GEDEON RICHTER

PHARMACOVIGILANCE POLICY

Gedeon Richter Plc. (referred to as "**Company**") considers pharmacovigilance as an area of outstanding priority, thinks of it as a service, with the **aim to be able** to continuously monitor the benefit-risk balance and **to ensure the safe administration of our medicinal products for the patients and healthcare professionals.**

To achieve this aim, we perform our tasks according to the following principles:

- we **comply with all health authority regulations**, and ensure that these highest standards of pharmacovigilance 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 pharmacovigilance data;

- we pay special attention **to ensure** that any adverse event related to the administration of any products of the Company shall be identified and collected, and the global analyses of the gathered data shall contribute to the appropriate drug administration and to the prevention of the occurrence of adverse reactions. The Company's **pharmacovigilance system connects** to the international adverse reaction surveillance networks, alerts and intervenes if a new adverse reaction is identified, or if a change in the safety profile of a product is observed;

- 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 occurred related to drug administration will be answered and resolved without any delay. For this purpose, we maintain communication channels and information sharing surfaces with 24/7 availability.

Each employee of the Company Group is responsible to ensure the collection and reporting of safety information to the Company's Global Pharmacovigilance Department. When necessary, further information is sought from individuals who have reported the potential adverse event, and the data is recorded in a computerised database for ease of retrieval and analysis.

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

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Gábor Orbán
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