

## **BAYER PRIVACY POLICY FOR PHARMACOVIGILANCE DATA**

Policy last updated: [2018-07-06]

### **Bayer takes product safety and your privacy seriously**

Bayer develops and markets prescription and over the counter medicines as well as medical devices and cosmetics, for human and veterinary use ("**Bayer Health Products**").

As a pharmaceutical company, Bayer has a legal responsibility to monitor the safety of all Bayer Health Products worldwide that we have in development or are marketing in any country.

Humans and animals vary in their biological reactions to medicinal products or medical devices and not all adverse reactions or events (side effects) associated with the use of medicinal products and medical devices can be detected during clinical development, not even by the most comprehensive clinical trials. Capturing adverse events, however rare they may be in absolute terms, in the development and marketing phase from worldwide sources is of paramount importance.

Such monitoring of adverse events is called Pharmacovigilance ("**PV**"). PV requirements exist to allow us and competent regulatory authorities (such as the European Medicines Agency and other authorities) to manage adverse events and to protect public health and ensure high standards of quality and the safety of Bayer Health Products.

Our Pharmacovigilance obligations require us to process certain personally-identifiable information ("**Personal Data**") of a patient and/or the reporter of an adverse event that we receive in order to comply with strict obligations to perform benefit-/risk assessments of Bayer Health Products continuously and report suspected adverse reactions or events to relevant regulatory authorities (the "**PV Purposes**").

This Pharmacovigilance Privacy Policy ("**Policy**") provides important information to you about how we process Personal Data for PV Purposes, in line with our obligations under applicable data privacy laws and in particular the EU General Data Protection Regulation ((EU) 2016/679) ("**GDPR**").

**All Personal Data is processed exclusively for the PV Purposes and only where relevant and appropriate to document, assess and report your adverse event properly in accordance with our Pharmacovigilance obligations.**

If you have any questions about this policy or about how we use your Personal Data, please contact us via our [contact details](#) at the end of this Policy.

## 1. Personal Data we process for the PV Purposes

We may need to process the following Personal Data to comply with the PV Purposes:

### About the Patient:

- patient name and / or initials;
- date of birth / age group;
- gender;
- weight;
- height;
- ethnicity;
- medical history and status, which may include:
  - details of the Bayer Health Product causing the adverse event, including the dosage you have been taking or were prescribed, the reason you have been taking or were prescribed the Bayer Health 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 adverse event, 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 event you suffered, the treatment you received for that event, and any potential long-term effects the adverse event 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.

### About the Reporter:

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 the person reporting the adverse event to us ("Reporter"), who may be the patient, a healthcare provider, a family member or any other person to allow us to contact you once we have received the report. The Personal Data that we may collect about you as a Reporter is:

- 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.

### Special Category Data

Some of the Personal Data we collect is considered by law to be particularly sensitive and constitutes a special category of personal data in accordance with GDPR. This includes any information that tells us about a patient's:

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

Bayer processes such PV relevant Personal Data, including special category data, in accordance with the GDPR

- to comply with legal obligations under applicable Pharmacovigilance laws and regulations and its legitimate interests in ensuring the PV Purposes (Art 6 GDPR),

considering that

- PV EU or Member State law has been issued for reasons of substantial public interest in the area of public health and safety of medicinal products or medical devices (Art 9 GDPR)

and using state of the art technical and organizational measures to safeguard your Personal Data as more particularly described in this Policy. Where reasonably possibly, we use your Personal Data in key coded/pseudonymized form.

## **2. Use of your Personal Data for the PV Purposes**

We will only use your Personal Data where the law allows us to and in order to comply with the PV Purposes.

As part of meeting our Pharmacovigilance obligations, we may use Personal Data to:

- investigate the adverse event;
- contact you for further information about the adverse event you reported;
- collate the information about the adverse event with information about other adverse events received by Bayer to analyze the safety of a production batch, Bayer Health Product or active ingredient as a whole; and
- provide mandatory reports to national and/or regional competent regulatory authorities so that they can analyze the safety of a production batch, Bayer product, generic or active ingredient as a whole alongside reports from other sources.

## **3. Sharing/disclosure of your Personal Data for the PV Purposes**

We do not disclose or share any Personal Data for the Purposes except as permitted by law.

As part of meeting our Pharmacovigilance obligations, we may share and/or disclose Personal Data:

- within the Bayer Group in order to analyse and process a reported adverse event;
- in respect of a suspected adverse event to relevant regulatory authorities;
- with our third party service providers. These third party service providers may include safety database providers, call centre operators, and in the event that you disclose details of your suspected adverse reaction to our market researchers, that particular market research provider. Please note that we have appropriate data protection safeguards in place with our third party business partners with whom we share Personal Data and who are providing services or functions on our behalf;
- with other pharmaceutical companies who are our co-marketing, co-distribution, or other license partners, where pharmacovigilance obligations for a product require such exchange of safety information. Please note that we have appropriate data protection safeguards in place with our third party business partners with whom we share Personal Data and who are providing services or functions on our behalf;

- with a third party successor in business in the event of a sale, assignment, transfer, or acquisition of the company or a specific product or therapeutic area, 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 publish information about adverse events (such as case studies and summaries); we will remove identifiers from any publications so that no individual can easily be recognized.

#### **4. Transfer of your Personal Data to a Third Country**

Our Pharmacovigilance databases are hosted in Germany by Bayer.

As outlined in Section 3 of this Policy, we may need to transfer your Personal Data to Bayer affiliates or to third party business partners and regulatory bodies. These may be based outside of the European Economic Area (“EEA”) in a country for which the European Commission has not decided that it ensures an adequate level of data protection (“**Third Country**”).

Unless a legal derogation applies under applicable law, whenever we need to transfer your Personal Data for the PV Purposes to a third party business partner located in a Third Country, we ensure a similar degree of protection is afforded to it by ensuring that we have a data transfer agreement in place with such third party business partner incorporating specific protective clauses approved by the European Commission (the “EU Standard Contractual Clauses”). You may obtain a copy of such EU Standard Contractual Clauses by contacting our Corporate Data Protection Officer via our [contact details](#) at the end of this Policy.

#### **5. Keeping your Personal Data secure**

We have implemented appropriate state of the art technical and organisational measures to safeguard Personal Data processed for the PV Purposes, including safeguards and procedures designed to restrict access to Personal Data to those employees who need it to perform their job responsibilities.

We maintain physical, electronic and procedural measures to safeguard Personal Data from accidental loss, destruction or damage and unauthorised access, use and disclosure.

#### **6. Retention periods for use of your Personal Data**

We will use and store your Personal Data in accordance with mandatory legal requirements governing storage and reporting of Pharmacovigilance related information. Such mandatory requirements oblige us to archive PV information which may include Personal Data at least for the duration of the product life-cycle and for an additional ten years after the respective medicinal product and medical devices has been taken from the market.

#### **7. Access to and control over your Personal Data**

You have legal rights under applicable law in relation to your Personal Data.

You may be entitled under applicable law to ask Bayer for a copy of your information, to correct it, erase or restrict its processing, or to ask us to transfer some of this information to other organizations. You may also have rights to object to some processing.

Please note however, that these rights may be limited in order to fulfil Pharmacovigilance obligations. Your rights are limited for example where we can demonstrate that we have a legal requirement to process your personal data. For legal reasons, we cannot delete information that has been collected as part of an adverse event report unless it is inaccurate. We may require you to provide proper identification before we comply with any request to access or correct your Personal Data.

## **8. Contact Us**

If you want to exercise your privacy rights or have any question to this Policy, please send your request to:

Bayer AG  
Corporate Data Protection Officer  
51368 Leverkusen  
Germany  
[data.privacy@bayer.com](mailto:data.privacy@bayer.com)