

General data protection notice

Data protection information for patients in accordance with the EU General Data Protection Regulation

With the following information, we would like to give you an overview of the processing of your personal and of special categories of your personal and company-related data by us as well as your rights under data protection law. Which data is processed in detail and how it is used largely depends on the services requested or agreed upon. The following data protection information applies in particular to patients, interested parties and authorized representatives.

1. Who is responsible for data processing and whom can I contact?

Responsible:

AMW GmbH

Birkerfeld 11, 83627 Warngau, Germany

Phone: +49 8024 470999 0, E-Mail: info@amw-pharmaceuticals.com

You can reach our data protection officer, Stephan Krischke, via e-mail: datenschutz@amw-pharmaceuticals.com

2. Joint responsibility for data processing

AMW GmbH and Endomedica GmbH (Weinbergweg 23, 06120 Halle/Saale) have a joint responsibility in accordance with Art. 26 GDPR within the framework of the legal obligation to pharmacovigilance (monitoring of adverse events and reactions in connection with the use of medicinal products, in short "drug safety"). This joint responsibility comprises:

- a. the definition of common technical and organizational measures for drug safety,
- b. the appointment of a stage plan officer,
- c. the maintenance of the record of processing activities,
- d. our obligation to block the data if consent is withdrawn,
- e. the joint obligation regarding the rights and information obligations of data subjects,
- f. the commissioning of subcontractors and service providers,
- g. the definition of processes for data protection incidents.

3. Which sources and data do we use?

We process personal data that we receive from our customers/patients and doctors or pharmacists in order to fulfill our obligations. Relevant personal data for recording pharmacovigilance may include personal details (name, address, telephone number, e-mail and other contact details), personal details and contact details of your relatives/reporting persons and health data (e. g. health status/medical history, details of side effects or interactions, details of medicines used, height and weight if applicable and details of existing pregnancy).

4. What do we use your data for (purpose of the data processing) and on which legal basis?

We process personal data in order to be able to fulfill our legal obligations. This is done in accordance with the provisions of the European General Data Protection Regulation (GDPR) and the German Federal Data Protection Act (BDSG):

- a) Based on legal requirements (Art. 6 (1) (c) GDPR) or public interest (Art. 6 (1) (e) GDPR) as well as Art. 9 (2) (i) GDPR in connection with Art. 22 (1) (c) BDSG (Protecting public health and ensuring high quality and safety standards for medicinal products)

5. Who has access to my data?

Within our administration, those employees who need your data to fulfill our legal obligations will have access to it. Service providers and vicarious agents employed by us may also receive data for this purpose if they maintain the relevant confidentiality.

With regard to the transfer of data to recipients outside our company (e. g. external service providers/stage plan officers, competent authorities or other bodies entitled to receive information), it should first be noted that we ourselves undertake to maintain confidentiality about all personal facts and evaluations of which we gain knowledge. We may only pass on information about you if this is required by law, if you have given your consent or if we are legally obliged to provide information.

6. Are data transmitted to third countries or international organizations?

Data are not transferred to countries outside of the European Economic area (so-called third countries).

7. For how long do you store my data?

Due to legal obligations, pharmacovigilance data and documents for the respective medicinal products/active substances concerned are stored for as long as the product is authorized. After expiry of the authorization or registration, these are stored for another 10 years. This ensures that the data is only used to fulfill the retention obligations and not for other purposes.

8. Data security

The processing of health data, so-called special categories of personal data, is subject to special requirements to ensure data security. This involves the establishment of a procedure to regularly review, assess and evaluate the effectiveness of the technical and organizational measures in accordance with Section 22 (2) BDSG. We have implemented measures to fulfill these requirements according to the state of the art and to secure your data accordingly.

When transmitting data electronically, we always ensure that it is adequately secured and use various encryption technologies.

9. Which data protection rights do I have?

Each data subject has

- the right of information according to Art. 15 GDPR,
- the right of correction according to Art. 16 GDPR,
- the right of deletion according to Art. 17 GDPR,
- the right of restriction of processing according to Art. 18 GDPR,
- the right to object according to Art. 21 GDPR as well as
- the right of data portability according to Art. 20 GDPR.

The right of information and the right of deletion are subject to the restrictions under Sections 34 and 35 BDSG. In addition, you have the right to file a complaint with a competent data protection supervisory authority (Art. 77 GDPR in conjunction with Section 19 BDSG). You can withdraw your consent to the processing of personal data at any time.

Please note that any revocation is only effective for the future. Processing that took place before the revocation is not affected by this.

10. Is it mandatory for me to provide my data?

For patients, there is no legal or contractual obligation to provide personal data. The provision of personal data is required by law for doctors and pharmacists due to the obligation to report side effects. Anonymous reporting is not possible for doctors or pharmacists.

11. To what extent is there automated decision-making or profiling?

In principle, we do not use automated decision-making in accordance with Art. 22 GDPR to justify and perform the services. Profiling does not take place