

As a pharmaceutical company, we are obligated to continually monitor our products to detect, assess and understand adverse events (pharmacovigilance) in order to ensure drug safety. The law requires us to process information reported to us on adverse events (“**Pharmacovigilance Data**”) and to forward it to the competent authorities, even if such information permits direct or indirect identification of a natural person (“**Personal Data**”).

Statutory pharmacovigilance obligations refer to our human pharmaceuticals. Our cosmetics are subject to comparable regulations. Therefore, we will use the term of pharmacovigilance obligation with regard to both aforementioned products (“**Wörwag Pharma Products**”). Once food supplements are regulated in terms of safety, our food supplements will fall hereunder as well.

This data protection notice for Pharmacovigilance Data is to inform you about the type, scope, and purpose of the Personal Data collected and processed by us for pharmacovigilance purpose, as well as your rights in this context.

Person responsible for data processing

This data protection notice applies to the processing of Personal Data by

Wörwag Pharma GmbH & Co. KG
Flugfeld-Allee 24
71034 Böblingen
Germany

Telephone: +49 7031 62 04-0

Fax: +49 7031 62 04-620

Data Protection Officer for Wörwag Pharma GmbH & Co. KG, Germany

The company’s data protection officer can be reached at

Flugfeld-Allee 24
71034 Böblingen
Germany

E-Mail: [datenschutz\(at\)woerwagpharma.com](mailto:datenschutz(at)woerwagpharma.com)

Categories of Personal Data processed by us

Concerning a patient:

- Name (the report to an authority shall, however, only contain the patient's initials rather than the full name)
- Date of birth, age
- Gender
- Health status, information on diseases
- Information on medical product risks/adverse events
- Details of products used and concomitant medication (Wörwag Pharma Products and others)

Concerning the reporting party (if this is not the patient directly):

- Name (however, neither name nor address or phone number will be disclosed when reporting to an authority)
- Contact details, such as address, email address, phone and fax numbers
- Job-related information
- Information on the relationship with the patient in question

Purpose and legal basis of Personal Data processing

Personal Data are collected when you provide them to us within the scope of notification. As far as specific fields of a report form are marked as “mandatory data”, we shall collect legally required data with these fields. Of course, you may voluntarily provide us with further data if you wish.

The legal basis for processing of Personal Data, including special categories of Personal Data, is the fulfilment of our legal obligations as well as public interest in the area of public health that comprise in particular ensuring high safety and quality standards of Wörwag Pharma Products (point (i) of Art. 9 (2) GDPR, point (c) of sentence 1, Art. 6 (1) GDPR in conjunction with point (c) of § 22 (1) of the Federal Data Protection Act (*Bundesdatenschutzgesetz*; BDSG)).

Categories of recipients

Personal data shall only be passed on if this is permitted by data protection law. Categories of recipients of Personal Data include in particular:

- European, national, or regional competent supervisory authorities and registry offices to comply with our legal obligations
- Companies affiliated with us (in accordance with §§ 15 of the German Stock Corporation Act (*Aktiengesetz*; AktG))
- Processors in accordance with Art. 28 GDPR who have been carefully selected by us and with whom we have entered into the agreements required by data protection law, e.g. IT service providers that provide us with platforms for processing adverse events
- Sales partners and other pharmaceutical companies acting as our co-marketers, co-distributors, or licensing partners, as far as our pharmacovigilance obligations require us to disclose information to them
- Legal successors if our company, a therapeutic area, the business, or the Wörwag Pharma Product in question is sold, assigned, transferred, or taken over.

We may transfer Personal Data – to the required extent – to affiliated companies as well as to sales partners and other companies acting as our co-marketers, co-distributors, or licensing partners in countries outside of the European Union or the European Economic Area for which the European Commission has not determined that an adequate level of data protection is guaranteed in order to

comply with legal reporting requirements. In such cases, we shall use the standard data protection contractual clauses adopted by the European Commission as an appropriate guarantee of an adequate level of data protection.

Where appropriate, information concerning a (suspected) adverse events or other (suspected) product risks may be disclosed in case studies, press releases, summaries, or other public communications. In such a case, the characteristics suitable for identifying individuals shall be removed before disclosure.

Data storage and deletion

We shall store the Personal Data for as long as is necessary for the respective purpose of the processing activities in compliance with the statutory storage obligations (point (c) of sentence 1, Art. 6 (1) GDPR). The legal provisions stipulate that Pharmacovigilance Data must be stored for at least the duration of the validity of the marketing authorization of the Wörwag Pharma Product in question and for another ten years after such marketing authorization has ceased to exist.

Storage beyond the statutory retention periods is possible if you have consented to this in accordance with point (a) of sentence 1, Art. 6 (1) GDPR, or if the purpose of the processing activities has not ended yet.

Rights of data subjects

Subject to the conditions of Art. 15 to 20 GDPR, you have the right to receive information on the data we have stored concerning you free of charge, to have incorrect data rectified, and to demand their erasure or restriction of processing as well as to transfer of your Personal Data. However, individual rights of data subjects are restricted by law based on the considerable relevance of Pharmacovigilance Data for the public good. For example, the law forbids erasure of correctly stated Pharmacovigilance Data at your request.

If we process any data based on your consent, you may revoke your consent at any time, effective for the future.

Please also note your right of appeal to a competent data protection supervisory authority. The supervisory authority responsible for us is the “Landesbeauftragte für Datenschutz und Informationsfreiheit Baden-Württemberg” (State Commissioner for Data Protection and Freedom of Information Baden-Württemberg), which contacts details could be found at [BfDI - Landesbehörden - Baden-Württemberg](#).