**Privacy Notice for the Reporting of Adverse Event**

## 1) General Legal Notice

This data processing notice outlines the rules governing the processing of personal data (including special categories of data, in particular health data) related to the reporting of adverse events associated with medicinal products marketed by MEDINER Gyógyszerkereskedelmi, Marketing és Szolgáltató Korlátolt Felelősségű Társaság (hereinafter: the Data Controller), in its capacity as the marketing authorization holder, as well as provides information regarding such data processing.

The reporting and investigation of adverse events associated with authorized medicinal products is a key activity for ensuring the safe use of medicines. To this end, we kindly request that patients and healthcare professionals report any adverse events observed in connection with medicinal products for which MEDINER Kft. holds the marketing authorization, using one of the following contact points:

**MEDINER Kft.**
H-4025 Debrecen, Miklós u. 16. I./1.
Phone: +36 52 535-708
Email: pv@mediner.hu

**Nemzeti Népegészségügyi és Gyógyszerészeti Központ (NNGYK)**
P.O. Box 450, H-1372 Budapest, Hungary
Website: www.nngyk.gov.hu
Electronic adverse event reporting: https://mellekhatas.nngyk.gov.hu
Email: adr.box@nngyk.gov.hu

**RAD-MED-PHARMA Kft.**
H-1119 Budapest, Andor u. 24. C. Ground floor 7.
Phone: +36 30 921-9216, +36 1 208-0269
Email: radmedpharma@radmedpharma.hu

To avoid duplicate submissions, please send your adverse event report to only **one** of the above addresses.

## 2) Identification of the Data Controller

Name: MEDINER Gyógyszerkereskedelmi, Marketing és Szolgáltató Korlátolt Felelősségű Társaság
Registered seat: H-4025 Debrecen, Miklós Street 16, 1st floor, no. 1
Tax number: 12537288-2-09
Company registration number: 09-09-007544
Electronic contact for pharmacovigilance-related matters (email): info@mediner.hu

## 3) Legal Basis for Data Processing

As the marketing authorization holder, we – MEDINER Gyógyszerkereskedelmi, Marketing és Szolgáltató Kft. – are legally obliged, pursuant to Section 18 of Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Laws Related to the Pharmaceutical Market (hereinafter: Gytv.), and Section 6 of Decree No. 15/2012 (VIII. 22.) of the Ministry of Human Resources (hereinafter: Decree), to investigate all reports of suspected adverse events (both serious and non-serious) received from patients and healthcare professionals, and to submit the relevant data

electronically in accordance with Article 24 of Regulation (EC) No. 726/2004 into the EudraVigilance database (hereinafter: EV Database) operated by the European Medicines Agency.

Please note that submission of data to the EV Database does not necessarily mean that the entirety of your report will be forwarded. If the reporting person is the patient, personally identifiable data required for identification (such as the patient's name and contact information) will not be forwarded to the EV Database. In case of reports submitted by healthcare professionals, the identifying information of the healthcare professional will be forwarded in order to allow follow-up contact, however, the patient's identifying information will still not be transmitted under any circumstance.

In accordance with the above, the data processing is based on Section 6(1)(c) of Regulation (EU) 2016/679 of the European Parliament and of the Council (General Data Protection Regulation – GDPR), and in the case of special categories of personal data (e.g. health data), on Article 9(2)(g) of the GDPR, as it is necessary for compliance with a legal obligation to which MEDINER Kft. is subject, and for reasons of substantial public interest under Hungarian law, as specified in Act CXII of 2011 on the Right of Informational Self-Determination and Freedom of Information (Info Act).

**4) Purpose of Data Processing**

The purpose of the present data processing activity is to fulfil our legal obligations as set out in the Gytv. and the Decree, to investigate all reported suspected adverse events, and to ensure that the adverse event reports — excluding any data that could directly identify the patient — are submitted to the EudraVigilance database.

**5) Categories of Personal Data (Including Special Categories, in Particular Health Data)**

In order to investigate a reported adverse event, the following personal data are required:

- NAME (FOR PATIENTS, INITIALS/MONOGRAM ARE SUFFICIENT)
- CONTACT INFORMATION (TELEPHONE NUMBER AND EMAIL ADDRESS)
- NAME OF THE MEDICINAL PRODUCT SUSPECTED OF CAUSING THE ADVERSE EVENT
- DESCRIPTION OF THE SUSPECTED ADVERSE EVENT

In the course of investigating a reported suspected adverse event, we may also request additional personal data, including but not limited to the following:

- PATIENT'S AGE/YEAR OF BIRTH, SEX, AND THE REFERENCE NUMBER OF THE GENERAL PRACTITIONER, SPECIALIST, OR HOSPITAL
- DETAILS OF THE SUSPECTED MEDICINAL PRODUCT
    - BATCH NUMBER
    - EXPIRY DATE
- DETAILS OF THE SUSPECTED ADVERSE EVENT
    - DATE OF ONSET
    - DATE OF RESOLUTION (IF APPLICABLE)

If the report contains any data that are not necessary for the investigation of the suspected adverse event, such data will be deleted.

All personal data are processed exclusively to the extent required by the applicable legislation, and only to the extent necessary for the investigation and transmission of the adverse event report.

## 6) Data Processing and Data Transfer

On behalf of MEDINER Kft., RAD-MED-PHARMA Kft. acts in matters of pharmacovigilance, including the investigation of adverse events and suspected side effects related to the use of medicinal products. MEDINER Kft. has concluded the necessary contractual agreements with RAD-MED-PHARMA Kft. for the investigation of reported adverse events. RAD-MED-PHARMA Kft. processes any data made available to it solely for the purpose of investigating the reported adverse event. All such reports are forwarded to RAD-MED-PHARMA Kft.

As stated in Section 3 of this Privacy Notice, RAD-MED-PHARMA Kft. then submits the adverse event reports — excluding data that could identify the patient — to the EudraVigilance database.

Where required to do so by a competent supervisory authority, we will transfer personal data to such authority in order to comply with a legal obligation.

To ensure the secure transmission of data received via email, MEDINER Kft. engages the following external IT service provider, which provides only the technical infrastructure and has no access to the content of adverse event reports submitted by email:

- SERVICE PROVIDER NAME: WEBSUPPORT MAGYARORSZÁG KFT.
- REGISTERED ADDRESS: H-1119 BUDAPEST, FEHÉRVÁRI ÚT 97–99.
- COMPANY REGISTRATION NUMBER: 01-09-381419
- PURPOSE: HOSTING SERVICE PROVIDER

## 7) Duration of Data Processing

Adverse event reports are retained for a period of 10 years following the expiry of the marketing authorization for the relevant medicinal product, in accordance with the European Medicines Agency's Guideline on Good Pharmacovigilance Practices (GVP), Module VI and Module I.

We implement appropriate technical, organizational, and personnel measures to ensure the protection of the personal data we process, including against unauthorized access or alteration.

## 8) Data Storage

If the report is submitted in paper form, the data are stored at the registered office of MEDINER Kft. (H-4025 Debrecen, Miklós u. 16. I./1).

If the report is submitted electronically, the data are stored within MEDINER Kft.'s own IT systems, including its email and physical servers, as well as in the secure IT environment operated by its contracted partner, Websupport Magyarország Kft., as referenced in Section 6.
All data storage takes place exclusively within the territory of the European Union.

Access to personal data is granted only to those employees whose job duties require such access.

Please note that our data processing activities comply with all applicable data security requirements and have been designed and are implemented in accordance with our internal data protection policies and the relevant technical and organizational safeguards, with due regard to the protection of your privacy.

## 9) Data Subject Rights and Legal Remedies

If your personal data (including special categories of data) are being processed, you are entitled to exercise a range of rights at any time by submitting a request using the contact details provided in Section 2 of this notice.

Right of Access and Rectification

You have the right to access your personal and special category data at any time, request a copy of such data, and request that the data be corrected or updated if it is inaccurate or incomplete.

Under the right of access, you are entitled to receive information about the following:
a) the purposes of the data processing;
b) the categories of personal data concerned;
c) the recipients or categories of recipients to whom the personal data have been or will be disclosed, in particular recipients in third countries or international organisations;
d) where applicable, the planned retention period for the personal data;
e) your right to request from the Data Controller the rectification, erasure, or restriction of processing of your personal data, and to object to such processing; and
f) your right to lodge a complaint with a supervisory authority.

We understand the importance of these rights; therefore, if you wish to exercise any of them, please contact us using one of the contact methods provided in Section 2 of this notice.

Right to Data Portability

You have the right to data portability with respect to your personal and special category data. This means that your data can be moved, copied, or transmitted electronically.

If you wish to exercise your right to data portability, please contact us using one of the contact methods provided in Section 2 of this notice.

Right to Erasure

You have the right to request the erasure of your personal data where one of the following applies:
a) your personal data are no longer necessary in relation to the purpose(s) for which they were collected; or
b) you withdraw your consent to the processing of your personal data and there is no other legal basis for processing; or
c) you object to the processing of your personal data;
d) your personal data have been processed unlawfully; or
e) the erasure of your personal data is required in order to comply with a legal obligation.

However, the Data Controller is not obliged to fulfil your request for erasure if the processing of your data is necessary for any of the following reasons:
a) for exercising the right of freedom of expression and information;
b) for compliance with a legal obligation which requires processing by Union or Member State law to which the controller is subject, or for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;
c) for reasons of public interest in the area of public health;

d) for archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes, insofar as the erasure of data is likely to render impossible or seriously impair the achievement of the objectives of that processing; or
e) for the establishment, exercise, or defence of legal claims.

Right to Restriction of Processing
You have the right to restrict the processing of your personal and special category data in the following cases:
a) if you believe that the personal data we hold about you are inaccurate; or
b) if the processing is unlawful, but instead of requesting erasure, you prefer to restrict the processing; or
c) if the Data Controller no longer needs the personal data for the original purposes of collection, but you require the data for the establishment, exercise, or defence of legal claims; or
d) if you have objected to the processing of your data and are awaiting verification as to whether your legitimate interests override the legal basis for the processing.

If you wish to request a restriction on the processing of your data, please contact us via one of the methods listed in Section 2.

Right to Object
You have the right to object at any time to the processing of your personal data.
If you wish to exercise this right, please contact us using one of the contact details provided in Section 2 of this notice.

Right to Lodge a Complaint with a Supervisory Authority
You have the right to lodge a complaint at any time with the National Authority for Data Protection and Freedom of Information (Hungarian: Nemzeti Adatvédelmi és Információszabadság Hatóság), as the competent supervisory authority:
Address: H-1055 Budapest, Falk Miksa utca 9–11.
Postal address: H-1363 Budapest, P.O. Box 9
Phone: +36 (1) 391-1400
Email: ugyfelszolgalat@naih.hu

Dated: Debrecen, 3 April 2024