FIDIA Privacy Notice – Safety, Quality monitoring and Medical Information

pursuant to Article 13 and 14 of the UK GDPR (hereinafter "UK GDPR" and in general "UK Data Protection Legislation").

Controller

Fidia Pharma UK LTD, having its principal place of business at c/o Rodl & Partner Legal Limited, 170 Edmund Street, Birmingham, England B3 2HB, (in the following "FIDIA").

Should you request any additional information or for exercising your rights under the personal data protection legislation, you can contact our DPO (Data Protection Officer), by sending an email to dpo@fidiapharma.it or an ordinary mail to this address: Fidia Pharma UK LTD, at c/o Rodl & Partner Legal Limited, 170 Edmund Street, Birmingham, England B3 2HB - to the attention of the DPO.

Essential Definitions for helping in reading this Privacy Notice

Pharmacovigilance: *it has been defined by the World Health Organization (WHO) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.*

Vigilance*: activities aim to improve the protection of health and safety of patients, healthcare professionals, and other users by reducing the likelihood of reoccurrence of adverse event related to the use of a product).*

Product: *drugs (for which Fidia is Marketing Authorization), medical devices (for which Fidia is Manufacturer), food supplements and cosmetics (for which FIDIA is Responsible Person, that places the product in the market).*

Adverse event*: unwanted, unintended or harmful event in relation to the use of a FIDIA product.*

Personal data: *any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.*

Health Data: *personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.*

Enquirer: *person disclosing to FIDIA information about their healthcare professionals, relatives or personal data related to their physical or mental health.*

Medical Enquiry: *Enquiry raised by Health Care Professionals (HCPs), Member of the Public (MoP), patient advocacies, Commercial Partners concerning the usage, efficacy and safety of Fidia's products.*

Scope of this Privacy Notice

Ensuring patient safety is extremely important to FIDIA and we take the safe use of all our products seriously. We need to be able to get in touch with people who contact us about our products in order to follow-up and obtain further information, give answers to requests or to send requested material.

This Privacy Notice describes how we collect and use personal data and health data whether received, to help us fulfil our duty to monitor the safety of all medicinal products (also known as our Pharmacovigilance obligations). FIDIA can also process your personal data to answer medical enquiries (as medical information service) and the product complaints sent by you respectively in order to obtain additional information and to report a quality issue regarding our products.

The notice is also applicable to medical devices, food supplements and since the relevant regulations on such products require essentially same safety and quality monitoring (Vigilance obligations). This Privacy Notice applies to information we collect from or about you online, by phone, fax, e-mail or ordinary mail, or as part of the adverse event or quality reporting regulations applicable to us or as part of the processing of medical information or product complaints. We may also collect this information about you through specific forms submitted by you on FIDIA website, that is owned or controlled by us. If you are a patient, we may also receive information about you by a third party (e.g. healthcare professionals, relatives or health public services) reporting an adverse event that affected you or a request of information about our product regarding how it has been used or how it should be used.

Purpose and legal basis of personal data processing

With reference to the pharmacovigilance data processing and the product complaints sent by you, we are under a legal obligation in order to comply with relevant EU/national binding regulations regarding safety of health related products (UK GDPR Article 6(1)(c)) for the reasons of public interest in the area of public health (UK GDPR Articles 9(2)(g) and (i)). Moreover, with reference to the request of medical information sent by you, the processing of personal data is necessary to fulfil your request (UK GDPR Article 6(1)(b)) and, in case your request makes reference to health data the corresponding legal basis is according to UK GDPR Article 9(2)(e) ('processing relates to personal data which are manifestly made public by the data subject').

Data Retention period

We retain all pharmacovigilance/medical information request/product complaints related documents for the relevant time periods reported in the applicable laws concerning medicinal products, medical devices, food supplements and cosmetics.
The data retention period could be extended, on a case by case basis, for the establishment, exercise or defence of legal claims.

The personal data that we may collect about you

You as patient/consumer

To the maximum extent we may collect the following information about you:

- name and surname or initials;
- age and date of birth;
- gender;
- weight and height;
- details of the product causing the reaction or to which the request of information relates, including the dosage you have been taking or were prescribed, the reason you have been taking or were prescribed the product and any subsequent change to your usual regimen;
- details of other medicines or remedies or medical devices you are taking or were taking at the time of the reaction or request of information, including the dosage you have been taking or were prescribed, the period of time you were taking that product, the reason you have been taking that product and any subsequent change to your regimen;
- details of the adverse reaction you suffered, the treatment you received for that reaction, and any long term effects the reaction has caused to your health;
- other medical history considered relevant by the Enquirer, including documents such as lab reports, medication histories and patient histories. Some of this information could include, about you: health data, ethnicity, religion, sexual life. Such information shall only be processed where relevant and necessary to document your reaction/provide answers properly and for the purpose of fulfilling the pharmacovigilance/vigilance requirements, as well as any other applicable legal requirement.
- The data you have voluntarily provided in your medical information request/product complaints

You as Enquirer other than the patient/subject of the request

We collect information about you when you provide us with information in relation to an adverse event/ request of information you report. Pharmacovigilance/vigilance laws require us to ensure that such events are traceable and available for follow-up. As a result, we must keep sufficient information about Enquirers to allow us to contact you once we have received the request/report.

The personal data that we may collect about you:

- name and contact details (which may include your address, e-mail address, phone number or fax number);
- relationship with the subject of the request/report.

How we use and share information

In order to meet our legal obligations, we may use and share the information received to:

- investigate the adverse event/complaint;
- contact the Enquirer or you for further information about the request/case report;
- collate the information about your case report with information about other requests received/ other adverse events/complaint received in order to analyse the matters for pharmacovigilance/vigilance purpose;
- provide mandatory reports to national and/or regional and/or international competent authorities.

We may also share personal data with other pharmaceutical companies who are our co-marketing, co-distribution, contract manufacturers or other license partners, where pharmacovigilance/vigilance obligations for a product, medical information request and product complaints require such exchange of information.

Furthermore, we can involve service providers in processing data for the purpose of this Privacy Notice, properly selected and working under binding contractual data protection clauses.

Security Measures

We take adequate measures to secure the data processed from accidental loss and from unauthorised access, use, alteration or disclosure. Additionally, we take further information security measures including access controls, stringent physical security and robust information collection, storage and processing practices.

International transfers

In case the data need to be transferred to entities established outside UK, it shall be adopted, case by case, the relevant instruments to lawfully transfer the data.
UK adequacy decision or standard contractual clauses according to UK GDPR Article 45 and 46 or applicable derogations on a case by case basis (UK GDPR Article 49).

Your privacy rights

With regards to the processing described above, at any time as data subject you can exercise the rights provided for by the UK GDPR. In general, the data subjects will be able to exercise the right to:

- access their personal data, obtain evidence of the purposes pursued by the Controller, the categories of data processed, the recipients to whom they may be communicated, their retention period, the existence of automated decision-making processes, including profiling and in such cases information on the logics used, and the possible consequences for the data subjects;
- obtain without delay the correction of inaccurate personal data concerning them;
- obtain, for cases allowed by law, the erasure of their data;
- obtain the limitation of processing the data, for cases foreseen for by law;
- object the processing of the data, when appropriate, based on the rules applicable to the specific case;
- in the cases foreseen by the law, obtain the portability of the data provided to the Controller as well as receive it in a structured format, commonly used and readable by automatic devices or request the transmission of such data to another Controller where possible;

The data subject shall have the right to lodge a complaint with the Commissioner (https://ico.org.uk/make-a-complaint/data-protection-complaints/data-protection-complaints/) if he/she considers that the processing of personal data relating to him/her infringes the UK GDPR.

Effective date of this Notice: January 10, 2023