GALENA PHARMA DATA PROTECTION STATEMENT ON PHARMACOVIGILANCE AND MEDICAL DEVICE SAFETY

Data controller

Galena Pharma Oy, Sammonkatu 10, 70500 Kuopio, Finland.
Business ID: 1057172-0

Contact information

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General

Galena Pharma Oy, founded in 1996, is a pharmaceutical company specializing in contract manufacturing and packaging. A significant part of the service includes product development, registration & marketing authorization and post market surveillance. The wide range of our products comprises human and veterinary medicinal products, medical devices in classes IIa and IIb, cosmetics, food supplements, animal care products and nutritional supplements. The products we manufacture are sold mainly in pharmacies.

Galena Pharma has a legal obligation to monitor the adverse events and the effects of their products in the countries where they are getting sold and carry out a continuous risk-benefit assessment. It is called pharmacovigilance and medical device safety operation. With the help of this system and quality assurance management, Galena Pharma can manage adverse events and protect public health. Thanks to this, the safety of Galena Pharma's products is guaranteed. It is the responsibility of the competent authority to inspect and evaluate the pharmacovigilance and medical device safety activities of the company and validate it.

Pharmacovigilance and medical device safety obligate Galena Pharma to process the information of the patient and/or the notifier of the adverse reaction, based on which a person can get directly or indirectly identified. These are personal data whose processing is mandatory for Galena Pharma in order to comply with its pharmacovigilance and medical device safety obligations and report any adverse reactions or events that come to their notice to the competent authorities in a relevant and appropriate manner.

This data privacy statement describes how personal data gets processed for pharmacovigilance and medical device safety purposes under applicable data protection laws and the obligations set out in the EU Data Protection Regulation (EU 2016/679). If you have any questions about this privacy statement or the use of your personal information, please contact the data controller.

The purpose of data processing in pharmacovigilance and medical device safety

As part of its statutory obligations, Galena Pharma may process personal information:

- to investigate the adverse event
- to contact you regarding a reported adverse event
- to combine adverse event data with other adverse events reported to Galena Pharma to obtain a comprehensive assessment of the safety of the product
- to submit the required reports to the competent authority

Classification of personal data

Galena Pharma may process the following personal data given in adverse reaction notification, which may include sensitive information:

- Information on the patient
  - patient's name and/or initials
  - date of birth/age group, sex, height, weight
  - information on health status, race or ethnic origin
  - previous health information, e.g.
    - information on Galena Pharma's product that may have caused the adverse event, dosage information, reason for using or prescribing the product and any possible changes to the treatment
    - information on the use of other products or treatments during the adverse event/treatment (dose information, duration of use, reason for using or prescribing the product and any changes to the treatment)
    - information on the reported adverse event and its effects on health, treatment received and other information that is related to the adverse event (including laboratory tests, previous medication, and patient records)

- Information on the notifier of an adverse reaction
  - name
  - contact information (e.g., address, e-mail address, telephone number)
  - profession (the content of questions according to presumed medical knowledge)
  - relationship with the person to whom the notification relates

Transfer of personal data

As part of pharmacovigilance and medical device safety requirements, Galena Pharma may share or disclose personal information:

- within Galena Pharma for analyzing and processing an adverse event
- with competent authorities in connection with a suspected adverse event
- with service providers used by Galena Pharma, e.g., concerning safety databases and medical assessments
- with marketing companies that market or distribute products that come under Galena Pharma's responsibility
- with licensing partners in cases where pharmacovigilance and safety obligations require the exchange of information
- when publishing information on adverse events, e.g., case studies, where all identifying information are removed from the publication while the identity remains confidential

The pharmacovigilance and medical device safety database of Galena Pharma is in Finland. However, anonymized personal data may require transfer to third parties (business partners) and public authorities.

Whenever we need to transfer your personal data to a third-party business partner located in a Third Country, we apply standard data protection clauses adopted by the European Commission as appropriate safeguards.

Protection of personal data

Galena Pharma has appropriate technical and organizational measures for protecting personal data processed for pharmacovigilance and medical device safety purposes. Access to personal data is limited only to persons with obligatory duties to process the data. Data processors are obliged with the obligation of confidentiality.

Galena Pharma has appropriate systems to protect personal data against possible loss, destruction, or damage.

Retention

Personal data is retained in our protected database and used only to handle the case or report according to regulatory requirements.

Galena Pharma retains personal data under the requirements specified in the pharmacovigilance and medical device safety legislation: throughout the life cycle of the medicinal product and 50 years after the marketing authorization for the medicinal product has expired or the medical device has withdrawn from the market.

Legal grounds for the processing of personal data

According to the EU General Data Protection Regulation (GDPR), the legal grounds for the personal data processing of Galena Pharma are the legal obligations set out in the laws and regulations on pharmacovigilance and medical device safety.

Right to information

You have the right to ask

- for information about your personal data processed by Galena Pharma
- for correction of your personal data if there are errors or omissions
- for the transfer of your personal data to yourself
- to complain to the Data Protection Authority
- to object to the processing of your personal data, if it is based solely on Galena Pharma's legitimate interests
- for the deletion of your personal data

It is to note that the rights mentioned above may be restricted if it is a prerequisite for obligations related to pharmacovigilance and medical device safety operations. The rights may get restricted if there is a legal basis for processing them. Galena Pharma will verify the identity of the requester before processing any possible request. The request for information must be sent in writing to the data controller. The data controller will reply to the customer within the set time frame set under the EU Data Protection Regulation (typically within one month). The right to request for information is free of cost when performed once per year maximum.

Changes to this statement

We reserve the right to update this statement as necessary as a part of legislation requirements or the development of our services or website.

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