Information on privacy for pharmacovigilance

In order to create more transparency in the processing of personal data by companies, the European legislator has introduced a new information obligation. As a patient, legal guardian or healthcare professional (reporting party), you should be informed at the time of data collection what happens to your personal data in the context of pharmacovigilance and for what purposes they are processed. You will receive the following information based on Art. 13, 14 GDPR.

1. Verantwortlicher und Datenschutzbeauftragter

The Controller for the processing of personal data is HWI pharma services GmbH, Rheinzaberner Str. 8, 76761 Rülzheim, Germany, represented by the Managing Directors: Dr. Frank Böttcher; Dr. Stefan Wissel. You can reach the Controller under the following contact details: phone +49 (0) 7272 - 77670, fax +49 (0) 7272 - 7767 11, e-mail info@hwi-group.de.
You can reach the Data Protection Officer at ISO Schmiede GmbH, Am Hardtwald 7, 76275 Ettlingen, and by email service@isoschmiede.de and by phone +49 (0) 6232 100 119 44.

2. Details zur Datenverarbeitung

Personal data are processed in the context of the legal obligation for pharmacovigilance (monitoring of adverse events and reactions in connection with the use of medicinal products). In this respect, side effects, interactions and other pharmacovigilance-relevant information shall be recorded, evaluated and, if necessary, reported to the competent authorities.

Your personal data are processed for the following purposes:

- Detection, assessment, understanding and prevention of reported side effects, interactions or other medicine-related problems
- Contacting patients (especially for clarifying questions and follow-up)
- Comparison of reported information (from patients, health professionals, clients) with other reports and findings from literature searches
- Examination and decision on the obligation to report side effects and interactions to supervisory authorities
- In the event of a reporting obligation, submission of the corresponding information to the competent authority (entry in database)
- To respond to and monitor a medical request relating to a product complaint

The following information concerning yourself are usually be required for such purposes:

Patient: name, contact details, gender, date of birth or age, state of health / medical history, details of side effects or interactions, details of medicinal products used, height and weight if applicable, and details of existing pregnancy.
Legal guardian (parents): name, contact details, relationship to the data subject

Reporting party: name, contact details, occupational data, relationship to the data subject

The processing of your personal data is based on Art. 6 para. 1 c) GDPR (legal obligation) as well as Art. 9 para. 2 i) GDPR in connection with Section 22 para. 1 c) Federal Data Protection Act ("BDSG") (protection of public health and ensuring high quality and safety standards of medicinal products).

The provision of personal data is neither legally nor contractually required for patients.

The provision of personal data is required by law for doctors and pharmacists due to the obligation to report side effects. Anonymous reporting shall not be permitted for doctors or pharmacists.

3. Recipients of your personal data

Your personal data can be disclosed to the following recipients in the context of pharmacovigilance:

- Bodies that receive data on the basis of legal requirements (competent authorities and other bodies entitled to receive information)
- Departments and internal offices involved in the performance of the respective pharmacovigilance activities (e.g. pharmacovigilance department, management, IT department)
- External service providers (processors according to Art. 28 GDPR)
- Contractual partners (clients)

We do not intend to transfer your personal data to a third country outside the EU or EEA.

4. Storage period

The personal data collected in the context of pharmacovigilance shall be stored for as long as necessary to achieve the corresponding purpose. Pharmacovigilance data and documents for the respective medicinal products / active ingredients concerned shall be stored on the basis of a legal obligation for as long as the product is authorised. After expiry of the authorisation or registration, they shall be kept for another 10 years. It shall be ensured that the data are only used to fulfil the retention obligations and not for other purposes

5. Rights of data subjects

You have the following rights: right of access (Art. 15 GDPR), rectification (Art. 16 GDPR), erasure (Art. 17 GDPR), restriction of processing (Art. 18 GDPR) and data portability (Art. 20 GDPR). We make every effort to process requests promptly.

6. Questions and complaints

You have the right to refer to a supervisory authority (e.g. Art. 77 GDPR).