

# ADVANZ PHARMA Privacy Notice for Medical Information, Pharmacovigilance and Product Complaints

Last Updated: 03 March 2025

For a printable version of this Privacy Notice, please click [here](#).

## 1. Scope of this Privacy Notice

This Privacy Notice for Medical Information, Pharmacovigilance and Product Complaints (“**Privacy Notice**”) is intended to explain how Advanz Pharma Services (UK) Limited and its group entities (together “**ADVANZ PHARMA**”, “**we**”, “**us**”, “**our**”) collect and process your personal data for the purposes of managing medical information enquiries, pharmacovigilance reports, and product and/or service complaints related to ADVANZ PHARMA’s medicinal products and medical devices.

In particular, this notice describes how we collect and use personal data to help us fulfil our duty to monitor the safety of all our products, including medicinal products and medical devices we market or have in clinical development (also known as our pharmacovigilance obligations), to handle any medical enquiries appropriately, to manage any complaints you may have about our products, and to ensure the quality and safety of all our products.

This Privacy Notice is also applicable to medical devices since the international (including European) regulations on such products require similar safety and quality monitoring as for medicinal products. Further references to medicinal products in this Privacy Notice include references to medical devices.

This Privacy Notice applies to information we collect from or about you online, by phone, fax, e-mail or post, or as part of an adverse event report, a medical information enquiry, or a product complaint. We may also collect information about you through specific forms submitted by you on a website that is owned or controlled by ADVANZ PHARMA.

For information about ADVANZ PHARMA’s privacy practices in other areas and about how this website uses cookies, please refer to our general Privacy Policy, available at: <https://www.advanzpharma.com/privacy-policy>

## 2. Data Controller and Contact Information

If you have any questions regarding this Privacy Notice or wish to exercise any of your data protection rights (as outlined below), please contact us at:

Advanz Pharma Services (UK) Limited, Dashwood House, 2nd Floor, 69 Old Broad Street, London, EC2M 1QS, United Kingdom

E-mail: [enquiries@advanzpharma.com](mailto:enquiries@advanzpharma.com)

### **3. Information we collect and why we collect it**

#### **A. Medical Information Enquiries**

Any personal data provided by you to ADVANZ PHARMA related to a medical enquiry will be used to analyze and manage your enquiry appropriately, to follow up with you to request additional information, and to respond to your enquiry.

If you do not wish to provide your personal details to us, we will not be able to contact you and to reply to your request.

For managing medical information enquiries, we may collect identifiers and professional or employment related information, such as the name and surname of the requestor, their contact details (such as phone number and email address), and their affiliation or profession. If provided on a voluntary basis, we may also process the requestor's sensitive personal data, including medical history.

#### **B. Pharmacovigilance Reports**

Pharmacovigilance laws and regulations require us to take detailed records of any potential adverse event or any event that may potentially impact patients' safety (e.g. Pharmacovigilance Special Situations or Pharmacovigilance-relevant information). This information is collected to be evaluated and collated with other recorded potential adverse events or events that may potentially impact patients' safety and to make efforts to prevent similar events from happening in the future.

Please note that if you are a patient on any of ADVANZ PHARMA's medicinal products, we may also be provided with information about you by a third party reporting an adverse event that affected you. Such third parties may include healthcare professionals ("HCPs"), our partners (e.g. distributors of our products, wholesalers, etc.), care takers, relatives, other persons linked with you or other members of the public, or competent authorities.

Any personal data provided by you as a patient or as reporter to ADVANZ PHARMA related to the reporting of adverse events or other pharmacovigilance related activities will be collected and used solely for pharmacovigilance management purposes.

When you are involved as the subject or reporter of an adverse event or pharmacovigilance-related report, we may collect the following personal data:

#### **Personal Data relating to the Patient:**

- Patient's name (if the patient is the reporter for himself/herself) or initials (in case an HCP is the reporter);
- For effective follow-up activities, contact details (such as address, e-mail address, phone number) are requested on a voluntary basis, in case the patient is also the reporter;
- Date of birth/age/age group, sex, weight, height;

- Information about health, ethnic origin; and
- Medical history and status, which may include, but is not limited to, administered treatments, test results, the nature of the adverse effect(s), details of other treatments, medicines or remedies taken, personal or family history, sexual activity in relation to associated reported events, associated diseases or events, risk factors, genetic data in relation to what is needed for the proper use of our products, information on how medicinal products are prescribed and used and on the therapeutic conduct of the prescriber or of the HCPs involved in the management of the disease or adverse health event.

**Personal Data relating to the Reporter:**

- Reporter's name;
- Contact details (such as address, e-mail address, phone number) needed to perform effective follow-up activities to ensure complete and accurate data is collected;
- Profession (if the reporter is an HCP; this information may determine the questions you are asked about an adverse event, depending on your assumed level of medical knowledge); and
- Relationship with the subject of the report.

**C. Product Complaints**

Any personal data provided by you to ADVANZ PHARMA related to a product complaint will be used solely for the purposes of management of such product complaint.

We may collect the name and contact details of the individual reporting the complaint. In case the complainant is a healthcare professional, we may also collect details regarding their affiliation/profession.

**4. How we use your Personal Data and Legal Basis**

**A. Medical Information Enquiries**

Answering your request is based on the implied consent that you provide by actively contacting us with the expectation to receive an answer. Processing your enquiry is further based on our legal obligations and industry regulations to provide a medical information service for our products. We also rely on consent or our legitimate interests, as applicable, to further store and maintain medical information in a medical information database for future historic reference, record keeping, auditing and compliance purposes as well as for the establishment, exercise, or defence of legal claims and/or rights. The processing of special/sensitive categories of personal data, such as health data, will be conducted to the extent necessary for reasons of public interest in the field of public health.

If your medical information enquiry consists of or requires further reporting of an adverse event, your data (including special/sensitive categories of personal data) will be processed to comply with our legal pharmacovigilance obligations imposed on

ADVANZ PHARMA by applicable international and local pharmacovigilance laws and regulations. Also, in case that your medical enquiry comprises a product complaint, your data may be processed to comply with our legal obligations in the context of drug and product safety.

## **B. Pharmacovigilance Reports**

We will collect personal data related to the reporting of adverse events or other pharmacovigilance related activities and use such data to investigate the adverse event, to follow-up with the patient, or the patient's physician or the reporter, or in general, to collect additional information about the adverse event, to analyse the safety of the product by combining and collating the information from one adverse event with information about other adverse events and to provide relevant pharmacovigilance reports to competent regulatory authorities as necessary to continuously assess the benefit/risk ratio of our products.

Processing related personal data is necessary for ADVANZ PHARMA to comply with international and local pharmacovigilance-related legal and regulatory obligations. In terms of a follow-up to a reporter of an adverse event, the reporter's consent may be necessary for the processing of personal data as per applicable law.

The processing of special/sensitive categories of data, such as health data, is necessary for reasons of public interest in the field of public health and aims at the detection, assessment, and understanding of adverse events and any other problem related to a medicinal product as well as to ensure compliance with high standards of quality and safety of health care and medicinal products in accordance with applicable data protection laws.

## **C. Product Complaints**

Processing of personal data provided by you related to a product complaint might be required for ADVANZ PHARMA to comply with international and local legal obligations in the context of drug quality and safety or based on our legitimate interest in managing and processing the complaint. The processing of special/sensitive categories of personal data is necessary for reasons of public interest in the field of public health and will be used for the evaluation, classification, and assessment of the product complaint, to follow up on such requests for healthcare purposes, to request additional information, and/or to respond to you.

# **5. Data Retention**

## **A. Medical Information Enquiries**

Personal data retained as part of a medical information inquiry are kept within our systems for as long as required under applicable laws for record keeping purposes and regulatory compliance. At the end of this period, the data will be deleted or archived in an anonymized form.

## **B. Pharmacovigilance Reports**

Mandatory requirements oblige us to retain all product-related documents for at least ten (10) years after the withdrawal of the product in the last country where the product is marketed. Longer retention periods may apply under local laws. After the expiration of this period and any additional period applicable legislation may require us to retain your data, the data will be securely deleted or archived in an anonymized form.

### **C. Product Complaints**

As information related to product complaints is necessary to comply with our legal obligations relating to our products, we must retain all product-related documents for record keeping purposes and regulatory compliance as long as required according to applicable laws.

## **6. How we share your Personal Data**

We may share your information with selected third parties including:

- **ADVANZ PHARMA group:** ADVANZ PHARMA group entities exchange safety data and collaborate on related medical information, pharmacovigilance and drug quality, and safety activities on our products for the purposes explained in this Privacy Notice.
- **Partners:** We may share personal data with our business partners, e.g. other pharmaceutical companies who are our co-marketing, co-distribution, or licensing partners, in cases where relevant medical information, pharmacovigilance, or drug quality and safety obligations for a product require such exchange of information.
- **Service providers:** When we use other companies to provide services on our behalf, e.g. technology, IT, and cloud providers, professional advisors and support services, to operate our global or regional medical information, pharmacovigilance, or product complaint databases.
- **Business transfers:** Personal data collected from you in accordance with this Privacy Notice may also be transferred to a third party in the event of a sale, assignment, transfer, or acquisition of the company or a specific product or therapeutic area, in which case we would require the buyer, assignee, or transferee to treat that personal data in accordance with applicable data protection laws.

Further, we may disclose your personal data to **public authorities, regulators or other third parties:**

- We share information with national, provincial, and/or regional authorities such as the European Medicines Agency, in accordance with our obligations to report certain pharmacovigilance and product related information. These reports will contain details about specific cases, but will only contain limited personal data, in particular:
  - Patients: Information as provided, including date of birth/age/age group and gender;
  - Reporting individuals: Information as provided, including name, profession, initials (to identify any duplications), address, email, phone number (to allow the regulatory authority to follow up with the reporting individual).

- To comply with any court order or legal obligation;
- When data is requested by regulators, government agencies, or law enforcement agencies;
- We may publish information about adverse events and/or drug quality and safety (such as case studies and summaries); in these cases, we will remove identifiers from any publications so that no individual can easily be identified.

## **7. International Transfers**

As part of our activities as described above, we may need to transfer your data to countries/provinces outside your country/province of residence. For example, to meet our pharmacovigilance obligations that require us to review patterns across reports received from every country where we market our products, information provided as part of an adverse event report is shared within the ADVANZ PHARMA group on a worldwide basis for analysis and reporting to government agencies as per applicable law. The same applies for the appropriate and lawful handling of medical enquiries and product complaints.

This means that your personal data relating to medical information, pharmacovigilance, or product complaints is transferred to countries/provinces which may not provide a level of data protection equivalent to that provided in your country/province, and may be subject to disclosure to the governments, courts, or law enforcement, or regulatory agencies of such other country/province, pursuant to the laws of such country or province. For such transfers, ADVANZ PHARMA is ensuring compliance with applicable rules and regulations on cross-border transfers of personal data, in particular by applying so-called standard contractual clauses adopted by the European Commission or other contractual safeguards as required under applicable law. ADVANZ PHARMA is further applying legal, technical, and organizational measures to ensure the members of the ADVANZ PHARMA group and all partners we collaborate with ensure an adequate level of data protection.

You may ask for further information on the measures which we have put in place to safeguard the transfer of your personal data. Please contact us using the details set out under 'Contact Information' above to obtain further information about our policies including our service providers.

## **8. Your Data Protection Rights**

You may be entitled under applicable law to ask ADVANZ PHARMA for a copy of your information, to correct it, erase or restrict its processing, to ask us to transfer some of this information to other organisations, to be informed of any automated decision-making, if applicable, used to make decisions about you, or to request information about data processing related to your personal data. You may also have rights to object to specific data processing activities. These rights may be limited in some situations – for example, where we can demonstrate we have a legal requirement to process or retain your personal data. If data processing is based on your consent, kindly note that you have the right to withdraw your consent at any time, however, without affecting the lawfulness of any processing activities based on consent before its withdrawal. If we do not handle your request in a timely manner, or if you are not

satisfied with our response to the exercise of these rights, you are entitled to submit a complaint with the competent supervisory authority of your country/providence of residence or place of work. Further information and contact details of the European competent supervisory authorities can be found at [https://edpb.europa.eu/about-edpb/about-edpb/members\\_en](https://edpb.europa.eu/about-edpb/about-edpb/members_en). UK residents may submit a complaint to the UK Information Commissioner's Office (ICO) here: <https://ico.org.uk/make-a-complaint/>. Swiss residents may contact Federal Data Protection and Information Commissioner (FDPIC) here: <https://www.edoeb.admin.ch/edoeb/en/home/deredoeb/kontakt.html>. Canadian residents may contact the Office of the Privacy Commissioner here: <https://www.priv.gc.ca/en/report-a-concern> or the applicable provincial privacy commissioner.

Depending on applicable law, additional rights may apply.

Please note that for legal reasons, we cannot delete information that has been collected as part of an adverse event report unless it is inaccurate.

If you would like to exercise any of these rights, please contact us using the details set out under 'Contact Information' above. We may require you to provide proper identification before we comply with any request to access or correct personal data.

## **Your U.S. State Privacy Rights**

Depending on their state of residence, U.S. residents may have the right to object to our collection and use of their personal information at any time, or to require us to review, transmit, change, or delete their information that we have collected and retained about them. We will fulfill your request to exercise any of these rights within the applicable time period prescribed by applicable law. You can exercise these rights, express concerns, or obtain additional information about the use of your personal information by contacting us as outlined below.

### **Residents of California may have the following rights:**

- You have the **right to know and right to access** information about the categories and specific pieces of personal information we have collected about you, as well as the categories of sources from which such information is collected, the purpose for collecting such information, and the categories of third parties with whom we share such information. You also have the right to know if we have sold or disclosed your personal information. You may also request a copy of the personal information we have collected, and upon request, we will provide this information to you in portable, electronic form.
- You have the **right to request the deletion** of your personal information, subject to certain legal exceptions.
- You have the **right to opt out of the sale or sharing** of your personal information to third parties.
- You have the **right to correct** your personal information if inaccurate.
- You have the **right to limit the use and disclosure of your sensitive personal information** if we use such information to infer characteristics about you.

- You have the **right to not be discriminated against** for exercising any of these rights.
- You have the **right to opt out of profiling using automated decision-making technology**. You may have the right not to be subject to a decision based solely on profiling, except under certain exceptions under local law.

**Submitting a Rights Requests:** You may send your request by email to [enquiries@advanzpharma.com](mailto:enquiries@advanzpharma.com) or by toll-free phone to +18333350881. An authorized agent, such as another individual or business, may submit a request on your behalf. We will not discriminate against you for exercising your rights under applicable law. Once you have submitted your request, we will respond within the time frame permitted by applicable law. Please note that we may charge a reasonable fee for multiple requests in the same 12-month period, as permitted by law.

We may have a reason under the law why we do not have to comply with your request, or why we may comply with it in a more limited way than you anticipated. If we do, we will explain that to you in our response.

**Verification.** We must verify your identity before responding to your request. We may verify your identity by asking you to provide personal identifiers that we can match against information we may have collected from you previously. We may need to follow up with you to request more information to verify your identity. We will not use personal information we collect in connection with verifying or responding to your request for any purpose other than responding to your request.

**Appeals.** Residents of California have the right to appeal a denial of their request by contacting us as described in the notice of denial.

## 9. Security

ADVANZ PHARMA uses reasonable technical, administrative, and physical safeguards to ensure appropriate security of personal data being collected and processed in relation to the management of medical information enquiries, pharmacovigilance reports, and product complaints. Your personal data will be securely stored in information assets owned by ADVANZ PHARMA or managed on behalf of ADVANZ PHARMA by third party service providers and may be hosted outside your home/work jurisdiction. We will take necessary steps to ensure that adequate safeguards are put in place.

ADVANZ PHARMA will maintain any information related to a medical enquiry, a pharmacovigilance report, or a product complaint in the respective database, for as long as necessary (see above for more specific retention periods) and to the extent permitted under applicable legal and regulatory requirements governing the storage and reporting of related information for future historic reference, record keeping, auditing, regulatory and compliance purposes, as well as for the establishment, exercise, or defence of legal claims.

## 10. Changes to this Privacy Notice

We may update this Privacy Notice from time to time in response to technical, legal, or business developments.

Updates of our Privacy Notice will be published on our website. Any amendments become effective upon publication. We therefore recommend that you regularly visit the website to keep yourself informed on any possible updates.