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PRIVACY STATEMENT FOR PHARMACOVIGILANCE - REPORTING ON ADVERSE REACTIONS TO MEDICINAL PRODUCTS
of the limited liability company "LMP"

General information

1. The purpose of this privacy statement (hereinafter referred to as the Statement) shall be to provide information, in accordance with Articles 12 and 13 of the General Data Protection Regulation[1] (hereinafter referred to as the GDPR), on the processing of personal data of reporters of adverse reactions to medicinal products conducted by limited liability company "LMP", registration No. 40103046409 (hereinafter referred to as the Company) (concerning activities related to information regarding identified or identifiable individuals), which shall be performed upon the receipt of reports from patients, their representatives or healthcare professionals regarding adverse reactions to medicinal products of the Company (hereinafter referred to as the Report).
2. The Company highly values the personal data protection requirements and provides information by issuing this Statement in order to ensure the possibility for the Reporter of adverse reactions to medicinal products to understand what, why and in what way is done with the personal data by ensuring the monitoring (pharmacovigilance) of the use of medicinal products by the Company in accordance with the procedures specified in the regulatory enactments.
3. The terms "controller", "processor", "personal data", "processing", "data subject" used in the Statement shall be used as defined in Article 4 of the GDPR.

Controller – the party responsible for data processing

4. Controller: limited liability company "LMP", registration No. 40103046409 (Company). Contact details of the Controller regarding matters related to personal data protection:
    4.1. Registered office: Vietalvas street 1, Riga, LV-1009;
    4.2. E-mail address: zane@lmp.lv, info@lmp.lv;
    4.3. Phone No. +371 67040788.

Data subjects whose personal data are processed and the source of personal data

5. The Company shall receive personal data when the Report is submitted to it. The Report may be submitted to the Company by the patient himself or herself, or by his or her representative or by a healthcare professional.
6. The Report shall always contain personal data of the patient. The Patient's Report may include personal data of a healthcare professional. Consequently, the Company may, upon receipt of the Report, obtain personal data relating to the various data subjects, including:
    6.1. patient;
    6.2. patient's representative (for example, parent, advocate);
    6.3. healthcare professional.
7. If the Report is submitted by a patient's representative, that person shall be fully responsible and shall ensure that he or she has the right to submit the personal data of the patient in accordance with the GDPR, including the right to allow the Company to contact the patient's doctor on behalf of the patient (for example, the representative is the legal representative of the patient who is a minor – the parent, or the representative is a sworn advocate who is acting on the basis of the

[1]REGULATION (EU) 2016/679 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April2016 on the protection of individuals with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation)

patient's authorization), and the representative shall be responsible for providing the patient with the information contained in the Statement.

Types of personal data processed

8. The following personal data of patients can be obtained and processed by the Company:
    8.1. The initials or given name, surname of the patient;
    8.2. Contact details – telephone number, e-mail address;
    8.3. Information on sex, age, weight;
    8.4. Information on medicinal products used;
    8.5. Information on the diagnosis that led to the use of the medicinal product;
    8.6. Information on adverse reactions caused by the medicinal product;
    8.7. Other information on the health of the patient related to adverse reactions to medicinal products;
    8.8. Information about the healthcare professional and his or her relationship with the patient;
    8.9. Information about the representative and its relationship with the patient.
9. The Company may obtain and otherwise process the following personal data of a healthcare professional and the representative of the patient:
    9.1. Given name, surname;
    9.2. Contact details – telephone number, e-mail address;
    9.3. Information on professional activity;
    9.4. Information about the relationship with the patient.
10. The Company mostly processes pseudonymised or anonymised data, but the submission of personal data, by including the data in the Report, shall be necessary to enable the Company to obtain additional information on the situation described in the Report, if necessary, and to enable the Company to determine whether several Reports relate to the same case or to a number of cases of adverse reactions caused by the medicinal product. We invite to provide only the information indicated in the Report form by following the instructions specified in the Report form.

Purpose and justification for the processing of personal data

11. The Company shall process personal data in order to comply with the obligations of the Company specified in regulatory enactments within the framework of public health protection measures – in order to obtain, collect, analyse and take into account information regarding the observed adverse reactions to medicinal products. This information will help to reduce and eliminate the potential risks associated with the use of the medicinal products, and it will contribute to the safe use of the medicinal products.
12. The duties previously specified by the Company are derived from the following regulatory enactments – Pharmaceutical Law, Cabinet Regulation No.47 of 22 January 2013, Pharmacovigilance Procedures, Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.
13. The Company shall assess the report, analyse the information contained in it, contact the Reporter if necessary, within the framework of conducting the aforementioned obligations, or, if the patient has given authorisation, contact the patient's doctor for additional information. The information contained in the report may be provided by the Company to "EudraVigilance", the European database of adverse drug reaction reports and/or to the competent national authorities, but no personal data contained in the Reports shall be submitted – the data shall be submitted in an anonymised manner in order to make it impossible to identify a natural person neither directly nor indirectly.

14. Consequently, the justification for the processing of personal data stems from Article 6(1)(c) and Article 9(2)(g) and (i) of the GDPR. Personal data shall not be used for the purposes of automated individual decision-making within the meaning of Article 22 of the GDPR.

Personal data recipient

15. The Company shall be entitled to transfer personal data to its data processor: it shall not be a third party, but a merchant or individual processing the personal data in the name of the Company and on its behalf on the basis of specific instructions provided by the Company and under the supervision of the Company. The processor shall be bound by the obligation to ensure the security of personal data and shall be entitled to use the personal data only for the purposes of the specific activities and purposes specified by the Company. For example, the Company may use the data processor in order to ensure the storage of personal data.
16. Upon receiving a permission from the patient, the Company shall be entitled to contact the patient's doctor in order to obtain additional information. In this way, the Company may provide the personal data contained in the Report to the patient's doctor to the extent necessary for obtaining the necessary additional information and for fulfilling the obligations laid down in the aforementioned regulatory enactments.
17. In cases specified in regulatory enactments, the Company may have an obligation to transfer personal data to an institution that performs supervision of the activities of the Company, such as the State Agency of Medicines of the Republic of Latvia or the European Medicines Agency, or which has the need for the information that is at the disposal of the Company for the carrying out of its duties.

Duration of storage of personal data

18. The Company shall store the personal data in accordance with the GDPR for as long as necessary for achieving a legitimate purpose. Personal data shall be deleted, anonymized or destroyed after the legitimate purpose has been achieved.
19. In conformity with the requirements of regulatory enactments, the Company shall keep the Reports and the information related to the examination thereof for 10 years after the end of the validity of the sales authorisation of the specific medicinal products to which the Report applies.

Rights of the data subject – patient, patient's representative, healthcare Professional

20. The data subject shall have the following rights:
    - 20.1. Requesting a copy of the Statement, additional information, explanations on the information contained in the Statement, and the processing of personal data conducted by the Company;
    - 20.2. Requiring confirmation from the Company regarding whether or not any personal data is processed in respect of the data subject;
    - 20.3. Requiring the Company to provide access to their personal data;
    - 20.4. Objecting to the processing of personal data by the Company, to require the Company to rectify, delete, restrict the processing of personal data;
21. These rights of the data subject are regulated in more detail in Articles 12 to 21 of the GDPR. These rights are not absolute, and their enforcement may be limited, for example, the Company shall be entitled to refuse the cessation of the processing of personal data if the Company refers to compelling legitimate or regulatory grounds for the processing that are more important than the interests, rights and freedoms of the data subject.
22. In order to exercise his or her rights, the data subject shall have the right to send an application to the Company by sending it to an e-mail address: zane@lmp.lv / info@lmp.lv or by sending a letter to the address: Vietalvas street 1, Riga, LV-1009, addressing it to the limited liability company "LMP".

23. The activities of the Company with regard to the protection of personal data shall be monitored by the Data State Inspectorate. In order to resolve any disagreement or questions as soon as possible, we encourage the data subject to first contact the Company in accordance with Paragraph 22 of the Statement. The data subject shall also have the right to lodge a complaint with the Data State Inspectorate (address: Elijas street 17, Riga, LV-1050, e-mail: info@dvi.gov.lv; telephone No. +371 67223131, website address**:** **www.dvi.gov.lv).**