

VIFOR PHARMA PRIVACY NOTICE

for reporting safety information and handling product quality complaints

This privacy notice explains what information we collect and use for pharmacovigilance activities for product safety and for processing product quality complaints. How we store, process and protect this information is explained, as are your data privacy rights.

This privacy notice applies regardless of how we receive the safety information or product quality complaint, whether by telephone, post, email, verbal communication or another channel. It applies whether you provide the information yourself or whether it is reported by a healthcare professional or another third party. Finally, this privacy notice applies to the person about whom safety information has been collected and to the person who reports the information ("reporter").

What is safety information?

Safety information is information about any of the following types of events that a person might experience.

1. An "adverse event": any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with the product.

2. An "adverse drug reaction": a noxious and unintended response to a medicinal product related to any dose is considered an adverse drug reaction. This means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility.

3. An event relevant to the safety of a medicinal product, such as exposure to the product during pregnancy or breastfeeding, intentional off-label use, abuse or misuse of the product, overdose, medication errors, occupational exposure, drug interaction, lack of efficacy or unexpected therapeutic or clinical benefit.

What personal data do we collect and why?

Personal data is information that relates to a person who is, or who could be, identified.

To monitor, investigate, evaluate and collate adverse events and other safety information relevant to our medicinal products and to report such information to health authorities in accordance with our legal obligations, we collect some or all of the following personal data, some of which is sensitive personal data such as health data:

a) Data on the person about whom the safety information is collected, such as a patient or clinical trial participant. This type of data can include:

- demographic information such as initials, date of birth, gender, weight and height and, if the person is also the reporter, name and contact information;
- details about the product(s) taken at the time, their dosage and use, the circumstances and description of the safety-related event, medical history including laboratory reports and other medical records, and any other relevant information.

b) Data on the reporter:

- Name and contact details such as email, physical address, telephone number and/or on-line identifier where the information is collected from social media;
- Profession and relationship to the person about whom the safety information is collected.

We or our service providers may contact reporters about safety information they have provided to clarify relevant details or to seek further information. In some cases third parties may be contacted for this purpose.

We collect some or all of the following personal data in the course of collecting and processing product quality complaints, some of which relates to health and therefore constitutes sensitive personal data:

- name, physical address, email address, telephone number, on-line identifier such as social media user name;
- profession, gender, date of birth;
- information relevant to the product quality complaint, possibly including safety information or other health information.

The legal basis for collecting and using your personal data in the course of processing safety information and handling product quality complaints is compliance with legal obligations and public interest in the area of public health to ensure high standards of quality and safety of medicinal products.

With whom do we share your personal data?

Your personal data and related safety information are stored electronically. Your personal data may be entered into our global databases which are accessible by multiple Vifor Pharma Group companies for analysis and reporting purposes. We apply strict security standards to these databases.

We work with third-party service providers who help us to collect and process safety information and information concerning product quality complaints or who provide other services such as technical support or data hosting. These service providers may have access to your personal data in order to provide the services.

We may also disclose your personal data to:

- health authorities when we report safety information and information regarding quality complaints, as required by law;
- other official authorities if required by law, court order or in connection with investigations or legal proceedings;
- distributors, license partners or other companies with whom we collaborate for the purposes specified in this privacy notice;
- legal and other expert advisors.

These service providers and collaboration partners are legally bound to keep all personal data confidential.

We could disclose your personal data to third parties in connection with the sale or transfer of all or part of our business, in which case we would require the third parties to treat that information in accordance with this privacy notice.

Some of the above-mentioned recipients of your personal data are located outside the country where you live, including in the United States, India and other countries that are not regarded by the competent authorities as providing an adequate level of protection for personal data. In such cases we ensure that appropriate safeguards are in place to protect your personal data such as the EU standard contractual clauses. A copy of the EU standard contractual clauses may be obtained from our group data protection officer (GroupDPO@viforpharma.com).

How long do we store your personal data?

By law we must store your personal data collected for safety reporting purposes for at least ten years after the relevant medicinal product is no longer available in the market.

We retain personal data and other information collected in connection with product quality complaints for as long as necessary to achieve the purposes described above.

What are your rights regarding your personal data?

You are entitled at any time to request access to your personal data. You can request that errors be corrected or that processing of your personal data be restricted. You can also object to our processing of your personal data or request it to be erased.

If you would like to exercise your rights, please contact us as described in the section "How to contact us" below. Please note that applicable laws may prevent us from complying with requests to erase safety information or to restrict our processing of it.

You are entitled to lodge a complaint with a supervisory authority if you wish.

How to contact us

Please contact us if you have any questions about this privacy notice or if you wish to exercise your privacy rights in relation to your personal data.

- Our group data protection officer:
GroupDPO@viforpharma.com
- safety@viforpharma.com
- The "controller" of the personal data:
Vifor Pharma Management Ltd.
Flughofstrasse 61
P.O. Box
CH-8152 Glattbrugg
Switzerland
+ 41 58 851 80 00
- Vifor's representative in the European Union/European Economic Area for data privacy purposes:
Vifor Pharma Deutschland GmbH
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- Vifor's representative in the UK for data privacy purposes:
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