



GLOBAL PRIVACY NOTICE PHARMACOVIGILANCE

Version 1.0

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Introduction

In this Privacy Notice, “AdvaGen”, “our”, “we” or “us” refers to AdvaGen Pharma Limited. AdvaGen is responsible for the processing of your personal information that you share with us, therefore acting as the “Data Controller”. This notice describes how we collect, use and protect personal information of individuals who share such information as part of an Adverse Event reporting and how they can exercise their privacy rights.

Personal Information

Processed by us, associated purposes and legal basis:

Based on our legal obligations, we process your personal information for the purposes of monitoring the safety of medicinal products and medical devices, which includes detecting, assessing, and preventing adverse events. It additionally involves reporting of such information to health authorities and for any other purposes imposed by law and authorities. When you report an adverse event concerning one of our products, using the channels provided on our websites, we will require your name and contact details to be able to contact you in case additional information is needed and/or to respond to your report. We may also request and process the following personal information categories, if necessary, for assessment of the adverse event reported by you:

- Patient identifiable data, such as: patient number or code, and other information such as age, year or date of birth, sex, weight, height
- Professional qualification in case you are a healthcare professional
- Name, and contact information of the prescribing physician and/ or pharmacist
- Health data, including but not limited to treatments administered and their results, nature of the adverse effect(s), personal or family medical history, diseases or associated events; information on how the prescribed medicines were used and condition management in general
- Information on patient’s lifestyle, habits (incl. consumption of tobacco, alcohol, etc) and behaviour, including, e.g., dependency, physical exercise (intensity, frequency, duration), diet and eating behaviour, sex life
- Patient’s current and past occupational data
- Ethnicity, in cases where the Summary of Product Characteristics (SmPC) includes specific information relating to the ethnic origin and according to the criteria defined in the SmPC

Recipients of your Personal Information

We will not share, or otherwise transfer your personal information to third parties other than those with a need to know, for the purposes mentioned above, as part of our ongoing operations. Your personal information, can be accessed by, or transferred to:

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- Our Global Head of Pharmacovigilance and Drug Safety, the Regional Heads of Pharmacovigilance and relevant teams responsible for facilitating management of your reports
- Members of our legal and regulatory affairs department, depending on their responsibility
- Our audit or compliance department to check compliance with regulatory or internal requirements
- Other AdvaGen affiliates
- Other pharma companies whose product may be at stake (we will not disclose your identity)
- Healthcare providers who are concerned with your report
- Service providers acting on our behalf, such as providers of IT systems, hosting providers and adverse events processing services. Such third parties are contractually obligated to protect the confidentiality and security of your personal information, in compliance with applicable law

Your personal information can also be accessed by or transferred to international regulatory, enforcement, or other authorities where we are required to do so under applicable law or at their request. Your personal information may also be processed, accessed, or stored in a country outside of the country where you are located. If we transfer your personal information to third parties in other jurisdictions, we will make sure it is protected by:

- Applying the same level of protection as required under the local data protection/privacy laws
- Acting in accordance with our policies and standards

Retention of your Personal Information:

We store personal information only for as long as we reasonably consider necessary for the purposes referenced in this Privacy Notice as well as required and/or permissible under applicable laws.

Your Data Privacy Rights

Whenever we process Personal information, we take reasonable steps to keep your personal information accurate and up to date for the purposes for which they were collected based on your requests. We will provide you with the ability to exercise the following rights under the conditions and within the limits set forth in the applicable local laws:

- The right to be informed about what personal information we have about you and how we process your data including requesting an access to it
- If you believe that any information relating to you is incorrect, obsolete, or incomplete, to request its correction or updating
- The right to erasure of your personal information or the restriction thereof to specific categories of processing based on the purposes of processing
- The right to withdraw your consent at any time, without affecting the lawfulness of the processing before such withdrawal
- The right to object, in whole or in part, to the processing of your personal information. With certain exceptions, this includes the right to object to direct marketing and the right to object to your data being used for research

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- The right to grievance redressal for any grievances you may have related to the way your personal information is processed
- The right to nominate another individual to exercise your privacy rights on your behalf in case of your death or inability to do so
- The right to request its portability, i.e., that the personal information you have provided to us be returned to you or transferred to the person of your choice, in a structured, commonly used and machine-readable format without hindrance from us and subject to your confidentiality obligations
- The right to object to automated decision-making including profiling, i.e., you can request a human intervention in any automated decision-making process related to processing of your data and where such processing is not based on your consent, authorised by law or necessary for the performance of a contract. However, we don't currently make decisions solely using automated processes.

If you have questions or grievances regarding how we use your personal information or if you wish to exercise the above rights, please email our Data privacy Officer at privacy.governance@advagenpharma.com. If you still do not receive a resolution for your grievance, you also have the right to file a complaint with the competent data protection authorities, in addition to your rights above.

Changes to this Privacy Notice

We may change or update this Privacy Notice from time to time by publishing a revised version on our website – www.advagenpharma.com. Please keep checking this notice occasionally so that you are aware of any changes.

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