Privacy policy for pharmacovigilance/ cosmetovigilance data

Pharmacovigilance (PV)/cosmetovigilance (CV) means the ongoing and systematic monitoring of the safety of a drug/cosmetic product with the aim of detecting, assessing and understanding its adverse effects in order to take appropriate measures to minimize risks.

Biofrontera AG, 51377 Leverkusen, Germany (hereinafter referred to as "us", "our" or "we") develops and distributes prescription and over-the-counter medicinal products, medical devices and cosmetics for human use. As a pharmaceutical company, Biofrontera has a legal responsibility and duty to monitor the safety of all Biofrontera products that we develop or market worldwide. To protect public health and ensure a high standard of quality and safety of Biofrontera products, PV/CV regulations require us to document adverse events and report the information to the relevant regulatory authorities.

Because humans exhibit a wide variety of biological responses to drugs or medical devices, and only a limited subject size participates in clinical trials, not all adverse reactions or events (side effects) associated with the use of drugs and medical devices can be detected during clinical development - even by the most extensive clinical trials. That is why the recording of adverse events from global sources, regardless of how often the event occurs in absolute terms, is of great importance in both, the development and distribution phases.

In the course of recording an adverse event, our PV/CV obligations require us to process certain information provided by a patient and/or the reporting party of an adverse event that allows direct or indirect identification of a natural person ("personal data"). As a pharmaceutical company, we are required to process this data to comply with strict regulations to conduct ongoing benefit-risk assessments of Biofrontera products and to report suspected adverse reactions or events to the relevant regulatory authorities.

This PV/CV Privacy Policy (“Policy") contains important information regarding the processing of your personal data for PV/CV purposes in accordance with our obligations under applicable laws, in particular the General Data Protection Regulation ((EU) 2016/679) ("GDPR").

All personal data will be processed solely for PV/CV purposes and only when relevant and appropriate to properly document, assess and report your adverse event in accordance with our PV/CV obligations.

If you have any questions about this policy or about the processing of your personal data, please contact the data protection officer of Biofrontera AG. You will find the contact details at the end of this policy.

1. Categories of personal data

We may need to process the following personal data.

1.1 About the patient

- Name and/or initials of the patient,
- Date of birth/age group, sex, weight, height.
- Health information, pregnancy information if applicable, racial or ethnic origin.
- Date of treatment, medical history and health status, for example:

    - Details of the use of the Biofrontera product suspected to have caused the adverse event, including the dose, the indication underlying the treatment, and details of the treated area of the body.
    - Details of any other medicines/cosmetics or agents you are taking or were taking at the time of the adverse event, including the dose you were taking or were prescribed, the length of time you were taking the medicine/cosmetic, the reason for taking the medicine/cosmetic, and any subsequent changes in your therapy,
    - Details of the adverse event that affected you, the treatment you received for that event, and any potential impact the adverse event may have on your health, and other information about your medical history that is considered relevant by the reporting party, including documentation necessary to evaluate the report, such as laboratory reports, medication history, and patient history, and other documents as appropriate.

1.2 About the reporter:

- Name,
- Contact information (e.g., your address, email address, telephone number, or fax number),
- Occupation (this information may affect the questions you are asked depending on your assumed level of medical knowledge about the adverse event), and
- Relationship to the person affected by the report.

2. Purposes of processing ("PV/CV purposes")

In the course of fulfilling our PV/CV obligations, we may process your personal data to:

1. investigate the Adverse Event,
2. contact you to obtain further information about the adverse event you have reported,
3. match the information about the adverse event with information about other adverse events reported to Biofrontera and, on that basis, analyze the safety of a production batch, of the Biofrontera product; and
4. submit prescribed reports to the appropriate regulatory authorities to enable them to analyze the safety of a production batch, of the Biofrontera Product together with reports from other sources.

3. Disclosure of personal data

In the course of fulfilling our PV/KV obligations, we may share and/or disclose personal data as follows:

- within the Biofrontera Group, in order to analyze and process a reported adverse event.
- To the relevant regulatory authorities, with regard to a suspected adverse event.
- to third-party service providers of the Biofrontera Group. In the PV/KV area, we work together with PV/KV service providers. The database operated by the service provider is located in Germany.

  Appropriate data protection safeguards are implemented at our service providers to whom the Biofrontera Group transfers personal data and who provide services on our behalf.
- To other pharmaceutical companies acting as co-distributors or other licensed partners of the Biofrontera Group, if the PV/KV obligations for a Biofrontera product require such exchange of security information.
- to a successor in title to the business in the event of a sale, assignment, transfer or acquisition of the business or a specific Biofrontera product or therapeutic area, in which case we will require the purchaser, assignee or transferee to process personal data only in accordance with applicable data protection laws.
- when information about adverse events is published (for example, in the form of case studies and summaries); in these cases, all identifiers will be removed from publications to keep your identity confidential.

3.1 Third countries

Due to the company structure and marketing strategy, we may need to transfer your personal data to other members of the Biofrontera Group or to external business partners and regulatory authorities. These may be located outside the European Economic Area ("EEA") in a country for which the European Commission has not decided that an adequate level of data protection is guaranteed ("third country"). For example, the U.S. Food and Drug Administration ("FDA") requires that notifications of drugs that are also marketed in the U.S. also be submitted to the FDA if those notifications meet certain criteria.

If your personal data must be transferred for PV purposes to an external business partner located in a third country, we use the standard data protection contractual clauses adopted by the European Commission as an appropriate guarantee of an adequate level of data protection.

4. Security of your personal data

In accordance with Article 32, GDPR, we have implemented appropriate and state-of-the-art technical and organizational measures to protect personal data processed for PV/CV purposes. These include safeguards and procedures that limit access to personal data to those employees who need it to perform their job duties.

We implement physical, electronical and procedural measures to protect personal data from accidental loss, destruction, damage and unauthorized access, use and disclosure.

Where appropriate and reasonable, we process personal data in anonymized or pseudonymized form.

5. Retention periods

We will process, store and archive your personal data in accordance with mandatory legal and internal company requirements for storing and reporting pharmacovigilance/ cosmetovigilance information.

6. Legal basis for the processing of your personal data

Biofrontera processes PV/CV-relevant personal data, including special categories of personal data, in accordance with the GDPR

1. In order to comply with the applicable legal requirements under the applicable laws and regulations on PV/CV and the legitimate interest in ensuring PV/CV purposes (Art. 6 GDPR),

taking into account that

2. EU or Member State law has been adopted on the basis of a substantial public interest in the field of public health and the safety of medicinal products, cosmetics or medical devices (Art. 9 GDPR).

7. Information about your rights ("data subject rights")

You have the right to:

1. Request information about your personal data processed by Biofrontera (Art. 15 GDPR),
2. To request the rectification of your personal data if it is incorrect or incomplete (Art. 16 GDPR).
3. Request the transfer of your personal data to you or to another person in a commonly used format (Art. 20 GDPR),
4. File a complaint with a data protection supervisory authority (Art. 77 GDPR),
5. object to the processing of your personal data, provided that the processing is based exclusively on a legitimate interest of Biofrontera (Art. 21 GDPR),
6. to request the deletion of your personal data if the processing is no longer necessary for the underlying purpose of the processing or if there is no legal basis for further processing (Art. 17 GDPR).

Please note, however, that these rights may be limited in order to comply with our legal PV/CV obligations. Your rights are not fully applicable if there is a legal basis for processing your personal data. For example, we cannot delete information collected as part of reporting an adverse event unless it is false. We may require you to provide reasonable proof of your identity before we will comply with a request to access or correct your personal data.

8. Contact

For your concerns regarding data protection in connection with pharmacovigilance/cosmetovigilance or data protection in general, please contact the Data Protection Officer of Biofrontera AG at the following address:

Data Protection Officer
Biofrontera AG
Hemmelrather Weg 201, 51377 Leverkusen, Germany

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