

## **Data protection information on pharmacovigilance**

Confidentiality and data protection are of great concern to us. As a European authorisation holder, we ensure compliance with the GDPR (General Data Protection Regulation (2016/679)). With the following information, we would like to inform you which personal data we process within the scope of pharmacovigilance and which purposes the processing is intended for. General information on the processing of personal data at Laurus Generics GmbH can be found in the [Privacy Policy](#).

The monitoring of adverse reactions related to the use of medicinal products is known as pharmacovigilance. An adverse reaction can occur as a reaction to a medicinal product which is harmful and unintended.

Against this background, we are obliged to process information that identifies or makes identifiable ("personal data") a consumer or other reporting person by providing us with knowledge of adverse reactions. Under certain conditions, we may have an obligation to report these adverse reactions to the competent authority.

### **I. Contact details of the controller**

Laurus Generics GmbH  
Van-der-Smissen-Straße 1,  
22767 Hamburg, Germany  
Email: [info@laurusgenerics.eu](mailto:info@laurusgenerics.eu)

### **II. Contact details of the data protection officer**

Niklas Hanitsch  
Datenschutz Hoch 4 GmbH  
Franz-Mayer-Straße 1  
93053 Regensburg

### **III. Processing of product-related adverse events within the scope of pharmacovigilance management**

We are required by law to record and evaluate adverse reaction reports and other relevant information in connection with pharmacovigilance and, if necessary, to report them to the competent authority.

### **IV. We use the data for the following purposes:**

- Analysis of the side effect messages- To establish contact and clarify questions- Compare your reported information with other reported adverse reaction reports
- Transmission of the described information to the competent authorities

## **V. For these purposes we process the following personal data:**

### **1. About the patient:**

- Name: (will not be forwarded to the authorities, but will be stored by the controller for identification and traceability purposes)
- Contact details: E-mail, telephone number, address etc. (will not be forwarded to the authorities, but will be stored by the controller for identification and traceability purposes)
- Date of birth and age
- State of health and medical history, such as
  - Details of the Laurus Generics product suspected of having caused an adverse reaction, including information about the dose taken and/or prescribed and the reason for taking or prescribing it
  - Details of any other medicines or medications you are taking or were taking at the time of the adverse event
- Details of adverse reaction reports

### **2. About the reporting person:**

- Name: (will not be forwarded to the authorities, but will be stored by the controller for identification and traceability purposes)- Contact details: E-mail, telephone number, address etc. (will not be forwarded to the authorities, but will be stored by the controller for identification and traceability purposes)
- Work-related data (e.g. medical specialist)
- Relationship to the affected patient

## **V. Legal basis**

The legal basis is compliance with our legal obligations and the guarantee of high quality and safety standards in the health care system and for our pharmaceuticals (Art. 9 para 2 lit. (i) GDPR, Art. 6 para 1 lit. (c) GDPR und § 22 para 1 lit. (c) BDSG (Federal Data Protection Act).

Your contact data will only be stored after your consent according to Art. 6 para 1 lit. a) GDPR.

## **VI. Retention period**

The data will not be kept longer than necessary for the purposes for which the personal data are processed. Pharmacovigilance data and documents relating to the medicinal products concerned shall be stored under legal obligations for as long as the product is authorised on the market and for not less than 10 years from the date of expiry of the authorisation.

## **VII. Transmission of data**

As a matter of principle, your personal data is only transmitted within the scope of fulfilling our pharmacovigilance obligations. In order to fulfil our pharmacovigilance obligations, we may transfer your personal data to the following categories of recipients:- Affiliated companies of Laurus Generics GmbH directly involved in pharmacovigilance obligations

- Data processors

In some cases, we assign carefully selected service providers who are bound by the obligation of secrecy and confidentiality to process personal data and who perform pharmacovigilance-related tasks on our behalf in accordance with Art. 28 of the GDPR.

- Distributors and possibly other companies (within the EU/EEA) acting as co-marketers, co-distributors or other license partners of Laurus Generics, if the pharmacovigilance obligations for a Laurus Generics product require such exchange of safety information.
- Competent authorities

Where appropriate, we publish information on adverse events (e.g. in case studies and summaries). In this case, in order to prevent the identification of individuals, all appropriate information for possible identification is removed before each publication.

#### **VIII. Transfer of data to third countries (outside the EU/EEA)**

A transfer to third countries (outside the EU/EEA) with the corresponding guarantees through standard data protection clauses in accordance with Art. 46 GDPR can be made to the following recipients or recipient categories on the basis of our pharmacovigilance obligations:

- Affiliated companies with Laurus Generics GmbH with headquarters in a third country
- Sales partners and possibly other companies (based in a third country) acting as co-marketers, co-distributors or other license partners of Laurus Generics GmbH, if the pharmacovigilance obligations for a Laurus Generics product require such an exchange of safety information

Carefully selected service providers, bound by the obligation of secrecy and confidentiality, who perform pharmacovigilance-related tasks on our behalf

#### **IX. Updating and amending this data protection notice**

This data protection notice is currently applicable and has the date of June 2020.

It may become necessary to change this data protection notice as a result of the further development of our websites and offers or due to changed legal or official requirements. You can access and print out the current data protection notice at any time on the website under <https://www.laurusgenerics.eu/20200625EN.pdf>