NEW F210318 data protection statement for adverse events – NB. Kabicare website needs to link to this ..

Data Protection Statement for Vigilance

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

In our capacity as a manufacturer of medicinal products and medical devices, Calea UK Limited ("us/we") (part of the Fresenius Kabi group of companies) will collect, use and report personal data of patients using our products and reporters of adverse reactions or events.

This data protection statement informs you about the processing of personal data when making an adverse event report.

Please be aware that we also may process your personal data 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 data in such situations.

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Why We Collect and Use Your Data

The quality and safety of Calea's products (medicinal products, nutritional products, 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. Calea, 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, Calea ensures that the safety of its products is in line with regulatory requirements, 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.

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What Data We Collect and How We Do That

We may collect and use your personal data in the following situations:

Information you provide to us

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

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

Information we collect from other organizations

We collect and use the data as provided to us by healthcare organisations or organisations otherwise involved in the provision of care such as hospitals, our customers, 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 (including Initials, 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)
    - Signature
- 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
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Legal Basis for Processing Your Data

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We process your personal data on the following legal bases:

- The processing of your personal data 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 (Art. 6.1 e and Art. 9.2 i GDPR)
- You have given us your consent for the intended processing (Art. 6.1 a GDPR) and the processing relates to personal data which
    - is made public by you (Art. 9.2 e GDPR)
    - is part of your participation in a clinical trial or research study (Art. 9.2 a GDPR)
- 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 data (Art. 6.1 f GDPR). This legitimate interest is explained under 'Why we collect and use your data'
- The processing of your personal data is necessary for us in order to comply with a legal obligation we are subject to (Art. 6.1 c GDPR and Art. 9.2 i GDPR). More specifically we are obliged to have post market surveillance based on Regulation (EU) No 1235/2010 and Directive 2010/84/EU concerning the pharmacovigilance of medicinal products for human use. See also Commission Implementing Regulation No 520/2012 of 19 June 2012 and the European Medicines Agency (EMA) Guidelines on Good Pharmacovigilance Practices (GVP). Furthermore, legal obligations arise as part of a clinical trial, see Regulation (EU) No 536/2014 and as part of medical device regulations EU 745/2017 and 746/2017

We Share Your Data

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

- Other Fresenius Group companies if such a transfer of personal data 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 data 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 data 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

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International Data Transfers

We may send your personal data 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 data 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 data 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 data 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

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

How Long We Retain Your Data

Calea only stores personal data 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, Enquiries and Complaints

Depending on the situation you have certain rights regarding your personal data. 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 or by contacting our Local Data Protection Adviser on data.protection-UK@fresenius-kabi.com.

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Controller and Contact

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

Calea UK Limited

Cestrian Court
Eastgate Way, Manor Park
Runcorn WA7 1NT
You also have the right to lodge a complaint with our data protection officer or the supervisory authority.

Data Protection Officer:

Fresenius Kabi Limited
Data Protection Officer
Else-Kröner-Straße 1
61352 Bad Homburg
Germany
E-mail: dataprotectionofficer@fresenius-kabi.com

Data Protection Authority:

Information Commissioner's Office

https://ico.org.uk/global/contact-us/
Tel: 0303 123 1113

Further Information for Specific Situations

Requirements to provide personal data

If you do not provide all necessary personal data, 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 data may change over time, we might also modify this data protection statement to always correctly reflect our data processing practices. We encourage you to review it from time to time.