PERSONAL DATA PROTECTION POLICY

IN RELATION TO PHARMACOVIGILANCE

Last updated: 23.05.2018

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1. What is Pharmacovigilance?

Pharmacovigilance, as defined by the World Health Organization, is: "Science and activities related to the detection, evaluation, understanding and prevention of adverse events and any other drug-related problem".

Pharmacovigilance is governed by a system for monitoring and evaluating the safety of Medicinal Products in order to minimize the risk and improve the therapeutic effects of their use. In order to achieve this, it is necessary, inter alia, to record the adverse reactions of medicinal products, to report them to the competent authorities and to evaluate them.

ELPEN procedures are in place to ensure that:

• The sources of information are systematically checked

• The necessary actions take place in the event of new information

• Competent authorities, healthcare professionals and patients are informed about any changes in the product characteristics

2. Definitions

For the purposes of this Privacy Policy:

"Personal Data": means any information relating to an identified or identifiable natural person (the "data subject"); an identifiable natural person is one whose identity can be ascertained, directly or indirectly, in particular by reference to an identifier such as a name, an identity number, location data, an online identity identifier, or one or more factors specific to physical, viral, genetic, mental, economic, cultural or social identity of that individual.

“Special categories of personal data” : means personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs or membership of a trade union, as well as the processing of genetic data, biometric data for the undeniable identification of a person , data relating to health or data relating to the sexual life of a natural person or sexual orientation.

“Health data”: means personal data relating to the physical or mental health of a natural person, including the provision of healthcare services, which reveal information about his / her state of health.

"Processing": means any act or set of operations carried out with or without the use of automated means in personal data or in sets of personal data such as the collection, registration, organization, structuring, storage, adaptation or change, retrieval, retrieval of information, use, disclosure by transmission, dissemination or any other form of disposal, association or combination, restriction, erasure or destruction.

“Controller”: means a natural or legal person, a public authority, a service or another body which, alone or jointly with others, defines the purposes and the manner in which personal data are processed; where the purpose and method of processing are determined by Union law or the law of a Member State, the controller or the specific criteria for his appointment may be provided for by Union law or the law of a Member State.

"Processing manager": means a natural or legal person, a public authority, a service or another entity that processes personal data on behalf of the controller.

“Data protection officer”: means the natural person designated by the controller and the processor for the reasons provided for by law, on the basis of his professional qualifications and his expertise in the field of data protection law and practices, with a primary duty to participate in all issues related to the protection of personal data.

"Consent" of the data subject: any indication of will, free, specific, explicit and in full knowledge, by which the data subject expresses agreement with a declaration or with a clear positive action to process the personal data they concern it.

"Undesirable effects" means any undesirable, unintentional or detrimental event related to or as a result of the use of a medicinal product of ELPEN

3. Responsible for the processing of personal data relating to Pharmacovigilance:

ELPEN CO INC, 95 Marathonos Avenue, 190 09, Pikermi,

Greece Phone: +30 211 1865 000,

Email: info@elpen.gr , Website: www.elpen.gr

4. Scope of this Policy

This Privacy Policy relating to Pharmacovigilance describes how ELPEN collects and processes personal data in order to fulfil its Pharmacovigilance Obligations i.e. Its obligation to monitor the safety of all products that ELPEN markets or of those for which clinical studies are conducted and ELPEN markets as its own products as well as products of cooperation on the Greek market and abroad.

This Privacy Policy applies to the information that ELPEN collects from you by phone, fax and email, following your own communication with the company, through its

social media and website. If you are a patient, we may be able to tell you about side effects that affected you during the intake of an ELPEN product and by a third person, such as health professionals, relatives, lawyers or others.

5. Purpose of collecting and processing personal data on Pharmacovigilance

Thank you for reporting any side effects or other Pharmacovigilance related information in relation to a product of ELPEN. Your report is very important for public health. Ensuring patient safety and safe use of our medicines is extremely important for ELPEN.

ELPEN needs to be able to communicate with people who have reported about the products.

The information requested when submitting your report to the company is necessary in order to allow further communication from the Pharmacovigilance Department for the purpose of receiving additional information from you, monitoring your case, answering your questions. At the same time, the data of the recipient of the drugs is necessary to avoid multiple recording of the same incident in the database of ELPEN

All information you provide under this update of ELPEN are strictly confidential and are intended for use exclusively by the competent health professionals / scientists of ELPEN with a view to meeting its pharmacovigilance obligations. We will use and / or disclose your personal data solely for the purposes of Pharmacovigilance

6. Personal data collected in the context of your Pharmacovigilance referral

ELPEN collects your personal data either directly from you following your referral to our company or through a third person following our referral to our company about the adverse effects of one of our products that have affected you.

Given the great importance of Pharmacovigilance, when reporting, please provide as much information as possible, including information on the description of the adverse reaction, the start and end dates of the treatment, the time of the occurrence of the adverse reaction, the medical history your co-administration of other medicines, etc.

The personal data you will need to disclose to our company include "health data", and may include other data belonging to "special categories of personal data" in accordance with applicable law. Particular care is taken for these data, which are disclosed to us and processed, according to all legal formalities.

In particular, the personal data we may collect for you as long as you are a patient - recipient of the product that caused the side effects is:

• Name or first name of your name

• Contact details

• Age and date of birth

• Your gender

• Your weight and height

• Details of the product that caused the side effects, such as the dose you received, the prescription and / or prescription ratio.

• The starting and ending dates of the treatment

• The date (s) for the occurrence of the side effects

• Details (such as dose, prescription ratio, treatment time, etc.) regarding other medicines or medicinal products that have been given at the same time and received at the time of the occurrence of side effects

• Your medical history

• Your history of taking medication and pharmaceuticals

• Other information about the incident and the occurrence of the adverse reaction.

Furthermore, under the legal obligations of ELPEN, Pharmacovigilance and the purposes of collecting and processing your personal data as described above may be collected from the patient receiving the product as well as from the petitioner if it is a third person and not the recipient's own patient the following information:

• Your name

• Your contact details including postal address, e-mail, telephone, fax

• Your profession

• Your relationship to the patient the product.

7. Managing your Pharmacovigilance Report

All reports collected in the above manner are processed by pseudonymization from the Pharmacovigilance Department of ELPEN, both with respect to the data of the petitioner and patient details. The relevant personal data are in principle only communicated to the Pharmacovigilance Department of ELPEN and, under certain conditions, to third parties, as described below.

Our company has developed and implemented detailed internal procedures (SOPs) for the proper and timely recording of adverse drug reactions and medical complaints and medical issues related to its products, the proper and safe maintenance and storage of this information, and their appropriate promotion to competent bodies and third parties.

In particular, the procedure followed by ELPEN in the case of a reference submitted to our company through the methods detailed below, is as follows:

1. The necessary information is received by the Pharmacopoeia Department of ELPEN for the completion of the petition form. If a representative of the company other than the Pharmacovigilance Department may receive the information, it shall immediately forward it to the Pharmacovigilance Department of ELPEN
2. Each of the reported cases of adverse reactions is recorded and evaluated by the specialist personnel of the company.
3. Each report shall be stored and maintained on paper in a special locked, watertight and flame retardant cabinet of the Pharmacovigilance Department and, on the other hand, after being digitized in company databases.
4. The necessary decisions are made for any further action or appropriate case-by-case promotion of the petition.

8. Processing your personal data in the context of Pharmacovigilance

In response to its legal obligations of Pharmacovigilance, ELPEN processes your personal data in order to investigate and evaluate the unwanted effects reported by you or for you relating r its products. In this context, the company may:

• Re-contact you for any further necessary information

• Collect, register, organize, structure and store your personal data as foreseen in its internal procedures

• Process your personal data submitted to referencing or combining them with other relevant reports submitted for the same product or for the same undesirable effects

• providing and promoting the necessary information to the competent operators and / or third parties

Your personal data collected by our company in accordance with the procedure detailed below and this Privacy Policy may also be communicated to third parties, especially other pharmaceutical companies with which it cooperates, if the adverse reaction report concerns a from the products that ELPEN trades in its cooperation with these companies. In this case, additional information can be provided on the companies to which the data is transmitted. The processing of your personal data by these companies - partners of ELPEN shall take place in accordance with their respective Personal Data Protection Policies on Pharmacovigilance and their respective Agreements.

In addition, the relevant information is also communicated to the competent national and regional authorities and bodies in line with existing pharmacovigilance legislation. ELPEN cannot guarantee the processing of your personal data by these Authorities and bodies. Subject to the anonymity of the petitioner and the patient, our company may disclose information about the reported adverse reactions for medical, public safety and / or other reasons.

9. Pharmacovigilance reporting period

Your personal data is kept in a record for as long as it is required under current pharmacovigilance legislation.

As patient safety is very important to us and your reports of any undesirable effects of our products are valuable for public health reasons, we do not destroy all the data and information we collect from you in the framework of Pharmacovigilance, in order to ensure that we are in a position to evaluate the safety over time a of our products

10. Security of your personal data on Pharmacovigilance

ELPEN shall take all necessary measures to protect your personal data and protect it from accidental loss and unauthorized access, use, modification or disclosure.

Particularly stringent safety measures shall be taken for any information and personal data communicated to us under Pharmacovigilance, with particular care for collection, storage and handling at all stages of this procedure.

In particular, the information and pharmacovigilance data relating to personal data provided to ELPEN stored and maintained on company servers databases, accessible

to a limited number of its specialized employees. In addition, each of your written forms of your reports, filled in by an authorized employee of our company, when the above information are provided by you or for you either in writing via fax or e-mail or the social media or the company's website, or verbally by phone, is stored in a special locked, waterproof and flame retardant cabinet in the Pharmacovigilance Department of ELPEN.

11. Your rights regarding the processing of your personal data under Pharmacovigilance

ELPEN protects your personal data that processes according to the update legislation and in full compliance with the General European Regulation on the protection of personal data (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of personal data processed in accordance with applicable law and in full compliance with the General European Regulation on Data Protection of natural persons with regard to the processing of personal data).

Your rights regarding the use and processing of your personal data are fully respected, with the only limitation the right of the company to lawfully process it if it is necessary to comply with its legal obligations of Pharmacovigilance.

At your request, you can ask from ELPEN to inform you of what personal data we collect and maintain and for what purposes, as well as to provide you with a copy of this information.

In justified cases, you may also ask the company to correct or restrict the processing of your personal data. You may also retain the right to object to their processing, without prejudice to the legitimate obligations of ELPEN, which require their processing.

If you have any questions about how we process your personal data under Pharmacovigilance and in order to exercise these rights, you can contact the Pharmacovigilance Department of ELPEN as well as with our Company's Privacy Policy, in the contact details provided below.

In addition, if you have exercised some or all of your rights and you continue to keep your concerns about our policy regarding the processing of your personal data, you may, in any case, contact and file a complaint with the competent supervisory authority, in this case, the Personal Data Protection Authority (ADAP):

Personal Data Protection Authority:

Kifissias 1-3 ZIP

Code 115 23, Athens

Telephone Center: 210 6475600

Fax: 210 6475628

Email: contact@dpa.gr

12. Modification of this policy

ELPEN reserves the right to modify and / or update this Privacy Policy at any time. Please review regularly the published Privacy Policy regarding our Pharmacovigilance. In the event of material changes to this, a relevant publication will take place on the company's website and the "update date" of this Policy will be modified accordingly. You may also be informed by other means via e-mail or other communications provided by you to ELPEN.

13. Submit a Report on Pharmacovigilance Adverse Reactions

To submit your report on any side effects you may have experienced when you receive ELPEN products, you can contact our company directly through:

- Telephone: 210.60.39.326
- Fax: 210.60.39.300
- Email: pharmacovigilance@elpen.gr

For more information, please refer to the following link on ELPEN's website: https://www.elpen.gr/article/373/egkritikes-ypotheseis-farmakoepagrypnhsh

It is recalled that adverse reactions may, according to the national spontaneous reporting system, be reported alternatively to the National Drug Agency (EOF) in the Adverse Event Section by submitting the Yellow Card in the following ways:

- Electronic submission of the Yellow Card through the online form available on the EOF website at the following link: https://kitrinikarta.eof.gr/
- Sending the Yellow Card in hard copy by post, free of charge, to the Department of Adverse Events of the EOF (Mesogeion 284, Cholargos, 15562). Contact number: 213.20.40.380 or 213.20.40.337

• Submit the Yellow Card by fax at 210.6549.585

For more information, please refer to the following link on the EOF website: http://www.eof.gr/web/guest/yellowgeneral

14. Communication

For any question about Pharmacovigilance, Privacy Policy and Privacy Policy regarding the Pharmacovigilance of ELPEN, you can contact our company directly: ELPEN PHARMACEUTICAL CO INC, 95, Marathonos Avenue, PC 190 09, Pikermi, Attiki.

For Pharmacovigilance

Tel: 210.60.39.326

Fax: 210.60.39.300

Email: pharmacovigilance@elpen.gr

For personal data protection issues

Tel: 2111865000 (e-mail: 200)

Email: dpo@elpen.gr