



## Privacy Notice for Medical Information, Pharmacovigilance Reports and Product Complaints

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### **Introduction**

At Blueprint Medicines Corporation (along with its subsidiaries and affiliates collectively “Blueprint”, “us” or “we”), we recognize the importance of protecting your personal data, and we are fully committed to respecting your privacy. For the purposes of this notice Blueprint is the data controller, meaning that is responsible for determining the means and the purposes of processing activities of personal data. This privacy notice is divided in three sections and is intended to explain how Blueprint and its affiliates within and outside the European Economic Area (EEA) (each acting as a Data Controller) will collect and process your personal data for the purposes of management of medical information enquiries, pharmacovigilance reports and product complaints (both including product complaints and service complaints (e.g., problem with delivery of the product) related to Blueprint medicinal products.

For more detailed information about Blueprint’s privacy practices, please refer to our Privacy Notice, available on our corporate website [here](#).

### **Medical information enquiries**

#### **a) Purpose and legal basis for processing**

Any personal data provided by you to Blueprint which relates to a medical enquiry may be used exclusively to manage your enquiry appropriately, follow up with you to request additional information in order to respond to your enquiry. Such a handling of your enquiry is based on our legal obligations and industry regulations to provide a medical information service for our products. We will also rely on our legitimate interests to further store and maintain medical information related data, to the extent required, in a medical information database for future historic reference, record keeping, auditing and compliance purposes as well as for the establishment, exercise or defense of legal claims. The processing of special categories of data, such as health data, is necessary for reasons of public interest in the field of public health.

If your medical information enquiry consists of or requires the further reporting of an adverse event, your data (including special categories of personal data) will be also processed to comply with our legal pharmacovigilance obligations imposed on Blueprint by European, national and local pharmacovigilance laws and regulations. Also, in case that your medical enquiry consists of a product complaint, your data may be processed to comply with our legal obligations in the context of drug and product safety.

Your data will not be used for any other purposes. If you do not wish to provide your personal details to us, we will not be able to contact you back or further deal with your request.

#### **b) Categories of personal data processed**

For managing medical information enquiries, we may collect the name and surname of the requestor, their contact details (such as phone number and email address) and their affiliation or profession.

#### **c) Retention period**

Personal data retained as part of a medical information inquiry are kept for a maximum of 25 years after receipt and closure of the enquiry. At the end of this period the data will be deleted or archived in an anonymized form.

### **Pharmacovigilance Reports**

#### **a) Purpose and legal basis for processing**

Any personal data provided by you as a patient or as a Healthcare Professional (HCP) to Blueprint, which relates to the reporting of adverse events or other pharmacovigilance related activities, will be collected and used solely for pharmacovigilance management purposes. In particular, we will collect and use such data to investigate the adverse event, to follow-up with the patient, or the patient's doctor or the reporter, or in general, to collect additional information about the adverse event, to analyze the safety of the product by combining and collating the information from one adverse event with information about other adverse events and to provide relevant pharmacovigilance reports to the competent regulatory authorities in and outside of Switzerland, UK and EEA as necessary, to continuously assess the benefit/risk ratio of our products.

Processing is necessary for Blueprint to comply with international, European and local pharmacovigilance related legal and regulatory obligations.

The processing of special categories of data, such as health data, is necessary for reasons of public interest in the field of public health and aims to the detection, assessment and understanding of adverse events and any other medicine-related problem as well as to ensure compliance with high standards of quality and safety of health care and medicinal products, in accordance with applicable data protection laws.

#### **b) Categories of personal data processed**

##### **Personal data relating to the Patient:**

- Patient's name (if patient is the reporter for himself/herself) or initials (in case the HCP is the reporter);
- For effective follow-up activities, contact details (address, e-mail address, phone number or fax number) are requested on a voluntary basis to patients, in case patient is also the reporter;
- Date of birth/age/age group, sex, weight, height;
- Information about health, ethnic origin; and
- Medical history and status, which may include but not limited to, for example include administered treatments, test results, nature of the adverse effect(s), personal or family history, sexual life in relation to associated reported events, associated diseases or events, risk factors, genetic data in relation to what is needed for the good use of our products, information on how medicinal products are prescribed and used and on the therapeutic conduct of the prescriber or of the HCPs involved in the management of the disease or adverse health event.

##### **Personal data relating to the Reporter:**

- Reporter's Name;

- Contact details (address, e-mail address, phone number or fax number) needed to perform effective follow-up to ensure complete and accurate data is collected;
- Profession (if the reporter is an HCP); and
- Relationship with the subject of the report.

**c) Retention period**

Mandatory requirements oblige us to archive pharmacovigilance related information at least for the duration of the product life cycle and for additional 25 years after the respective medicinal product has been taken from the market, in the absence of a legally imposed retention period by a European Union or national law, unless an additional territory imposes a longer retention period by regulation. At the end of this latest period imposed by a territory, the data will be securely deleted or archived in an anonymized form.

**Product complaints**

**a) Purpose and legal basis for processing**

Any personal data provided by you to Blueprint which relates to a product complaint will be used solely for the purposes of management of such product complaints.

Processing is necessary for Blueprint to comply with international, European and local legal obligations in the context of drug quality and safety. The processing of special categories of data, such as health data, is necessary for reasons of public interest in the field of public health and will be used for the evaluation, classification, and assessment of the product complaint, to follow up on such requests for healthcare purposes, to request additional information and/or to respond to you.

We will also use such information to analyze the quality and safety of our product by combining and collating the information from one product complaint with information about other product complaints and to provide relevant product quality reports to the competent regulatory authorities in and outside of Switzerland, UK and EEA, as necessary.

**b) Categories of personal data processed**

We may collect the name, contact details of the individual reporting the complaint. In case the complainant is an HCP we will also collect details regarding his/her affiliation/profession. We may collect some additional personal data related to health and medical history of the individual affected by the product complaint if such information is relevant to evaluate, classify and assess the product complaint.

**c) Retention period**

As information related to product complaints is necessary to comply with our legal obligations relating to public health reasons, complaint records, including personal data contained therein, are kept for a maximum of 25 years after the investigation on the complaint has been closed. At the end of this period the data will be deleted or archived in an anonymized form.

**Recipients of your personal data**

Blueprint may share your data among its affiliates worldwide, business partners and service providers, where required to operate a Blueprint global or regional medical information, pharmacovigilance or product complaint database and fulfill its obligations deriving from

relevant medical information, pharmacovigilance legislation and/or legislation regarding drug quality and safety.

Where our processing activities are outsourced to third party service providers, these entities will be acting for and on our behalf as data processors; in such cases we ensure that binding data processing agreements are in place and that such entities and their representatives and sub-contractors operate strictly under our instructions and only to the extent they are authorized to do so or are required to do so by applicable laws and company policies. All third parties acting on behalf of Blueprint are required to be appropriately trained and aware of their data protection obligations and to implement appropriate technical and organizational security measures.

Blueprint is also obliged to report certain pharmacovigilance and product relevant information to competent authorities worldwide (e.g., European Medicines Agency, Food and Drug Administration), including to authorities established in countries with different level of data protection compared to EU. These reports will contain details about the incident but will only contain limited personal data and in particular:

- Patients: Information as provided, including date of birth/age/age group and gender (note that patient name will never be provided);
- Reporting Individuals: Information as provided, including name, profession, initials (to identify any duplications), address, email, phone number, to allow the regulatory authority to follow up with the reporting individual.

In the exchange of data within Blueprint, business partners and service providers, your personal data may be transferred to third countries outside Switzerland, UK and EU/EEA that do not provide the same level of data protection as the country of your residence or place of work. Where data relating to medical information, pharmacovigilance or product complaints will be transferred to countries outside Switzerland, UK and EU/EEA, Blueprint will ensure the adequacy of the recipient country and the security of the processing of personal data being transferred.

### **Security and maintenance**

Blueprint Medicines will use reasonable technical, administrative and physical safeguards to ensure appropriate security of personal data being collected and processed in relation to the management of medical information enquiries, pharmacovigilance reports and product complaints. Your data will be securely stored in information assets owned by or managed on behalf of Blueprint by third party service providers and may be hosted outside your home/work jurisdiction. We will take necessary steps to ensure that adequate safeguards are put in place.

Blueprint will maintain any information related to a medical enquiry, a pharmacovigilance report or a product complaint in the respective database, for as long as necessary (see above more specific retention periods) and to the extent permitted under applicable legal and regulatory requirements governing storage and reporting of related information for future historic reference, record keeping, auditing, regulatory and compliance purposes, as well as for the establishment, exercise or defense of legal claims.

### **Information about your rights**

You have the right to request from Blueprint information on the types of personal data we store and the purposes for which we process them. You can also request access to and rectification of your personal data, as well as the restriction of their processing.



The exercise of your rights is subject to the specific conditions set forth in applicable data protection and privacy laws.

To the extent the processing is based on Blueprint's compliance with a legal obligation, your rights to object, to erase data or to data portability will be restricted.

If we do not handle your request in a timely manner, or if you are not satisfied with our response to the exercise of these rights, you are entitled to submit a complaint with the competent supervisory authority of your country of residence or place of work. Further information and contact details of the European competent supervisory authorities can be found [https://edpb.europa.eu/about-edpb/about-edpb/members\\_en](https://edpb.europa.eu/about-edpb/about-edpb/members_en). UK residents may submit a complaint to the UK Information Commissioner's Office (ICO) here: <https://ico.org.uk/make-a-complaint/>

All inquiries and requests with respect to the processing of your personal data by Blueprint or by third parties on Blueprint' behalf should be directed to Blueprint Privacy Office by email at: [euprivacy@blueprintmedicines.com](mailto:euprivacy@blueprintmedicines.com).

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