

## **DATA PROTECTION NOTICE**

### **MEDICAL INFORMATION & DRUG SAFETY SERVICE (Pharmacovigilance)**

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PHARMATHEN S.A. (hereafter, the "Company" or "us") is committed to complying with all applicable laws and good practices governing its operation while providing high quality services.

The protection of your personal data is a priority for us. Learn more about how the Company processes your personal data in the context of the Medical Information and Drug Safety Service (pharmacovigilance) by reading the following notice.

#### **1. What is the Medical Information and Drug Safety Service (Pharmacovigilance)**

The Medical Information and Drug Safety Service has a dual task: on one hand, it provides information to the public on pharmaceuticals products and, on the other hand, it documents events related to the safe use of these products and reports on adverse events.

The disclosure of data in the context of the Medical Information and Drug Safety Service is performed on a voluntary basis by users of said service and with the purpose of protecting public health and, in particular, ensuring the quality and safety of such products.

#### **1. Which data categories do we process**

The Company collects and retains the data required by the specific legislation governing the operation of the Medical Information and Drug Safety Service, as well as any other information you choose to disclose to us acting under the capacity of either a reporter or a patient. In particular, the following indicative data categories may be collected and processed, in case you chose to voluntarily disclose it to us:

- The name and surname of the individual requesting information or reporting adverse events (reporter);
- Patient's identification data (initials, gender, date of birth, weight, height, country of residence)
- Contact details of the individual requesting information or reporting adverse events (telephone number, area/city, email, capacity)
- Health data (disease, adverse events, medication, medical tests results, medical history, concomitant medication, use of alcohol or narcotic substances, smoking, pregnancy, allergy, metabolism disorder, surgery etc.)
- A summary of other substantial data disclosed during our communication

#### **2. Why we process your data**

We process your data to provide you with the best possible service and to communicate efficiently with you, exclusively for the following purposes:

<b>Purpose</b>	<b>Description</b>
Provision of Medical Information	We process the data you give us to respond to enquiries and/or complaints and provide you with the information you request. Data collected in this context, including your name and surname, is transmitted to the marketing authorization holder.
Drug Safety Service	When there are reasons of public interest in the field of public health, such as ensuring high standards of quality and safety of medicines, we will provide your data to the competent authorities and/or the marketing authorization holder. The data collected in the context of the Drug Safety Service (pharmacovigilance) are transmitted to the competent authorities in a pseudonymised or anonymised format, in accordance with applicable legislation. When we collect data on behalf of the marketing authorization holders, we normally transmit such data to them, in the way provided by applicable legislation and based on the contract signed between us, taking into consideration any monitoring requirements.
Monitoring	We may use your data in order to contact you and/or your doctor in order to monitor the adverse event at question.
Scientific research purposes	If you participate in clinical trials, your data is processed for the purpose of conducting the clinical trial. The data collected by the investigators is transmitted in a pseudonymized format to us, acting under the capacity of a sponsor of the clinical trial and to the competent authorities. When we act on behalf of the sponsor of the clinical trial or when there are multiple sponsors to a clinical trial, the data collected by the investigators is transmitted pseudonymized to us and to those sponsors.
Legal Obligation	We will collect and retain your data to the extent that is required by law and specific regulations and/or good practices governing the operation of the Medical Information and Drug Safety Service.
Legal Claims	We will retain and process your data to the extent necessary to establish, exercise or defend legal claims against the Company and/or the marketing authorization holder.

### **3. Who receives and processes your data**

Your data may be accessed by our duly authorized employees and, when required by law or regulation, by the marketing authorization holder or the sponsor of the clinical trial (per case), the competent authorities and third-party auditors who audit our internal procedures. When the marketing authorization holder or the sponsor of the clinical trial is established outside the European Economic Area (EEA), we will transmit your data to them and to the competent regulatory authorities ensuring that appropriate safeguards apply and implementing pseudonymization or anonymization procedures, where possible. Deviations from the obligation of applying appropriate safeguards may be only justified when the transmission is necessary for important reasons of public interest.

#### **4. For how long we retain your data**

When the Company is the marketing authorization holder, your data is retained for as long as the product is authorized and for 10 years after the marketing authorization has ceased to be effective, unless a longer retention period is required based on EU or national law.

When we collect data on behalf of the marketing authorization holder or the sponsor of the clinical trial, we will retain your data for the duration of our cooperation with these parties. We will transmit your data to the marketing authorization holder or the sponsor of the clinical trial upon termination of our cooperation and delete it from our records, unless otherwise provided by EU or national law or our contract with them. The maximum retention period of your data, for Pharmacovigilance purposes, pursuant to the applicable legal framework, is 10 years after the expiration of the marketing authorization issued for the medicinal product. Data collected is kept in hard copies and in digital format, with safety, at the Company's premises.

#### **5. Your rights**

Our company ensures your rights with respect to data processing and facilitates any exercise of such rights.

You have the right to request:

- Access to your personal data and information regarding which of your data we process, the purposes of processing, the recipients and the duration of processing.
- The rectification of your personal data if it is inaccurate or incomplete.
- The deletion of your personal data or transmission to third parties, unless their processing is necessary for the exercise of the legal rights of the Company or of third parties, for the fulfillment of a legal obligation, for public interest reasons or for defending our legal rights before judicial or other Authorities.
- The restriction of the processing of your personal data, only for specific purposes.
- The portability of your data, namely, to receive the data you have provided in a structured, commonly used format, or ask us to send it to a third party designated by you.
- To withdraw your consent for the processing of your personal data at any time, when processing is based on consent.

If you have any request or questions regarding the present notice, you may send us an email or written request using the below contact details. If you wish to exercise any of your above

described rights, we advise you to ask us for a Data Subject Request Form which you can then submit using our contact details.

**PHARMATHEN S.A.**

Email: [dpo@pharmathen.com](mailto:dpo@pharmathen.com)

Tel: +30210 6604300 (1374)

Address: ATT: DPO, 44, Kifissias Avenue,151 25, Marousi, Athens-Greece

Finally, if you believe that your data protection rights have been violated, you have the right to lodge a complaint with the Hellenic Data Protection Authority ([www.dpa.gr](http://www.dpa.gr)).

The present Notice updates and supersedes previous versions. We may change this Notice at any time. The “LAST UPDATED” section at the bottom of this page lists when this Notice was last revised. Any changes to this Notice will become effective when we make the revised Notice available on or through our website.

LAST UPDATED: 25/05/2018