Privacy Policy for Pharmacovigilance

The Privacy Policy for Pharmacovigilance herein shall be applied and be valid in conjunction with the provisions of the General Privacy Policy (further referred to as: 'General Policy') effective from 25th May, 2018 as published on the website (please click on the link: here).

Pharmacovigilance is a crucial public health activity performed to promote safety in the use of medicinal products. It involves the ongoing monitoring of the benefit/risk balance throughout the entire life cycle of medicinal products to identify and evaluate any changes to that benefit/risk balance and take necessary measures where appropriate to reduce and/or prevent those risks as well as to maximise the benefits resulting from the use of those medicinal products. Furthermore, its objective is to perform positive risk management activity to identify unknown or unclear risks associated with the use of medicinal products and to investigate these through the active collection of information so that they can be avoided or efficiently remedied in a timely manner.

Human BioPlazma Kft. as the Controller shall process, and in particular, collect personal data provided as well as collect and transfer information on the safety of its medicines in accordance with Article 18 of Act XCV of 2005 on medicinal products for human use and amending other acts regulating the pharmaceutical market and in line with legal obligations. Information on the safety of medicinal products shall be forwarded exclusively in an anonymous way. We do not disclose or share your personal data with any unknown organization that cannot be identified even as third party.

The Privacy Policy for Pharmacovigilance herein – in conjunction with the provisions of the General Privacy Policy – describes how the Company is managing personal data made available for the Company by visitors of the Website as well as by natural persons filling in and submitting the form(s) available on the Website as provided for in Regulation (EU) 2016/679 of the European Parliament and the Council of 27 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 (General Data Protection Regulation; further referred to as: 'EU Data Protection Regulation') and in Act CXII of 2011 on informational self-determination and freedom of information (further referred to as: 'Information Act'), in accordance with national and international legislation on pharmacovigilance.

I. Basic terms according to legislation on pharmacovigilance

pharmacovigilance: activity monitoring the benefit/risk balance of medicinal products to ensure safety, targeted at the reduction of risks and maximising benefits

adverse reaction: reaction to a medicinal product which is untoward and unintended; untoward and unintended reaction resulting from use within the terms of the marketing authorisation, untoward and unintended reaction resulting from

use out of the terms of the marketing authorisation as well as such reactions resulting from medication errors shall constitute adverse reaction

unexpected adverse reaction: an adverse reaction, the nature, severity or outcome of which is not consistent with the adverse reactions listed by the applicable summary of the product characteristics

serious adverse reaction: any adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect

information on the safety of medicines: adverse event, adverse reaction, use during pregnancy or breastfeeding, overdose, use beyond indication, transfer of infectious agent, inefficiency, abuse of medicine, improper use, medication error, exposure by profession

II. Purposes of processing and categories of personal data

The Controller shall process and use personal data electronically in accordance with purposes below:

Purpose of processing / Legal basis for processing / Scope of personal data / Period of processing / Persons entitled to acquaint themselves with personal data

II/1. Communication related to the management of the report on adverse reaction or other information on the safety of medicinal products

The consent of data subject [Article 6(1)(a) of EU Data Protection Regulation].

- full name of reporter or data subject;
- address of reporter or data subject;
- e-mail address of reporter or data subject;
- phone number of reporter or data subject;
- fax number of reporter or data subject

Until the withdrawal of consent and at the latest 30 (thirty) years (Act XLVII of 1997) or throughout the authorised marketing of the medicinal product, as well as 10 (ten) years after the date of withdrawal from the market.

Personal data can be accessed exclusively by authorised employees of the Controller

II/2. Evaluation and transfer of the report on adverse reaction or other information on the safety of medicinal products

Compliance with a legal obligation (based on Article 6(1)(c) of EU Data Protection Regulation and Article 18(1) of Act XCV of 2005)

- date of birth or age of reporter or data subject
- gender of reporter or data subject;
- start of experiencing adverse reaction;
- end of experiencing adverse reaction;

- detailed description of the adverse reaction (including the results of examination important from the aspect of adverse reaction and the description of the treatment of the adverse reaction);
- classification of the adverse reaction according to severity;
- data of the medicinal product believed to cause the adverse reaction (name and pharmaceutical form of the medicinal product or active substance, serial number, dosage and the method of administration, start and end of treatment, indication);
- data of the medicinal products administered in parallel (name and pharmaceutical form of the medicinal product or active substance, serial number, dosage and the method of administration, start and end of treatment, indication);
- medical history;
- other information on the safety of medicines: (use during pregnancy or breastfeeding, overdose, use beyond indication, transfer of infectious agent, inefficiency, abuse of medicine, improper use, medication error, exposure by profession),

30 (thirty) years (Act XLVII of 1997) or throughout the authorised marketing of the medicinal product, as well as 10 (ten) years after the date of withdrawal from the market

Personal data can be accessed exclusively by authorised employees of the Controller

If further personal data are necessary for duly fulfilling legislative obligations and properly managing the report, our authorised staff members may contact you.

If the data subject does not give consent with regard to processing for the purpose of communication it shall mean that the report relating to pharmacovigilance cannot be submitted electronically (online).

III. Data transfer

No personal data are transferred since the information on the safety of medicinal products shall be forwarded exclusively in an anonymous way.

AMENDING THE PRIVACY POLICY

The Privacy Policy for Pharmacovigilance herein can unilaterally be amended as necessary, in particular in case of legal or organisational changes. Any amendment to the Privacy Policy will be made available for the visitors of the Website.

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The Privacy Policy for Pharmacovigilance herein is based on the General Privacy Policy (please click on the link: here).

For issues not addressed or mentioned by the Privacy Policy herein, the provisions of the General Privacy Policy shall apply, in particular in terms of detailed information on the Controller (Chapter I), data safety measures (Chapter IV), provisions for the

Controller (Chapter V), rights of data subjects (Chapter VII) and legal remedies (Chapter VIII).

For data processing in accordance with purposes defined in the Privacy Policy herein, the technical provisions of the General Privacy Policy in terms of visiting the website (Chapter IX, e.g. information on cookies) shall also apply.