Data Protection Statement for Vigilance

Data protection information on processing personal information related to adverse reactions or events associated with the use of medicinal products and safety of medical devices (vigilance)

Last updated March 2021

In our capacity as a manufacturer of pharmaceuticals and medical devices, Fresenius Kabi (Pty) Ltd ("we") will collect, use and report personal information of patient using our products and reporters of adverse reactions or events.
This data protection statement informs you about the processing of personal information when making an adverse event report.
Please be aware that we also may process your personal information in other contexts, e.g. when you **visit our website**, when you are a **business contact for products or services** or when you interact with us in your capacity as a **healthcare professional**. Please see the specific information on the processing of your personal information in such situations.

Why We Collect and Use Your Personal Information

The quality and safety of Fresenius Kabi's products (drugs, enteral nutrition, medical devices), services and therapies are of paramount importance. Our interactions with patients using our products do not end with the supply of products or the provision of services but involve the monitoring and analysis of applicability, effectiveness and safety for patients of our products on the market. The gained insights are the basis for identifying opportunities for continuous improvement of products and services. Fresenius Kabi, therefore, monitors and evaluates relevant information and feedback on the products, services and therapies during its use and where necessary reports these to health authorities.

The monitoring of adverse reactions or events (side effects) associated with the use of medicinal products is referred to as pharmacovigilance (drug safety). The statutory

pharmacovigilance commitments relate to our medicinal products for human use. Similar regulations exist for medical devices.

With the help of our vigilance activities, Fresenius Kabi ensures that the patients' safety of its products is always guaranteed, and that the company is enabled to identify any changes in the benefit-risk-ratio at an early stage and react in a timely manner.

What Information we Collect and How We Do That

We may collect and use your personal information in the following situation:

Information you provide to us

We collect and use the information you provide directly to us (e.g. via phone, letter or webform), as patient using our products or as reporter of adverse reactions or events.

The exact amount and kind of information depends on the information submitted to us or the information that is published, posted or shared. Such information includes:

- Information identifying the patient (potentially including first and last name, date of birth, gender)
    - Medical history and other characteristics including laboratory data, pregnancy, weight and height, age,
    - Measures and treatment of adverse reaction(s)
- Information identifying the reporter
    - First and last name
    - Contact and address information (including address, e-mail address, social media account name, phone number)
- Information on the adverse event or other information on the safety of our products
    - Description of the adverse reactions related data including start, stop, duration
    - Drug/active substance related data including dosage, application, suspected causality indication and duration of treatment
    - Medical device related data including application, and malfunctioning
    - Seriousness criteria of reaction such as death, life threatening, hospitalization or prolonged hospitalization, permanent injury or disability, important medical event
    - Outcome of reaction(s)

Information we collect from publicly available sources

We collect and use the information as reported and published on publicly available sources such as social media and internet forums, literature or other reports we became aware of.

The exact amount and kind of information depends on the information submitted to us or the information that is published, posted or shared. Such information includes:

- Information identifying the patient (potentially including first and last name, date of birth, gender)
    - Medical history and other characteristics
    - Measures and treatment of adverse reaction(s)
- Information on the primary source of the data for potential follow-up requests
    - First and last name
    - Contact and address information (including address, e-mail address, social media account name, phone number)
- Information on the adverse event or other information on the safety of our products
    - Description of the adverse reactions related data including start, stop, duration
    - Drug/active substance related data including dosage, application, suspected causality indication and duration of treatment
    - Medical device related data including application, and malfunctioning
    - Seriousness criteria of reaction such as death, life threatening, hospitalization or prolonged hospitalization, permanent injury or disability, important medical event
    - Outcome of reaction(s)

Information we collect from other organizations

We collect and use the information as provided to us by healthcare organizations or organizations otherwise involved in the provision of care such as hospitals, our distributors and resellers or universities.

The exact amount and kind of data depends on the information submitted to us such data includes:

- Information identifying the patient (potentially including first and last name, date of birth, gender)

    - Medical history and other characteristics
    - Measures and treatment of adverse reaction(s)
- Information on the primary source of the data for potential follow-up requests
    - First and last name
    - Contact and address information (including address, e-mail address, social media account name, phone number)
- Information on the adverse event or other information on the safety of our products
    - Description of the adverse reactions related data including start, stop, duration
    - Drug/active substance related data including dosage, application, suspected causality indication and duration of treatment
    - Medical device related data including application, and malfunctioning
    - Seriousness criteria of reaction such as death, life threatening, hospitalization or prolonged hospitalization, permanent injury or disability, important medical event
    - Outcome of reaction(s)

Legal Basis for Processing Your Information

We process your personal information on the following legal basis:

- The processing of your personal information is necessary for reasons of public interest in the area of public health to ensure high standards of quality and safety of medicinal products and devices based on law (Section 11 (1)(e) Protection of Personal Information Act 4 of 2013)
- You have given us your consent for the intended processing (Section 11 Protection of Personal Information Act 4 of 2013)
- The processing is necessary for purposes of the legitimate interests pursued by us or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal information(Section 11 (1)(f) Protection of Personal Information Act 4 of 2013). This legitimate interest is explained under ‘Why we collect and use your data'
- The processing of your personal information is necessary for us in order to comply with a legal obligation we are subject to (Section 11 (1)(c) Protection of Personal Information Act 4 of 2013)

We Share Your Information

We collaborate with other organizations to fulfill or legal obligations. Therefore, we may send your personal information in parts or as a whole to other organizations. Such recipients are:

- Other Fresenius Group companies if such a transfer of personal information is required for the specific purpose (Please refer to the **overview of the locations** in which Fresenius Kabi Group companies are active)
- Service providers who process personal information on our behalf (e.g. for hosting or maintenance services) that have to follow our instructions on such processing; these service providers will not be allowed to use your personal information for other than our purposes
- Health authorities, other pharmaceutical companies, other courts, parties in a litigation in case we are required to do so to meet any applicable laws, regulations, legal processes or enforceable governmental requests
- Professional advisors or auditors, such as tax advisors, financial auditors, lawyers, insurers, banks and other external professional advisors in the countries in which we operate

International Data Transfers

We may send your personal information in parts or as a whole to Fresenius Group recipients in countries, which are not member states of the European Union or international organizations, for the purposes listed above. Please refer to the **overview of the locations** in which Fresenius Kabi is active.
We may send information to the following countries for which the European Commission has determined an adequate level of data protection to be in place that matches the level of data protection within the European Union in which Fresenius entities have been established: Argentina, Canada, Japan, New Zealand, Switzerland or Uruguay.

With regards to such international information transfers to third countries, for which the European Commission has not decided that an adequate level of data protection exists, we have provided appropriate safeguards in order to secure your personal information to a degree that equals the level of data protection in the European Union.

Safeguards used are:

- Standard Contractual Clauses that have been issued by the European Commission
- Participation in the EU-US-Privacy Shield

You can obtain a copy of these **standard contractual clauses** online, or upon request.

How Long We Retain Your Information

Fresenius Kabi only stores personal information that is required to be compliant with the current legislation in our global safety databases. Stored data will be kept 10 years after the marketing authorization for the respective product or device has ceased to exist.

Requests Inquiries and Complaints

Depending on the situation you have certain rights regarding your personal information.
You have the right to:

- Request access to your personal data
- Request rectification of your personal data
- Request erasure of your personal data
- Request the restriction of processing of your personal data
- Data portability
- Object on grounds specific to your situation

In these cases, please use our online **data protection contact form**.

You also have the right to lodge a complaint with our Information officer or the Information Regulator.

Information Officer:
Mikko Tiitinen
Fresenius Kabi (Pty) Ltd
Stand 7, Growthpoint Business Park
162 Tonetti Street
Midrand
1682
South Africa
E-mail: **Mikko.Tiitinen@fresenius-kabi.com**

Deputy Information Officer:
Leah Madiba
Fresenius Kabi (Pty) Ltd
Stand 7, Growthpoint Business Park
162 Tonetti Street
Midrand
1682
South Africa
E-mail: **Leah.Madiba@fresenius-kabi.com**

Information Regulator:
33 Hoofd Street
Forum III, 3rd Floor Braampark
P.O Box 31533
Braamfontein, Johannesburg, 2017
Mr Marks Thibela
Chief Executive Officer
Tel No. +27 (0) 10 023 5200, Cell No. +27 (0) 82 746 4173
Complaints email: **complaints.IR@justice.gov.za**
General enquiries email: **inforeg@justice.gov.za**

Further Information for Specific Situations

Requirements to provide personal information

If you do not provide all necessary personal information, we might not be able to respond or process your report properly because we cannot comply with the legal requirements as listed above.

Changes to this data protection statement

As the collection and use of your information may change over time, we might also modify this data protection statement to always correctly reflect our information processing practices. We encourage you to review it from time to time.

Controller and Contact

The controller and responsible entity for processing of personal information is:

Deputy Information Officer:
Leah Madiba
Fresenius Kabi (Pty) Ltd
Stand 7, Growthpoint Business Park
162 Tonetti Street
Midrand
1682
South Africa
E-mail: **Leah.Madiba@fresenius-kabi.com**