# Pharmacovigilance Privacy Policy

At Crescent Pharma, we prioritise patient safety and are committed to the responsible use of our products. Safeguarding your privacy is of utmost importance to us. This Pharmacovigilance Privacy Policy outlines how we collect, use, and protect personal information to fulfil our obligations in pharmacovigilance, product quality, and medical inquiries. We strive to monitor and ensure the safety and quality of all our marketed and clinically developed products, including medicines, cosmetic products, food supplements, and medical devices.

## Scope of this Privacy Policy

This Privacy Policy applies to the collection of information from or about you through various channels, including online platforms (website), telephone, fax, email, or postal mail. It encompasses adverse event reporting, quality complaints, medical inquiries, and relevant reporting regulations applicable to Crescent Pharma. We may also collect information through specific forms submitted on Crescent Pharma-owned or controlled websites.

## Adverse Event Reporting

If you report an adverse event related to a Crescent Pharma product as a patient, we may collect the following types of personal information:

- Name or initials
- · Contact details for follow-up purposes (when relevant)
- · Age (including date of birth if provided)
- Gender
- Weight and height
- · Details of the product causing the reaction and your usage
- Details of other medications or remedies used at the time of the reaction
- · Details of the adverse reaction, treatment received, and any long-term effects
- Other relevant medical history, such as lab reports, medication histories, and patient records.

#### Medical Inquiry

If you make a medical inquiry, we may collect the following types of personal information:

- Name
- · Contact details for follow-up purposes
- · Details of your inquiry as provided by you.

## **Quality Complaint**

If you file a quality complaint, we may collect the following types of personal information:

- Name
- · Contact details for follow-up purposes
- · Details of the relevant product and events
- · Reporting Adverse Events, Medical Inquiries, and Quality Complaints

When you report an adverse event, make a medical inquiry, or file a quality complaint, we collect and process your personal information to manage and address these reports or inquiries. Legal obligations require us to gather specific data for pharmacovigilance, product safety, and quality control purposes. This information enables us to evaluate adverse events, quality complaints, or medical inquiries and take appropriate actions to ensure the safety and quality of our products. Additionally, we process this data to respond to your requests or inquiries.

## Legal Basis for Data Processing (EU)

Regarding pharmacovigilance, Crescent Pharma is legally obligated under pharmacovigilance legislation, including

Good Pharmacovigilance Practices, to collect specific data for reasons of public interest in the area of public health (EU GDPR Art. 6(1)(c) and 9.2(i)).

For medical inquiries and quality complaints, Crescent Pharma may have a legal obligation under product safety and quality legislation to address your requests (EU GDPR Art. 6(1)(c) and 9(2)(i)). Alternatively, we may rely on our legitimate business interest (EU GDPR Art. 6(1)(f)) or obtain your consent (EU GDPR Art. 6(1)(a) and 9(2)(a)), which will be clearly obtained at the time of data collection.

#### Purposes of Data Processing

We process your information only when relevant and necessary to document adverse reactions properly and meet our pharmacovigilance, safety, quality, and other legal requirements. These requirements enable us and competent authorities, such as the European Medicines Agency, to evaluate adverse events, quality complaints, or medical inquiries and work toward preventing similar incidents in the future. Additionally, we need to process this information to respond to your requests or inquiries. Your data will not be used for any other purposes than those listed in this policy.

#### **Data Retention**

Any personal information collected for the purposes mentioned above will be retained in pseudonymized form, securely stored, and minimized in accordance with data protection principles. To ensure patient and product safety, we retain information related to adverse events, quality complaints, or medical inquiries. This retention period extends to 30 years following the product's market authorization to fulfil international legal requirements.

## Use and Sharing of Personal Data

We may use and share personal information to:

- · Investigate adverse events, quality complaints, or medical inquiries
- · Request additional information related to the reported event or inquiry
- · Analyse safety patterns by collating information with other reports (in pseudonymized form whenever possible)
- Provide mandatory reports to national and/or regional authorities for safety analysis (in pseudonymized form whenever possible).

To fulfil our pharmacovigilance and quality obligations, we review reports from all countries where our products are marketed. Sharing information within Crescent Pharma's global database is essential for these purposes. We may upload adverse event reports to relevant oversight authorities, such as the European Medicines Agency's Eudravigilance database, as required by applicable laws. We also maintain a global medical inquiry database for managing and responding to inquiries. Your personal information is pseudonymized and de-identified whenever possible to safeguard your privacy.

In specific circumstances, such as a sale, assignment, transfer, or acquisition of the company or specific products, personal information may be transferred to a third party. We ensure that the buyer, assignee, or transferee handles personal information in accordance with applicable data protection laws.

## Further Information Regarding Pharmacovigilance

For pharmacovigilance obligations, we may share personal information with other pharmaceutical companies that are our co-marketing, co-distribution, or licensing partners. Such sharing of safety information is required by pharmacovigilance laws.

In some cases, as part of market authorization for a particular product, you may be enrolled in a patient safety program. Further information regarding data processing, including additional data sharing or transfers, will be provided at the time of enrolment.

When sharing information with national and/or regional authorities, including the European Medicines Agency, we comply with pharmacovigilance laws. However, we only share pseudonymized information that does not directly identify individuals.

We may publish information about adverse events in pseudonymized form, such as case studies and summaries, to ensure individual recognition is not possible.



Under applicable law, you may have rights to access, correct, erase, restrict processing, or transfer your information to other organizations. You may also have the right to object to certain processing activities. These rights may be limited in some situations where we can demonstrate a legal requirement or lawful justification for processing your personal data. To exercise your rights or seek additional information, please contact Crescent Pharma's Data Protection Officer using the contact details provided below. We may request proper identification before addressing any requests related to personal data access or correction.

We aim to address any queries or concerns regarding our data processing practices. However, if you remain unsatisfied, you have the right to lodge a complaint with the data protection authority in your jurisdiction.

#### Security

Crescent Pharma implements measures to secure personal data against accidental loss, unauthorized access, use, alteration, or disclosure. We enforce information security measures, including access controls, robust physical security, and stringent practices for data collection, storage, and processing.

## Changes to this Privacy Policy

In the event of material changes to this Privacy Policy, we will provide prominent notice to ensure awareness of such changes.

## Contact Information

If you have concerns, questions, wish to exercise your rights, or obtain additional information, please contact Crescent Pharma's Data Protection Officer using the following contact details: Privacy@crescentpharma.com

We strive to address any queries or concerns about our data processing practices. However, if you remain dissatisfied, you have the right to lodge a complaint with the data protection authority in your jurisdiction.