

# Teva Pharmacovigilance Privacy Policy

## Definitions used in this Privacy Policy

“**Adverse event**” means an unwanted, unintended or harmful event in relation to the use of a Teva medicinal product.

“**Personal data**” means information that relates to any living identifiable individual (e.g. you, your medical practitioner or your family member).

“**Teva**” means Teva Pharmaceutical Industries Ltd. or its affiliated companies (or both), also referred to in this Privacy Policy as “we”, “us” and “our”.

## Teva and your privacy

Ensuring patient safety is extremely important to Teva and we take the safe use of all our products seriously. Teva needs to be able to get in touch with people who contact Teva about our products in order to follow-up and obtain further information, give answers to requests or to send requested material. This Privacy Policy describes how we collect and use your personal data to help us fulfil our duty to monitor the safety of all medicines we market or have in clinical development (also known as our pharmacovigilance obligations).

## Scope of this Privacy Policy

This Privacy Policy applies to information we collect from you online, by phone, fax, e-mail or post, or as part of the adverse event reporting regulations applicable to Teva. We may also collect this information about you through specific forms submitted by you on a site that is owned or controlled by Teva.

If you are a patient we may also be provided with information about you by a third party reporting an adverse event that affected you. Such third parties may include medical professionals, lawyers, relatives or other members of the public.

## Information we collect and why we collect it

**For pharmacovigilance purposes Teva is under legal obligations to collect specific data. This is specified in more detail below.**

### **Patients (subject of report)**

We collect personal data about you when you, or a third party, provide us with information about you in relation to an adverse event that affected you or someone else. Where you are reporting the adverse event yourself, please also refer to the **Reporters** section.

Pharmacovigilance laws require us to take “detailed records” of every adverse event passed to us, which allow the event to be evaluated and collated with other adverse events recorded about that product. The personal data that we may collect about you when you are the subject of an adverse event report is:

- name or initials;
- age and date of birth;
- gender;
- weight and height;

- details of the product causing the reaction, including the dosage you have been taking or were prescribed, the reason you have been taking or were prescribed the product and any subsequent change to your usual regimen;
- details of other medicines or remedies you are taking or were taking at the time of the reaction, including the dosage you have been taking or were prescribed, the period of time you were taking that medicine, the reason you have been taking that medicine and any subsequent change to your regimen;
- details of the adverse reaction you suffered, the treatment you received for that reaction, and any long-term effects the reaction has caused to your health; and
- other medical history considered relevant by the reporter, including documents such as lab reports, medication histories and patient histories.

Some of this information is considered by law to be “sensitive personal data” about you. This includes any information that tells us about your:

- health;
- ethnicity;
- religion; and
- sexual life.

This information is only processed where relevant and necessary to document your reaction properly and for the purpose of meeting our pharmacovigilance requirements. These requirements exist to allow us and competent pharmacovigilance authorities to diagnose, manage and prevent such adverse events from occurring in the future.

### **Reporters**

We collect information about you when you provide us with information about you in relation to an adverse event you have reported.

Pharmacovigilance laws require us to ensure that adverse events are traceable and available for follow-up. As a result, we must keep sufficient information about reporters to allow us to contact you once we have received the report. The personal data that we may collect about you when you report an adverse event is your:

- name;
- contact details (which may include your address, e-mail address, phone number or fax number);
- profession (this information may determine the questions you are asked about an adverse event, depending on your assumed level of medical knowledge); and
- relationship with the subject of the report.

Where you are also the subject of a report, this information may be combined with the information you provide in relation to your reaction. However, information about patients, relatives or other non-medical reporters is withheld from Teva’s Global PhV Database (see below).

### **How we use and share your information**

As part of meeting our pharmacovigilance obligations, we may use and share your information to:

- investigate the adverse event;
- contact you for further information about the adverse event you have reported;
- collate the information about the adverse event with information about other adverse events received by Teva to analyse the safety of a batch, Teva product or active ingredient as a whole; and

- provide mandatory reports to national authorities or the EU Eudravigilance database so that they can analyse the safety of a batch, Teva product, generic or active ingredient as a whole alongside reports from other sources.

Personal data collected from you for pharmacovigilance may also be transferred to a third party in the event that one of our products is sold, assigned or transferred, in which case we would require the buyer, assignee or transferee to treat that personal data in accordance with applicable data protection laws.

We may also share personal data with other pharmaceutical companies who are our co-marketing, co-distribution or other licence partners, where Pharmacovigilance obligations for a product require such exchange of safety information.

We share information with national and European authorities in accordance with pharmacovigilance laws. We are unable to control their use of your data.

### **Global PhV Database**

As our pharmacovigilance obligations require us to review patterns across reports received from every country where we market our products, the analysis is performed by an international group of highly-qualified safety physicians. To meet these requirements, information provided as part of an adverse event report is shared within Teva on a worldwide basis through Teva's Global PhV Database. This database is also the platform through which Teva uploads adverse event reports to the Eudravigilance database. All information about patients described in ***Patients (subject of report)*** may be uploaded to this database. Similarly, all ***Reporter*** data fields may be included, except where the reporter is not a health professional.

### **How we store information and your rights**

Because patient safety is so important, we retain all the information we gather about you as a result of an adverse event report to ensure that we can properly assess the safety of our products over time.

You may access and correct your information at any time by contacting Teva's Pharmacovigilance team at [safety.belgium@tevabelgium.be](mailto:safety.belgium@tevabelgium.be). For legal reasons we cannot delete information that has been collected as part of an adverse event report, unless it is inaccurate. We may also require you to provide proper identification before we comply with any request to access or correct your data. Your right to such access or correction may be limited by applicable law.

### **Security**

Teva takes measures to secure your personal data from accidental loss and from unauthorised access, use, alteration or disclosure. Data is transferred securely using SSL encryption and stored on secure servers. Additionally, we take further information security measures including access controls, stringent physical security and robust information collection, storage & processing practices.

### **International transfers**

All pharmacovigilance databases, including the Global PhV Database, are hosted in Israel by Teva. These are administered and supported around the clock by Teva's dedicated pharmacovigilance IT teams in Israel, Germany and the United States. Teva also engages Accenture Services Private Limited in India for data entry, administration and data cleansing of a limited part of the pharmacovigilance database.

Patient information may also be transferred worldwide as part of our Global PhV Database (see above).

These transfers may include transfers outside of your country to countries which do not implement an adequate level of protection for your personal data under your national law or European law. Teva however takes appropriate steps to ensure your data is adequately protected if transferred to these countries. While it remains in Teva's systems the security measures outlined in this Privacy Policy shall always apply and when processed in other parties' systems, Teva ensures agreements are in place with such parties that ensure the third party also has adequate security measures in place.

## **Changes to this Privacy Policy**

If we decide to change the substance of this Privacy Policy materially, we will post those changes through a prominent notice on our site.

## **Contact Information**

Your data is submitted to Teva and is hosted and stored in databases on servers situated in Israel, which are owned and maintained by Teva Pharmaceutical Industries Ltd., an Israeli limited liability company whose principal place of business is at:

Teva Pharmaceutical Industries Ltd.  
5 Basel Street  
PO Box 3190  
Petach Tikva 49131  
Israel

If, at any time, you have questions or concerns about this Privacy Policy, please e-mail [safety.belgium@tevabelgium.be](mailto:safety.belgium@tevabelgium.be). We will use reasonable endeavours to answer your question promptly or resolve your problem.