Privacy Policy for reporting adverse reaction

Budapest, 31st May 2024

1) GENERAL LEGAL NOTICE

This Privacy Policy contains the rules on the handling of personal data, including any special (health) data, relating to the reporting of adverse reactions to medicines marketed by PHARMA PATENT Kereskedelmi, Tanácsadó és Szolgáltató Korlátolt Felelősségű Társaság (the "Data Controller"), as well as information on data management related to the reporting of adverse reaction.

As the Data Controller, we are legally obliged to investigate adverse reactions to medicines marketed by our company, so if you report an adverse reaction to us, we must investigate and report it to the European Medicines Agency. However, we will only send an anonymous report to the European Medicines Agency, which will not contain any personal data.

We are kindly inform you that in case you reporting an adverse reaction, it is not mandatory to provide the name of the patient who suffered the adverse reaction. On the other hand, if you provide this information, we, the Data Controller, will also process specific (health) data relating to the patient.

2) DATA CONTROLLER

PHARMA PATENT Kereskedelmi, Tanácsadó és Szolgáltató Korlátolt Felelősségű Társaság (hereinftar referred to as PHARMA PATENT Kft.)
Registered seat: 1132 Budapest, Váci út 36-38. 4. em.
Trade Registry Number: 01-09-419169
VAT number: 11781006-2-41
Email: info@pharmapatent.hu

3) THE LEGAL BASIS OF DATA PROCESSING

We, PHARMA PATENT Kft. are subject to the effective provisions of Article 18 of Act XCV of 2005 on Medicinal Products for Human Use and on the Amendment of Other Regulations Related to Medicinal Products (hereinafter referred to as Gytv.) because of the doctors, pharmacists and marketing authorisation holders are obliged to monitoring and reporting of adverse drug reactions (serious and non-serious). Moreover, the effective provisions of Article 6 of Act 15/2012 (VIII. 22.) EMMI Regulation (hereinafter referred to as Regulation) also stipulates that we are obliged to investigate and electronically submit reports of suspected adverse reactions from patients and healthcare professionals to the EudraVigilance database (hereinafter: EV database) operated by the European Medicines Agency.

We are also kindly inform you that submitting data to the EV database does not imply forwarding your report. The personal (and any special) data contained in the adverse reaction report will be deleted from the document before it is transmitted to the EV database, so that no personal (and special) data will be transmitted to the European Medicines Agency.

The processing of data on the basis of the above is governed by Act CXII of 2011 on the Right to Informational Self-Determination and Freedom of Information (hereinafter referred to as Info tv.) and Article 6 (1) c) paragraph (i.e. necessary for compliance with a legal obligation) of the Regulation (EU) 2016/679 of the European Parliament and of the Council of April 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 referred to as GDPR). To comply with the effective Hungarian

law and legal obligation applicable to PHARMA PATENT Kft. under Article 9 (g) of the GDPR, if the patient's name as special (health) data also comes to our knowledge and the processing is necessary for reasons of substantial public interest.

The data provided in the adverse reaction report are therefore processed in accordance with Hungarian law, including the provisions of the Gytv. and the Regulation.

4) THE PURPOSE OF DATA PROCESSING

The purpose of this data processing is to comply with our obligations under the Gytv. and the Regulation, moreover to investigate all reported suspected adverse reactions.

5) SCOPE OF PERSONAL AND SPECIAL (HEALTH) DATA

In order to investigate an adverse reaction, we process the following personal and special data:

- name, address and contact details of the notifier (telephone number, email address), relationship to the person who suffered the adverse reaction (relative, professional qualification in case of a health professional)
- name/monogram, age/year of birth and sex of the person who suffered adverse reaction, reference number of the family doctor, specialist or hospital. Entering the name is not required!
- the medicinal product concerned by the adverse reaction
    - name,
    - the effectiveness of the medicine,
    - if applicable, the manufacturing number or the name of the active substance(s),
    - dose and frequency of dosage,
    - circumstances in which the event occurred and how it was handled,
    - other information considered relevant to the case.

6) DATA PROCESSING AND DATA TRANSFER

We, PHARMA PATENT Kft. have entered into a contract with RADAYDRUG Szolgáltató, Tanácsadó és Innovációs Korlátolt Felelősségű (registered seat: 4225 Debrecen, Rózsavölgy utca 151.; Trade Registry Number: 09-09-008329; tax number: 12726914-2-09; hereinafter referred to as RADAYDRUG Kft.) in order to fulfil our obligations under the Gytv. and the Regulation.

RADAYDRUG Kft. keep in contact with you as the notifier, informing you of the outcome of the investigation and monitor your condition, if necessary due to the nature of the adverse reaction. Furthermore, RADAYDRUG Kft. forwards the adverse reaction report to the relevant authorities - in a version free of personal (and sensitive) data - and keeps in contact with them.

We, PHARMA PATENT Kft. will record and store the data you provide as described in Section 8 and will forward the adverse reaction report to RADAYDRUG Kft., as the data processor. Please note that the adverse reaction report will be transmitted to RADAYDRUG Kft. as notified, so that it will contain all the data you have provided.

We have entered into a data processing agreement with RADYDRUG Kft. as the data processor and the data processing is designed and implemented in accordance with the technical and organisational measures set out in our internal data protection policy, in compliance with data security requirements and with your privacy in mind.

As stated in this Privacy Policy, personal data relating to the notifier and the name of the patient will not be transferred to the EV database. In compliance with our legal obligation, the adverse reaction report is submitted to this database in an anonymised form, for statistical evaluation and possible action.

7) DURATION OF DATA PROCESSING

The notification will be kept for 10 years from the expiry of the marketing authorisation of the medicinal product (based on the EMA - European Medicines Agency Guideline on good pharmacovigilance practices (GVP) Module VI and Module I).

We will delete your data immediately after the retention period has expired.

8) DATA STORAGE

We, PHARMA PATENT Kft. store the data on a server located at our registered seat at 1132 Budapest, Váci út 36-38, 4th floor.

The RADAYDRUG Kft. stores the data on a server located at it's registered place of business at 4032 Debrecen, Nagy Lajos király tér 1-5. 4. em. 62. ajtó.

Access to certain personal and special data is only granted to those employees who have the necessary access to the data for their job, but these employees may only access the data to the extent necessary.

No other service is used to store personal data. We will take appropriate IT, technical and personnel measures to ensure that the personal data we process is protected against, inter alia, unauthorised access or unauthorised alteration.

9) CONCERNED PERSONS'S RIGHT AND REMEDIES

You have a number of rights in relation to the processing of your personal data, including sensitive data, which you can exercise at any time by sending a request to us at the contact details set out in Section 2.

<u>Right of access and rectification of personal data</u>

You have the right to access, request a copy of, correct or update your personal data at any time.

Under the right of access, you are entitled to receive information about:
a) the purposes of the processing;
b) the categories of personal data concerned;
c) the recipients or categories of recipients to whom or which the personal data have been or will be disclosed, including in particular recipients in third countries or international organisations;
d) the envisaged period of storage of the personal data if applicable;
e) és the right of the concerned person to obtain rectification from the controller, erasure or restriction of the processing of personal data relating to him or her and to object to the processing of such personal data; and
f) the right to lodge a complaint with any supervisory authority.

We understand the importance of the above, so if you wish to exercise these rights, please contact us using one of the contact details set out in Section 2.

<u>Right to data portability</u>

Your personal data is portable. This means that it can be moved, copied or transmitted electronically. However, this right only applies where:
a) The processing is based on your consent;
b) The processing is carried out in the performance of a contract;
c) The processing is carried out in an automated way.

We understand the importance of the above, so if you wish to exercise these rights, please contact us using one of the contact details set out in Section 2.

Right to erasure of personal data
You have the right to request the erasure of your data if
a) your personal data is no longer necessary for the purpose(s) for which it was collected; or
b) you withdraw your previous consent to the processing of your personal data and there is no other legal basis for the processing; or
c) objects to the processing of your personal data;
d) the processing of personal data is not lawful; or
e) the erasure of your personal data is justified on grounds of compliance with the law.

However, the Data Controller is not obliged to comply with your request if the processing is necessary:

a) for the exercise of the right to freedom of expression and information;
b) a személyes adatok kezelését előíró, az adatkezelőre alkalmazandó uniós vagy tagállami jog szerinti kötelezettség teljesítése, illetve közérdekből vagy az adatkezelőre ruházott közhatalmi jogosítvány gyakorlása keretében végzett feladat végrehajtása céljából;
c) on grounds of public interest in the field of public health;
d) for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, where deletion of the data would be likely to render impossible or seriously impair such processing; or
e) for the establishment, exercise or defence of legal claims.

If you wish to exercise these rights, please contact us using one of the contact details set out in Section 2.

Right to restrict processing
You may restrict the processing of your personal data if.
a) you believe that the personal data held about you is inaccurate; or
b) the processing of personal data is not lawful but you would prefer to restrict the processing of your personal data rather than request its erasure; or
c) your personal data is no longer necessary for the purpose(s) for which it was originally collected but you need it for the purpose of bringing or pursuing a legal claim or defending against a claim; or
d) you have objected to the processing of your personal data and are awaiting confirmation as to whether your interests in objecting override the legal basis for the processing.

We understand the importance of the above, so if you wish to exercise these rights, please contact us using one of the contact details set out in Section 2.

Right to object

You can object to the processing of your personal data at any time. If you wish to do so, please contact us using one of the contact details set out in Section 2.

Right of recourse to 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 (address: 1055 Budapest, Falk Miksa utca 9-11; postal address: 1363 Budapest, PO Box 9; telephone number: +36 (1) 391-1400; email address: ugyfelszolgalat@naih.hu) as supervisory authority, and you also have the right to take legal action.