



RICHTER GEDEON

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PHARMACOVIGILANCE POLICY

Gedeon Richter Plc. (referred to as "**Company**") considers pharmacovigilance and patient safety as an area of outstanding priority, thinks of it as a service, with the **aim** to continuously monitor the benefit-risk balance of our medicinal products and **to ensure all circumstances of effective and safe use of our therapeutic options for the patients and healthcare professionals.**

To achieve this aim, the following principles shall be considered:

- We **comply with all health authority regulations**, and ensure that these highest standards of pharmacovigilance and patient safety shall continuously apply at all part of the Company Group regardless of geographical location.
- We **operate a robust quality system** and have the framework of policies and procedures that enable us to continuously monitor, evaluate and report safety and pharmacovigilance data.
- We pay special attention **to ensure** that any untoward effect occurring in connection with the administration of any products of the Company shall be identified and collected, and the global analyses of the gathered data shall be fed back to contribute to making drug administration even more safe and to preventing occurrence of adverse reactions.
- We **continuously evaluate the benefit-risk** profile of our medicines. We are **committed** to transparency regarding the results of the evaluation of these benefits and risks with patients, healthcare professionals and regulatory authorities.
- We provide **up-to-date information** to patients and healthcare professionals and ensure that all questions raised and all problems occurring during drug administration will be answered and resolved without any delay. For this purpose, we maintain channels of communication and sources of information with 24/7 availability.
- **Each employee of the Company Group is responsible for** reporting of safety information they become aware of to the relevant global and/or local safety responsible. All employees get new entry and yearly refresher pharmacovigilance trainings in order to ensure that a robust surveillance system is in place.

Pharmacovigilance and patient safety is our common responsibility and is our common interest, which provides strong protection to the patient, to the product and to the Company, at the very same time.

Budapest, 3rd March 2023

Gábor Orbán
Chief Executive Officer

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