we will provide you with a new privacy notice when we make any substantial updates. We may also notify you in other ways from time to time about the processing of your personal information.

10. Contact us

The joint data controllers for your personal data will be: Hormosan Pharma GmbH / Lupin Europe GmbH. If you are in the UK, this will also be Lupin Healthcare (UK) Limited.

If you have questions about this privacy notice or wish to contact us for any reason in relation to our personal data processing, or to exercise your data protection rights, please contact us at:

If you are located in the EU:	If you are located in the UK
Hormosan Pharma GmbH / Lupin Europe GmbH	**Lupin Healthcare (UK) Limited**
Hanauer Landstraße 139-141 60314 Frankfurt, Deutschland Phone: +49 (0) 69 47 87 30 Email: service@hormosan.de	The Urban Building, 3-9 Albert Street Slough, SL1 2BE, United Kingdom Phone: +44 (0)1565 751 378 E-Mail: information@lupin.com

In addition, you may also contact our relevant external Data Protection Officer at:

Bird & Bird DPO Services SRL
Avenue Louise 235 b 1
1050 Brussels, Belgium
Email: dpo@lupin.com