**GEN İLAÇ VE SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.**

**CLARIFICATION TEXT ON THE PHARMACOVIGILANCE ACTIVITIES**

This Clarification Text on the Pharmacovigilance Activities ("Clarification Text") has been prepared by **Gen İlaç ve Sağlık Ürünleri Sanayi ve Ticaret A.Ş.** ("Our Company" or "Company") as the data controller within the scope of Article 10 of the Law on the Protection of Personal Data No. 6698 ("**Law**") and the Communiqué on the Procedures and Principles to be Followed in the Fulfillment of the Disclosure Obligation, and is intended to provide information about the data controller and the data controller representative, the method of collecting personal data and the legal reason for informing the personal data owner and to enlighten himself about the rights of the personal data owner against the data controller within the scope of Article 11 of the Law.

## 1. INFORMATION ABOUT THE CONTROLLER AND THE DATA CONTROLLER REPRESENTATIVE

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|---|---|
| **Data Controller:** | Gen İlaç ve Sağlık Ürünleri Sanayi ve Ticaret A.Ş. |
| **Address:** | Mustafa Kemal Mah. 2119.Sok. No:3 D: 2-3<br>06520 Çankaya / Ankara Türkiye |
| **Phone:** | +90 312 219 62 19 |
| **Website:** | www.genilac.com.tr |
| **Data Controller Representative:** | Binnur MUTLU |

## 2. THE PURPOSES OF PROCESSING YOUR PERSONAL DATA AND PROCESSED PERSONAL DATA

Pharmaceutical companies are required to perform activities related to the detection, evaluation, identification and prevention of adverse reactions (side effects) and other potential problems related to medicinal products.

As a result of these activities called pharmacovigilance, it becomes possible to monitor drug safety and protect public health by taking certain measures at national or international level when necessary.

When an adverse reaction (side effect) report is received by our Company, there needs to be an "identifiable patient" and an "identifiable reporter" in order to fulfill pharmacovigilance requirements and some personal data needs to be collected for this purpose.

All personal data received by our Company regarding adverse reactions and other pharmacovigilance activities are used only for pharmacovigilance activities and for the



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info@genilac.com • genilac.com.tr

purposes specified in this Clarification Text. Your personal data are collected and processed in compliance with the Law and relevant regulations. We kindly ask you not to disclose any personal data other than the personal data required for adverse reaction (side effect) reporting to our Company.

In this context, we process the following personal data for an "**identifiable reporter**" during our pharmacovigilance activities:

| PERSONAL DATA SUPER-CATEGORY | PERSONAL DATA PROCESSED | PURPOSE OF PROCESSING PERSONAL DATA | LEGAL GROUNDS FOR DATA PROCESSING |
|---|---|---|---|
| **Identity Information** | Name and surname of the reporter | - Fulfillment of pharmacovigilance requirements stipulated under the relevant legislation, including monitoring drug safety, evaluation, detection and prevention of adverse reactions (side effects)<br><br>- Opening records of suspected adverse reactions, adverse reactions and serious adverse reactions and making the relevant notifications stipulated in the legislation<br><br>- Performing activities to detect, evaluate, identify and prevent other potential problems related to medicinal products<br><br>- Managing calls to our Company, answering your questions | Data processing being mandatory for the data controller to fulfill their legal obligation (5/2(ç))<br><br>Data processing is required for legitimate interests of the data subject without prejudice to the fundamental rights and freedoms of the data subject (5/2(f)) |



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| | | -Archiving and record keeping | |
| **Contact Information** | Phone number, address, e-mail address of the reporter | - Fulfillment of pharmacovigilance requirements stipulated under the relevant legislation, including monitoring drug safety, evaluation, detection and prevention of adverse reactions (side effects)<br><br>- Opening records of suspected adverse reactions, adverse reactions and serious adverse reactions and making the relevant notifications stipulated in the legislation<br><br>- Performing activities to detect, evaluate, identify and prevent other potential problems related to medicinal products<br><br>- Managing calls to our Company, answering your questions<br><br>-Archiving and record keeping | Data processing being mandatory for the data controller to fulfill their legal obligation (5/2(ç))<br><br>Data processing is required for legitimate interests of the data subject without prejudice to the fundamental rights and freedoms of the data subject (5/2(f)) |
| **Professional Experience and Education (in case the reporter is a healthcare professional)** | Occupation, institution and department of the reporter | - Fulfillment of pharmacovigilance requirements stipulated under the relevant legislation, including monitoring drug safety, evaluation, detection and prevention of | Data processing being mandatory for the data controller to fulfill their legal obligation (5/2(ç)) |



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| | | adverse reactions (side effects)<br><br>- Opening records of suspected adverse reactions, adverse reactions and serious adverse reactions and making the relevant notifications stipulated in the legislation<br><br>- Performing activities to detect, evaluate, identify and prevent other potential problems related to medicinal products<br><br>- Managing calls to our Company, answering your questions<br><br>-Archiving and record keeping | Data processing is required for legitimate interests of the data subject without prejudice to the fundamental rights and freedoms of the data subject (5/2(f)) |

We process the following personal data for an "**identifiable patient**" during our pharmacovigilance activities. During the processing of adverse reactions for pharmacovigilance purposes, we may need to collect additional personal data relating to the medical history and health of the person experiencing the adverse reaction, if necessary.

| PERSONAL DATA SUPER-CATEGORY | PERSONAL DATA PROCESSED | PURPOSE OF PROCESSING PERSONAL DATA | LEGAL GROUNDS FOR DATA PROCESSING |
|---|---|---|---|
| **Identity Information** | Initials of the patient's first and last name, gender, patient's age/age group | - Fulfillment of pharmacovigilance requirements stipulated under the relevant legislation, including monitoring drug safety, evaluation, detection and | Data processing being mandatory for the data controller to fulfill their legal obligation (5/2(ç)) |



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|---|---|---|---|
| | | prevention of adverse reactions (side effects)<br>- Opening records of suspected adverse reactions, adverse reactions and serious adverse reactions and making the relevant notifications stipulated in the legislation<br>- Performing activities to detect, evaluate, identify and prevent other potential problems related to medicinal products<br>-Archiving and record keeping | Data processing is required for legitimate interests of the data subject without prejudice to the fundamental rights and freedoms of the data subject (5/2(f)) |
| **Health Data** | Patient's weight/height, medical history, drugs used, current medical condition, pregnancy information | - Fulfillment of pharmacovigilance requirements stipulated under the relevant legislation, including monitoring drug safety, evaluation, detection and prevention of adverse reactions (side effects)<br>- Opening records of suspected adverse reactions, adverse reactions and serious adverse reactions and making the relevant notifications stipulated in the legislation<br>- Performing activities to detect, evaluate, identify and prevent other potential problems related to medicinal products<br>-Archiving and record keeping | Data processing is necessary for the protection of public health, preventive medicine, medical diagnosis, treatment and care services, and for the planning, management and financing of health-care services by persons subject to legal obligation of confidentiality or by competent public institutions and organizations pursuant to Article 6/3(e) of the Law |



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## 3. TRANSFER AND PURPOSE OF TRANSFERRING YOUR PERSONAL DATA

Your personal data and the information you provide will be used to fulfill our legal obligations stipulated in the legislation for the monitoring of drug safety and may be transferred to the Turkish Ministry of Health, Turkish Medicines and Medical Devices Agency. These data may also be anonymized and entered into the database of the World Health Organization within the scope of the Drug Monitoring and Cooperation Program.

Our Company may transfer the personal data you provide to us when necessary to its employees, business partners, licensors, shareholders, suppliers, service providers (especially call centers, electronic messaging intermediary service providers), group companies and affiliates located in the country or abroad for processing in the global pharmacovigilance database and fulfilling the requirements of pharmacovigilance legislation, may share the adverse reaction report with legally authorized institutions and organizations and legally authorized private legal entities, other pharmaceutical and medical device companies if the adverse reaction report is related to one of their products, and healthcare professionals involved in the adverse reaction report.

Our company is also required to report some pharmacovigilance data to other health authorities in Europe and around the world, including countries with varying levels of data protection. However, while these reports contain detailed information about the incident, they contain a limited amount of personal data.

> **Patients:** Information including age or date/year of birth, gender, patient initials (Patient name is not explicitly reported).
> **Reporter:** Information such as name, occupation, initials of first and last name, address, e-mail, phone number provided for the organization to trace the reporting person.

Your personal data may be transferred to judicial authorities or relevant law enforcement agencies upon demand in order to resolve legal disputes, to be used as evidence and/or in accordance with the relevant legislation/legal obligation.

Your personal data may also be transferred abroad in accordance with Articles 8 and 9 of the Law if the servers of the data storage and backup systems of our Company's business partners or service providers are located abroad.

## 4. METHOD OF AND LEGAL RATIONALE FOR COLLECTING YOUR PERSONAL DATA

Your personal data are collected by automatic or non-automatic methods, from the information and documents you provide to us through phone calls you make with us via our call center or e-mails you send to our drugsafety@genilac.com e-mail address dedicated to adverse reaction reports, from the person experiencing the adverse event or his/her relative or healthcare professional, in paper or electronic media.



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Our social media accounts and websites are not an appropriate means of communication for your adverse reaction (side effect) reports. If you would like to report an adverse reaction (side effect), you may report side effects by contacting your healthcare professional, your local health authority or by filling out the TÜFAM Adverse Reaction Reporting Form and sending it to drugsafety@genilac.com e-mail address or by contacting us at +90 312 219 62 19.

Your data related to pharmacovigilance is processed for the purposes of protection of public health and preventive medicine as set out in the third paragraph of Article 6 of the Law and on the basis of this article; your personal data is processed within the scope of "it is necessary for the data controller to fulfill its legal obligation" in subparagraph (ç) of the second paragraph of Article 5 of the Law and "data processing is necessary for the legitimate interests of the data controller, provided that it does not harm the fundamental rights and freedoms of the data subject" in subparagraph (f).

## 5. STORAGE OF YOUR PERSONAL DATA

Our Company shall store your personal data for

- the period stipulated in the relevant legislation,
- the period necessary for the purpose for which they are processed, or
- the period required based on the reason that the Company can establish, exercise and defend

its right in a possible dispute specified in Article 5/2 (e) of the Law.

In this context, since information related to pharmacovigilance (adverse event reports) is important for public health, as stipulated in the relevant legislation, we shall keep pharmacovigilance data and documents related to medicinal products for at least 10 (ten) years as long as the marketing authorization of the medicinal product exists and after the withdrawal of the medicinal product from the market in the last country where it was marketed. If this period expires and our Company no longer has any legal reason to process your personal data, your personal data shall be destroyed immediately.

## 6. YOUR RIGHTS REGARDING YOUR PERSONAL DATA

As a personal data owner, you have the following rights in accordance with Article 11 of the Law:

i. Find out whether your personal data has been processed,

ii. Request information if your personal data has been processed,
iii. Find out the purpose of processing the personal data and whether it has been used in line with its purpose,

iv. Be informed about third parties to whom your personal data has been transferred domestically or abroad,



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v. Make a request for correction in the event that your personal data has been processed deficiently or inaccurately, and request that the transaction made within this scope is notified to third parties to whom the data has been transferred,

vi. If the reasons that require processing of the data are eliminated even though the data has been processed in accordance with the provisions of the Law numbered 6698 and other relevant laws; request deletion or destruction of your personal data and request that the transaction made within this scope is notified to third parties to whom the data has been transferred,

vii. You may object to an outcome resulting against you by analyzing your processed data exclusively via automatic systems, and

viii. Request indemnification if you suffer damages due to processing of the personal data in violation of the applicable law.

However, in accordance with the obligations of pharmacovigilance legislation, our Company may not delete or restrict the processing of data processed for pharmacovigilance.

You can always apply to us regarding your rights in Article 11 of the Law and mentioned above in relation to your personal data. You can send your requests regarding these rights to Mustafa Kemal Mah. 2119. Sok. No: 3 D: 2-3 06520 Çankaya Ankara in writing or by e-mail to kvkk@genilac.com.

Depending on the nature of your request, your applications will be concluded free of charge as soon as possible and within thirty (30) days at the latest; however, if the transaction requires an additional cost, you may be charged a fee according to the tariff to be determined by the Personal Data Protection Board.

**Data Controller**

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**Phone:** +90 312 219 62 19

**E-mail:** kvkk@genilac.com



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