DATA PROCESSING NOTICE
– ON THE PROCESSING OF PERSONAL DATA PROVIDED ON THE ADVERSE EVENT REPORTING PLATFORM–
Effective date: 12.09.2024.

1. Information of the data controller and contact information of the data protection officer

Gedeon Richter Plc. (head office: 1103 Budapest, Gyömrői út 19-21., company registration number: Cg. 01-10-040944, tax number: 10484878-2-44, hereinafter: "***Richter***") hereby informs you, as the reporter via the https://www.gedeonrichter.com/en/contact-us/adverse-event-reporting page (hereinafter: ***"Adverse Event Reporting Platform"***) or as the person affected by the report (hereinafter: ***"Data Subject"*** or ***"You"***), about the processing of your personal data provided on the Adverse Event Reporting Platform.

The contact details of Richter's data protection officer are as follows: email address: dataprotection@richter.hu, postal address: Richter Gedeon Plc., Legal and Intellectual Property Department, Budapest 10, P.O. Box 27, 1475.

2. Basic Information on Data Processing

The purpose of the Adverse Event Reporting Platform is to enable the direct reporting of an Adverse Event/Drug Side Effect (hereinafter collectively referred to as ***"Complaint"***) related to a Richter product to Richter via the Adverse Event Reporting Platform operated by Richter, which is accessible on the Richter corporate website.

Definitions:

"Adverse Event" refers to any unfavorable (clinical, laboratory, or other) change that occurs in a patient's or clinical trial subject's body during the use of a particular drug, regardless of whether there is a causal relationship between the drug and the event.

"Drug Side Effect" or ***"Side Effect"*** refers to the harmful and unintended effect caused by medications. A causal relationship between the drug and the occurrence is presumed.

"EudraVigilance" is the centralized European electronic database for suspected Side Effects of medicines authorized or investigated in clinical trials conducted within the European Economic Area ("EEA").

2.1. The Purposes of Data Processing:

2.1.1. Communication

The email address or phone number of the reporter is used for communication purposes to confirm the submission of the report, clarify the report, and evaluate it.

If it is necessary to clarify the report, Richter will follow up on the Complaint and contact the reporter within a reasonable time at the provided contact details.

2.1.2. Fulfillment of Legal Obligations and Ensuring an Effective Pharmacovigilance System

Richter processes your personal data to fulfill its legal obligations related to Complaints and pharmacovigilance, particularly to comply with the reporting requirements for adverse reactions as mandated by regulations and to operate an effective pharmacovigilance system that supports its business interests as outlined below.

Richter considers a report valid if at least one piece of information is available for both the reporter and the patient, and the complained medicine/substance is identified. Additional information in the description of the Side Effect, which is not mandatory, will be evaluated from a medical/clinical perspective.

The report will be sent to drug regulatory authorities, including the EudraVigilance database, in a manner that does not identify the reporter or the patient. An evaluation based on other information will also be uploaded, indicating whether Richter identified the Complaint as an expected or unexpected event based on current knowledge.

The report will also be sent to Richter's commercial partners and subsidiaries, who distribute the same medicines in different countries under commercial agreements, in a manner that does not identify the reporter or the patient. This is to ensure that these partners can also meet their legal obligations regarding Complaints.

2.2. Legal Bases for Data Processing

The legal basis for data processing is Richter's legitimate interest (Article 6(1)(f) of the GDPR) or, if the report is assessable, Richter's legal obligation (Article 6(1)(c) of the GDPR). The laws serving as the basis for data processing are listed in Section 3 of this notice.

Richter's legitimate interest is to receive and screen reports, maintain records, and forward them to regulatory authorities and partners in accordance with the provisions of the laws listed in Section 3, in order to fulfill the purposes outlined in Section 2.1.2. This enables Richter to operate an effective pharmacovigilance system.

Regarding personal health data, the legal basis for data processing is supplemented by Article 9(2)(i) of the GDPR, as the data processing is necessary in the public interest in the field of public health, such as ensuring the high standards and safety of medicines.

2.3. Processed Data

Richter may process the following personal data about the patient:

- patient's initials (optional),
- date of birth or age (one of these two is mandatory),
- patient's gender (mandatory),
- information provided in the description of the drug Side Effects:
  - date of onset of the Side Effect, description of the Side Effect, circumstances of the Side Effect, patient's medical history, other illnesses (mandatory),
  - duration and outcome of the Side Effect, classification by severity, reason for classification (optional).
- details of the medication treatment:
  - suspected Richter drug (mandatory),
  - information about the drug and treatment, medical history (optional).
- any other information shared by the reporter in the adverse effect report with Richter.

Richter may process the following personal data about the reporter:

- Reporter's name (not mandatory),
- Contact details (email address or phone number) (mandatory),
- Nature of the occupation (doctor/pharmacist/patient/other) (mandatory),
- Country (mandatory).

2.4. Duration of data processing

Richter retains pharmacovigilance-related data for the duration of the marketing authorization of the relevant drug, as well as for an additional ten years after the expiration of the marketing authorization, in accordance with Article 12(2) of Commission Implementing Regulation (EU) No 520/2012, which implements the European Parliament and Council Regulation (EC) No 726/2004 and Directive 2001/83/EC concerning the execution of pharmacovigilance activities (June 19, 2012).

3. Applicable laws and regulations

3.1. Decree 15/2012 (VIII. 22.) EMMI on Pharmacovigilance of Medicinal Products for Human Use

"The marketing authorization holder is obliged to investigate any reports of suspected adverse effects that are received from patients and healthcare professionals electronically or by other means that allow for evaluation."

3.2. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use

"The marketing authorization holder shall be required to record and to report all suspected serious adverse reactions which are brought to his attention by a health care professional immediately to the competent authority of the Member State in whose territory the incident occurred, and in no case later than 15 calendar days following the receipt of the information."
"*The marketing authorization holder shall have permanently and continuously at his disposal an appropriately qualified person responsible for pharmacovigilance."*
"That qualified person shall be responsible for the following: (a) the establishment and maintenance of a system which ensures that information about all suspected adverse reactions which are reported to the personnel of the company, and to medical representatives, is collected and collated in order to be accessible at least at one point within the Community; (b) the preparation for the competent authorities of the reports referred to in Article 104, in such form as may be laid down by those authorities, in accordance with the guidance referred to in Article 106(1); (c) ensuring that any request from the competent authorities for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a medicinal product is answered fully and promptly, including the provision of information about the volume of sales or prescriptions of the medicinal product concerned; (d) the provision to the competent authorities, of any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post-authorization safety studies."

3.3. 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

"*When reporting suspected adverse reactions, Member States and marketing authorisation holders shall provide all available information on each individual case, including the following: (a) administrative information: report type, date and a worldwide unique case identification number as well as unique sender identification and sender type; the date on which the report was first received from the source and the date of receipt of the most recent information, using a precise date; other case identifiers and their sources, as well as references to additional available documents held by the sender of the individual case safety report, where applicable; … (e) information identifying the patient (and parent in the case of a parent-child report), including age at the time of the onset of the first reaction, age group, gestation period when reaction/event was observed in the foetus, weight, height or gender, last menstrual date and/or gestation period at time of exposure; … (j) information on the suspected adverse reaction(s): start date and end date of the suspected adverse reaction(s) or duration, seriousness, outcome of the suspected adverse reaction(s) at the time of last observation, time intervals between suspect medicinal product administration and start of adverse reaction, the original reporter's words or short phrases used to describe the reaction(s) and Member State or third-country of occurrence of the suspected adverse reaction;*"

"*Pharmacovigilance data and documents relating to individual authorised medicinal products shall be retained as long as the product is authorised and for at least 10 years after the marketing authorisation has ceased to exist. However, the documents shall be retained for a longer period where Union law or national law so requires*."

3.4. Guidelines on good pharmacovigilance practices (GVP) Module VI – Collection, management and submission of reports of suspected adverse reactions to medicinal products (Rev 2)

"When information is received directly from a consumer suggesting that an adverse reaction may have occurred, and if the information is incomplete, attempts should be made to follow-up with the consumer to obtain consent to contact a nominated healthcare professional to obtain further information. When the case is subsequently confirmed totally or partially by a healthcare professional, the medical confirmation should be captured in the ICSR in line with ICH-E2B (see VI.A.1.4. for healthcare professionals' definition, and VI.A.1.5. for ICSRs medical confirmation).
For some cases, it may not always be possible to perform follow-up activities taking into account that the reporter information may have been anonymised in accordance with local legal requirements or due to provisions that allow for anonymous reporting (see VI.C.6.2.2.10. for guidance on the processing of personal data in the EU), for example in case of medication error with harm and the reporter does not wish to disclose an identity. These cases should be considered valid for submission as ICSRs, providing that the notified organisation was able to confirm them directly with the primary sources and that the other minimum criteria for reports validation are satisfied (see VI.B.2. for ICSRs validation)."

3.5. Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance, Directive 2001/83/EC on the Community code relating to medicinal products for human use

3.6. Directive2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance

3.7. Regulation (EU) No 1027/2012 of the European Parliament and of the Council of 25 October 2012 amending Regulation (EC) No 726/2004 as regards pharmacovigilance

3.8. Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 amending, as regards pharmacovigilance of medicinal products for human use, Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, and Regulation (EC) No 1394/2007 on advanced therapy medicinal products

4. Source of Personal Data

Richter may receive a Complaint not directly from the patient but from other parties, such as:

- Healthcare professionals (e.g., doctors, nurses, dentists, midwives, physiotherapists, optometrists),
- Third parties (e.g., a patient's family member, legal representative, lawyer, colleague, friend).

In cases where the source of information is not the patient themselves, but the patient can be identified from the report, we will request a statement from the reporter confirming that they have informed the affected person (the individual directly involved in the report) about the contents of this data processing notice and its availability.

5. The Recipients or Categories of Recipients of Personal Data

Richter uses the following data processors for the following tasks:

Name of the Data Processor	Contact details	Scope of activities
ArisGlobal LLC	Corporate-Headquarters: Boston, MA	ArisGlobal LLC-s affiliate ArisGlobal Ltd (Office 500, Digital Office Centre, Balheary Road, Swords, Co. Dublin, Ireland) is a partner providing and support the pharmacovigilance software for Richter. We record and track Complaints in the software provided by

	201 Jones Road, 3rd FL EastWaltham, MA 02451 United States	ArisGlobal. This platform also supports reporting to pharmacovigilance authorities.
Qinecsa Solutions India Private Limited	Headquarters: India Silver Spirit Tech Park, No 317(P) and 318, Hebbal Industrial Area, Hebbal, Kasaba Hobli, Mysore- 570016.	Qinecsa Solutions India Private Limited performs case processing, case management, and reporting activities related to Complaints within the Richter Group using the pharmacovigilance software provided by ArisGlobal.
Gedeon Richter Romania S.A. (Richter Group member)	Headquarters: Romania 540306 Târgu Mureș, 99–105 Cuza Vodă street, Romania	Gedeon Richter Romania S.A. performs case processing, case management, and reporting activities related to Complaints within the Richter Group for certain medicinal products using the pharmacovigilance software provided by ArisGlobal.
Other members of Richter Group	https://www.gedeonrichter.com/hu-hu/richter-csoport	In the case of a complaint made in a language other than English or Hungarian, the report will be sent to a member of the corporate group that speaks the relevant language for further communication purposes, thereby ensuring smooth communication.
Dr. Komáromi Tivadar Bence individual entrepreneur	Hungarian individual entrepreneur registry number: 50078161 Hungary	Dr. Komáromi Tivadar Bence performs case processing (medical-professional analysis, medical evaluation), case management, and reporting activities related to Complaints within the Richter Group using the pharmacovigilance software provided by ArisGlobal.
Dr. Kónya Panka individual entrepreneur	Hungarian individual entrepreneur registry number: 54960808	Dr. Kónya Panka performs case processing (medical-professional analysis, medical evaluation), case management, and reporting activities related to Complaints within the Richter Group using the pharmacovigilance software provided by ArisGlobal.

6. Transfers of Data to Third Countries

Recipient	Country	Appropriate safeguards
ArisGlobal LLC	USA	Richter applies the Standard Contractual Clauses adopted by the European Commission in accordance with Article 46(2)(c) of the GDPR in contracts with data processors. The Commission Implementing Decision (EU) 2021/914 of June 4, 2021, regarding the Standard Contractual Clauses for the transfer of personal data to third countries under Regulation (EU) 2016/679, is available at: https://eur-lex.europa.eu/eli/dec_impl/2021/914/oj For any related questions, you can contact us at dataprotection@richter.hu.
Qinecsa	India	
Members of the Richter Group outside the EEA	https://www.gedeonrichter.com/en/richter-group	

7. Exercisable Data Subject Rights and Remedies

Under Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (hereinafter: "***GDPR***"), you are entitled to exercise the following data subject rights in relation to the personal data handled by Richter concerning the Adverse Event Reporting Platform through a request sent to the email address dataprotection@richter.hu.

Data Subject Right	**Legal Basis**	
	Legitimate interest	**Legal obligation**
Right of access *(Article 15 GDPR)*	Exercisable	Exercisable
Right to rectification *(Article 16. GDPR)*	Exercisable	Exercisable *(in compliance with legal requirements)*
Right to erasure (Right to be forgotten) *(Article 17 GDPR)*	Exercisable	Not exercisable
Right to restriction *(Article 18 GDPR)*	Exercisable	Exercisable *(in compliance with legal requirements)*
Right to data portability *(Article 20 GDPR)*	Not exercisable *(not applicable)*	Not exercisable *(not applicable)*
Right to object *(Article 21 GDPR)*	Exercisable	Not exercisable

The following table provides a detailed explanation of the content of the aforementioned data subject rights.

Data Subject Right	**Content**
Right of access	You are entitled to request information on whether your personal data is being processed and, if so, to gain access to the personal data being processed.
Right to rectification	You have the right to request that we complete any incomplete personal data and correct any inaccurate personal data.
Right to erasure (Right to be forgotten)	You have the right to request the deletion of your personal data if one of the conditions listed in the referenced article of the GDPR is met.
Right to restriction	You have the right to request the restriction of your personal data if one of the conditions listed in the referenced article of the GDPR is met.
Right to data portability	You have the right to receive your personal data concerning you, which you have provided to us, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from us to which the personal data have been provided, if the processing is based on consent or a contractual legal basis and the processing is carried out by automated means. *(Please be informed that the current data processing activities are not based on consent or contractual legal basis, so this right is not applicable to these data processing activities.)*
Right to object	You have the right to object at any time to the processing of your personal data based on Article 6(1)(e) and (f) of the GDPR, including profiling based on these provisions, for reasons related to your particular situation. *(The legal basis for the current data processing activities is our legitimate interest, so you can exercise your right to object in relation to this. Please be informed that we do not carry out profiling based on your personal data.)*

If you believe that Richter has acted unlawfully in the course of data processing, you have the following remedies available:

We recommend and request that before opting for administrative or judicial remedies, you contact Richter's Data Protection Officer at dataprotection@richter.hu. This consultation will allow us to review, assess, and resolve the situation you have observed and provide you with comprehensive information, as we have access to the relevant details regarding data processing.

Remedy	Content
Right to administrative remedy ***(Article 17 GDPR)***	You have the right to lodge a complaint with the Hungarian data protection supervisory authority, the National Authority for Data Protection and Freedom of Information (NAIH), without prejudice to any other administrative or judicial remedy, if you believe that the processing of your personal data violates the GDPR. You can contact the NAIH at the following details: - Mailing address: 1363 Budapest, Pf. 9. - Headquarters: 1055 Budapest, Falk Miksa utca 9-11. - Email: ugyfelszolgalat@naih.hu - Phone numbers: +36 (30) 683-5969; +36 (30) 549-6838; +36 (1) 391 1400 - Fax: +36 (1) 391-1410 - Website: www.naih.hu
Right to judicial remedy ***(Article 79 GDPR)***	You are entitled to effective judicial remedy, without prejudice to any available administrative or non-judicial remedies—including the right to lodge a complaint with a supervisory authority—if you believe that the processing of your personal data in violation of the GDPR has infringed your rights under the GDPR. You may initiate legal proceedings against Richter or the relevant data processor. These proceedings must be brought before the court of the Member State where Richter or the data processor is established. The court will handle the matter with priority. You can choose to file your claim at the court that has jurisdiction based on your place of residence (permanent address), your place of stay (temporary address), or Richter's registered office. You can find the court with jurisdiction based on your residence or place of stay at the following website: http://birosag.hu/ugyfelkapcsolati-portal/birosag-kereso. According to Richter's registered office, the Budapest-Capital Regional Court has jurisdiction over the case.

If you need further information, please contact us at dataprotection@richter.hu.