Data Privacy Notice Regarding Pharmacovigilance (Drug Safety)

As a pharmaceutical company and marketing authorisation holder, we are legally obliged to collect, evaluate, and forward to the competent authorities reports regarding adverse drug reactions (side effects), drug interactions, quality defects, administration/usage errors, and other safety-related events and information concerning our products.

In the following, we provide information about the associated processing of personal data according **to Art. 13 and 14 of General Data Protection Regulation (GDPR)**.

1. Data Controller

Responsible for data processing within the meaning of the GDPR is:

Abnoba GmbH
Allmendstraße 55
75223 Niefern-Öschelbronn
Germany
Phone: 07233 7043-200
E-Mail: info@abnoba.de

If you have any questions regarding drug safety, please contact our pharmacovigilance department:
E-Mail: pv@abnoba.de

2. Data Protection Officer

Our data protection officer can be reached via E-Mail: datenschutz@abnoba.de or by Mail to Abnoba GmbH, „Data Protection Officer/Datenschutzbeauftragter“, Allmendstraße 55, 75223 Niefern-Öschelbronn

3. Data Subjects and Source of the Data

This information is intended for all individuals whose data is processed for pharmacovigilance purposes. This includes, in particular:

- **Patients** who have experienced an adverse reaction or other safety relevant event related to one of our medications.
- **Reporters** who notify us of an incident. These may include patients themselves, family members of the patient, caregivers, or other individuals.
- **Healthcare professionals (HCPs**) - such as physicians, alternative practitioners, pharmacists, or nursing staff—who **act as reporters** or who initiate a report as part of their professional practice.

We receive the data either directly from you (Art. 13 GDPR) or from other sources (Art. 14 GDPR)—such as reporters, government agencies (BfArM—Federal Institute for Drugs and Medical Devices, PEI—Paul Ehrlich Institute, EMA—European Medicines Agency via the EudraVigilance database), distribution and licensing partners, scientific literature, or post-marketing surveillance.

4. Categories of Processed Data

In principle, we process only the data necessary for assessing and reporting a safety relevant event. Depending on the case, this may include:

- **Regarding the data subject:** Identifying information in pseudonymized form (initials, age/birth year, gender, if applicable weight/height) as well as **health data** (Art. 9 DSGVO: adverse drug reaction/safety relevant event, concomitant disease and medical history, concomitant medication, course and outcome of medical events). Other special

categories only to the extent medically necessary, in particular pregnancy/breastfeeding or ethnic origin (if relevant for pharmacogenetics)
- **Regarding the reporter:** Name, contact information, position/qualifications (if healthcare professional or working in related area), relationship to the patient

Reports to the authorities generally include only the **initials** of the person concerned, not their full name. When the report is forwarded to the authorities, neither the reporter's name nor phone number is provided; only the location (city, country) is included.

We ask reporters to provide us only with the information necessary for our assessment and to limit personal information about third parties to what is strictly necessary. If any necessary information is missing, we will contact you accordingly.

5. Purpose and Legal Bases for Processing

We process the data exclusively for the purpose of pharmacovigilance, in order to
- collect, document, and medically evaluate reports of adverse reactions and other safety relevant events;
- prepare and submit legally required individual case reports and periodic safety update reports (PSURs) to the relevant authorities (e.g. EudraVigilance)
- continuously monitor the benefit-risk profile of our medicines and identify signals;
- contact the patient or the reporting individual with questions to complete or follow up on a pharmacovigilance case;
- respond to regulatory inquiries and audits and fulfill our regulatory obligations.

The legal basis for all of these purposes is **Article 6(1)(c) of the GDPR** (legal obligation) in connection with Sections 63b et seq. of the German Medicines Act (AMG), Directive 2001/83/EC, Regulation (EC) No. 726/2004, and Implementing Regulation (DVO) (EU) No. 520/2012; for health data and other special categories, **Article 9(2)(i) of the GDPR** in combination with **Section 22(1)(1)(c) of the Federal Data Protection Act (BDSG)**. This expressly applies also to ongoing benefit-risk monitoring and signal detection (Article 104 of Directive 2001/83/EC, Good Pharmacovigilance Practices (GVP) Guideline, Module IX), as well as to responding to regulatory inquiries and conducting audits (Sections 62, 64 of the German Medicines Act (AMG)).

To the extent that voluntary tracking goes beyond legal obligations, we rely on **Article 6(1)(f) of the GDPR**; our legitimate interest in a comprehensive case assessment to protect public health prevails, as the processing is limited to what is necessary and participation remains voluntary. If, in exceptional cases, processing is based on consent **(Article 6(1)(a) / Article 9(2)(a) of the GDPR),** you may revoke this consent at any time with future effect; reports already submitted to authorities are excluded from this.

6. Data recipients

Internally, only departments involved in pharmacovigilance have access.

Possible **external recipients** include: regulatory and supervisory authorities (BfArM, PEI, EMA/EudraVigilance, foreign authorities); international sales, licensing, and collaboration partners based on Safety Data Exchange Agreements (SDEA); processors pursuant to Article 28 of the GDPR (including safety databases, clinical trial service providers/CROs, literature/signal screening, translation, IT/hosting/archiving); legal successors in the event of a transfer; as well as attorneys, insurers, or courts for the purpose of legal defense. We will provide a current list of processors upon request. In the case of public communications (e.g., case reports), identifying characteristics are removed beforehand.

7. Third countries

Depending on the medicinal product and the countries in which it is marketed, data may need to be transferred to recipients outside the EU/EEA—in particular to foreign health authorities as well as to distribution and licensing partners with Safety Data Exchange Agreements (SDEA).

If this is the case, the transfer is based on an adequacy decision **(Art. 45 GDPR)** or standard contractual clauses **(Art. 46(2)(c) GDPR)**, along with a prior risk assessment (Transfer Impact Assessment) and additional safeguards (encryption, access restrictions, pseudonymization). Only in strictly limited individual cases and **subordinately** we do rely on **Article 49(1)(d) of the GDPR** (public interest in the area of health); this exception does not apply to regular transfers. A copy of the safeguards is available upon request.

8. Retention period

We are legally required to retain pharmacovigilance data for the entire duration of a drug's marketing authorization and beyond. In accordance with **Article 12 of Implementing Regulation (EU) No. 520/2012**, the data is stored for the duration of the marketing authorization and for **at least 10 years after the expiration of the last marketing authorization** for the medicinal product in question. Thereafter, the data is deleted or anonymized, unless there are further statutory retention requirements.

9. Automated Decision-Making

There is **no** exclusively **automated decision-making within the meaning of Article 22 of the GDPR**; **no profiling** takes place.

We also do not use artificial intelligence techniques when processing your data.

10. Your rights

Under the GDPR, you have the following rights

- **Information** about the personal data stored about you (Art. 15 GDPR);
- **Correction** of inaccurate data (Art. 16 GDPR);
- **Deletion** (Art. 17 GDPR);
- **Restriction** of processing (Art. 18 GDPR);
- **Data transferability** (Art. 20 GDPR);
- **Objection to processing** (Art. 21 GDPR);
- **Withdrawal of consent** (Art. 7(3) GDPR).

You may submit any of these requests to us at any time. We review each request on a case-by-case basis and process it provided there are no legal restrictions to the contrary.

In the field of pharmacovigilance, legal restrictions apply: For example, the right to deletion is excluded to the extent that we need the data to fulfill legal obligations (Art. 17(3)(b)/(c) GDPR, § 35 BDSG).

There is no right to object to processing based on legal obligations (Art. 6(1)(c) of the GDPR); however, there is a right to object to processing based on Art. 6(1)(f) (case-by-case assessment).

We will inform you of the results of the review and the extent to which we can comply with your request within the statutory time limits. To exert your rights, please contact the data processor.

In addition, you have the **right to file a complaint** (Art. 77 GDPR), including with the supervisory authority responsible for us: The State Commissioner for Data Protection and Freedom of Information Baden-Württemberg, Heilbronner Straße 35, 70191 Stuttgart, poststelle@lfdi.bwl.de, www.baden-wuerttemberg.datenschutz.de.

11. Obligation to Provide Data

Reporting side effects is voluntary. However, without the relevant information, we may not be able to properly evaluate the reported event and fully comply with our legal reporting obligations.

12. Changes to This Privacy Note

We will update this privacy policy if the legal situation or our data processing activities change. The most current version, as published on the website, abnoba.de/pharmacovigilance is the one that applies.

As of: 07.2026