



# Pharmacovigilance Privacy Notice

## Introduction

The purpose of this Privacy Notice is to provide you with information on how we collect your personal data and subsequently store and process your data, including sharing with certain responsible third party organisations for adverse event reporting.

## Types of information we collect and why we collect it

The reason that we collect personal data from you is because pharmacovigilance laws require us to take detailed records in relation to every adverse event that relates to our manufactured products. These obligations on us are in place in order to ensure management of adverse events and to make efforts towards patient safety.

The types of personal data that we may collect about you when you are the subject of an adverse event:

- Name and/or initials
- Age and date of birth
- Gender
- Weight and height
- Details of the product causing the adverse event
- The reason you have been taking the product or were prescribed the product
- Details of other medicines or remedies you are taking or were taking at the time of the reaction
- The reason you have been taking the other medicines and any subsequent changes in your medicines
- Details of the reaction you suffered, the treatment you received for that reaction, and any long term effects the reaction has caused to your health
- Medical history considered relevant, including documents such as laboratory reports
- We may also collect additional data known as 'sensitive personal data' if considered relevant in relation to the reaction you experienced, and may include: health, ethnicity, religion and sexual orientation.

We also collect personal data about you when you are the reporter of an adverse event. We are legally required to ensure that adverse events are traceable. We therefore keep information about



reporters in order to contact you once we have received a report. The personal data we collect is comprised of:

- Name
- Contact details (which may include address, email, phone number or fax number)
- Profession (this information may determine the questions you are asked about an adverse event)
- Relationship with the subject of the report

Where you are also the subject of a report, the information will be combined with the information you provide in relation to the adverse event reaction.

### **Method of using the Personal Data & do we need your consent?**

As per our regulatory obligations, any adverse event reports that we receive from you will be compared with past and future reports that we may receive in order to analyse and assess the safety of our products and to update any required safety information to pass on to patients who use the products.

We always obtain consent from an individual before collecting or processing their personal data. In certain circumstances, however, we are not required to obtain consent. The personal data that is collected for the purpose of pharmacovigilance duties / requirements is done so in the public interest and to further the cause of public health. Therefore, consent is not applicable in this instance.

### **Using and sharing your personal data**

We may share your personal data with national regulatory authorities in accordance with national pharmaceutical / pharmacovigilance laws.

### **International transfer of your personal data**

We often use the services of external pharmacovigilance service providers who carry out the required function on our behalf, after we have collected the personal data from you. Therefore, for the provision of the service, the personal data which you provide needs to be transferred to the pharmacovigilance service provider, who may oftentimes be located in a country outside the EU, and which therefore provides data protection not strictly recognised by the EU. With regard to such transfers to a third party, we have an agreement in place with that third party to ensure that the third party also has adequate security measure in place with regard to the safe processing and protection of personal data.

### **Your rights**



Data protection law gives you certain rights as a data subject. These are as follows:

- You have the right to request a copy of the information we hold about you, or ask us what information we hold about you. You also have the right to ask us to correct any information, if an error is identified.
- For legal reasons we cannot delete information that has been collected and processed as part of adverse event reporting, unless it is inaccurate.
- You can ask us to transfer your personal data to other organisations – unless we are not permitted for reasons of public interest.
- Since the personal data is collected as part of the adverse event reporting for reasons of public health and interest, you cannot object to its processing / use.
- (Please be advised that we require you to provide proper identification before we comply with any request relating to the above, where applicable.)

### **Contact details**

Personal data submitted to us is stored in the databases or on servers that are accessible to authorised personnel only

The servers are owned by us and maintained by third party IT services providers. The pharmacovigilance database is managed by a pharmacovigilance service provider.

If, at any time, you have questions or concerns about this Privacy Notice, please e-mail: [dpo@bristol-labs.co.uk](mailto:dpo@bristol-labs.co.uk).