PRIVACY NOTICE FOR PHARMACOVIGILANCE, MEDICAL INFORMATION AND PRODUCT COMPLAINTS

General information

This Privacy Notice is intended to provide information on how Zwiers Regulatory Consultancy (ZRC) and/or its affiliate companies in the European Economic Area collect, store, use and process your personal data for the purposes of activities related to pharmacovigilance e.g. medical enquiries and product complaints.

This includes information provided when data subjects:

- report an adverse event/adverse drug reaction in connection with ZRC client's product(s),
- requests information about one or more of ZRC client's products, or
- submits other claims or questions connected to PV issues, adverse events/adverse drug reactions or medical issues.

For general information about data processing at ZRC, please visit https://www.az-regulatory.com.

ZRC takes data privacy seriously and treats all your personal data in accordance with applicable data protection laws, which include, for the European Economic Area, the General Data Protection Regulation (GDPR; Regulation (EU) 2016/679).

What are Personal Data?

'Personal Data' means 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 (GDPR).

What is processing?

'Processing' of Personal Data means any operation or set of operations which is performed on Personal Data or on sets of Personal Data, whether or not by automated means, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction (GDPR).

Why do we collect your Personal Data?

Any Personal Data provided to ZRC related to adverse events or other activities related to PV will be used solely for the purpose of monitoring of the safety of the medicinal products. This information is very important for public health and will be used for the detection, assessment, understanding and prevention of adverse events or any other medicine-related problem.

ZRC collects and processes your data for these purposes in order to comply with ZRC's legal obligations as described in:

- Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council;

– Guideline on good pharmacovigilance practices (GVP) – Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products;

– National legal acts implementing or specifying mentioned legal acts in more detail.

Purpose	Legal Basis	Citation
Your Personal Data related to adverse events or other activities related to pharmacovigilance will be used solely for these purposes.	This processing is necessary to comply with legal pharmacovigilance (GVP) obligations.	GDPR Article 6(1)(c) and Article 9(2)(i)
Your Personal Data related to a product complaint will be used solely for these purposes (e.g. will be used for the evaluation, classification and assessment of the product complaint, to follow-up on such requests and to maintain the information in a product complaints database for reference).	This processing is necessary to comply with legal obligations in the context.	GDPR Article 6(1)(c) and Article 9(2)(i)
Your Personal Data related to a medical enquiry may be used to answer the enquiry, follow-up on such requests and maintain the information in a medical information database for reference.	This processing is in the legitimate interest to follow-up on your enquiries. If you are a patient, we will process your Personal Data based on your explicit consent.	GDPR Articles 6(1)(a), 6(1)(f) and 9(2)(a)
Your Personal Data related to a medical enquiry where reporting of adverse event or other activities related to PV is required will be used solely for these purposes.	This processing is necessary to comply with legal pharmacovigilance (GVP) obligations.	Article 6(1)(c) and Article 9(2)(i) GDPR
Your Personal Data related to a medical enquiry that consist of a product complaint, will be used solely for these purposes.	This processing is necessary to comply with legal obligations in the context.	GDPR Article 6(1)(c) and Article 9(2)(i)

Who will see your Personal Data?

ZRC may share the data you provided among ZRC employees, business partners, service providers and Health Authorities worldwide in order to comply with PV legislation.

The reports contain details about the adverse events but will contain only limited Personal Data such as e.g. country, town, age group, gender. Of note, Personal Data will be anonymised in such way that a person cannot be recognised (a patient's name will never be provided).

Only a limited number of individuals within ZRC's PV and information technology departments as well as certain managers will have access to Personal Data processed by ZRC for PV purposes. Access to Personal Data is restricted to the people responsible for the processing of the data.

How do we keep your personal information secure?
ZRC has implemented appropriate technical and organisational measures to safeguard Personal Data processed for PV purposes, including safeguards and procedures designed to restrict access to Personal Data to those employees who need it to perform their job responsibilities.

ZRC maintains physical, electronic and procedural measures to safeguard Personal Data from accidental loss, destruction or damage and unauthorised access, use and disclosure.

Where reasonably possible, ZRC processes Personal Data in key coded/pseudonymised form.

How long will we keep your personal information?
MAHs will retain your personal information for the period required by law, which, for adverse events, is until at least 10 years after a marketing authorisation for the relevant product has expired or has been cancelled (Commission Implementing Regulation (EU) No 520/2012).

What are your rights as data subject?
You have the right to

- Know that your Personal Data are being processed and for which purpose (GDPR);
- Request copies of those data (GDPR);
- Request rectification or erasure of your personal data if it is inaccurate or processed for purposes not stated above (GDPR);
- Request ZRC to restrict the processing of your personal data (GDPR);
- In certain circumstances, object to the processing of your personal data (GDPR);
- Request information on the identities or categories of third parties to which your Personal Data are transferred (GDPR);
- Lodge a complaint with the data protection authority in your country (GDPR).

Whom should you contact for more information or for exercising your rights on the processing of personal data by ZRC?
Please direct any questions and requests related to the processing of personal data to PV@az-regulatory.com.