

CLARIFICATION TEXT ON THE PROCESSING OF PHARMACOVIGILANCE DATA

As **Avixa İlaç San. A.Ş.**, we give utmost care to the security and confidentiality of your personal data obtained within the scope of pharmacovigilance activities.

With the awareness of this responsibility, we process your personal data in the capacity of **Data Controller** within the scope of the Personal Data Protection Law No. 6698 ("Law") and the relevant legislation within the framework stated below.

1. Collection and Processing Purposes of Personal Data

Pharmacovigilance activities aim to monitor the safety of drugs during use, to carry out activities related to the detection, evaluation and prevention of adverse reactions (side effects) and to protect public health. As a result of these activities called pharmacovigilance, it becomes possible to monitor drug safety and to protect public health by taking some measures at national or international level when necessary. The personal data that may be processed in this context are as follows:

- **Initials of the patient's name and surname:** Identity verification and follow-up of notifications,
- **Age/age group and/or date of birth:** Evaluation of demographic data,
- **Gender:** Evaluation of adverse reactions in terms of population characteristics,
- **Weight and height:** Analysis of dose-dependent effects,
- **Medical history:** Determination of risk factors for drug use,
- **Drugs used:** Drug-specific evaluation of adverse reactions,
- **Current medical condition** (e.g. test results): Medical evaluation of adverse reactions,
- **Name and contact details of the reporter:** Contact if additional information is needed.

These data are processed in order to establish an effective pharmacovigilance system, to identify and evaluate possible risks and to take precautions when necessary.

2. Legal Reasons for Collecting Personal Data

Your personal data is collected and processed in all kinds of verbal, written, visual or electronic media in order to carry out all kinds of work related to the above-mentioned purposes and Avixa's pharmacovigilance activities within the legal framework and to fully and properly fulfill Avixa's contractual and legal obligations in this context.

Your general personal data is expressly stipulated in the law, Avixa's legal It is collected and processed on the basis of the processing conditions, which are mandatory for the fulfillment of its obligations and the fact that the processing is mandatory for the legitimate interests of

Avixa. The legislation on the subject is listed below:

- Regulation No. 28973 on the Safety of Drugs
- Good Pharmacovigilance Practice Guideline Module 1 - Management and Notification of Adverse Drug Reactions
- Medical Device Regulation No. 31499
- Law No. 6698 on the Protection of Personal Data

- **Guideline on the Protection of Personal Data in Pharmacovigilance Activities**

Pharmacovigilance data, which is considered as sensitive personal data, is processed by persons subject to the obligation of confidentiality for pharmacovigilance purposes and can be processed without seeking the explicit consent of the person concerned within the scope of public health protection and preventive medicine activities in accordance with the third paragraph of Article 6 of the Law No. 6698.

3. Transfer of Personal Data

Your personal data can only be shared with the following parties within the framework of the personal data processing conditions, legal requirements and regulations specified in Articles 8 and 9 of the KVKK:

Personal data is shared by Avixa with group companies, subsidiaries and subsidiaries located at home and abroad in order to ensure the centralization of systems and in line with mandatory legitimate interests, provided that rights and freedoms are not harmed due to the presence of servers abroad.

- Personal data is transferred to the Turkish Medicines and Medical Devices Agency in order to make the necessary notifications to the Turkish Medicines and Medical Devices Agency of the Ministry of Health in accordance with the legislation.
- In order to fulfill the obligations to provide information and documents to the authorized public institutions and organizations and judicial authorities and to exercise legal rights such as litigation and reply rights, the requested information is transferred to the relevant institutions and organizations.
- For the purpose of conducting market research, personal data is shared with market research companies.
- If the person concerned consents to be contacted, personal data is shared with electronic message intermediary service providers by taking the necessary security measures for the protection of personal data in order to ensure communication.

In the transfer processes of your data, the security is ensured by taking technical and administrative measures.

4. Measures Taken to Ensure the Security of Personal Data of Data Owners

In line with the importance that our Company attaches to the protection of personal data and ensuring data security, in accordance with Article 12 of the Law, data to ensure its safety,

- To prevent unlawful processing of personal data,
- To prevent unlawful access to personal data,
- To ensure the protection of personal data, and
- To ensure the appropriate level of security for the purpose of all kinds of technical and administrative measures are taken

5. RETENTION

Since information on pharmacovigilance (adverse event reports) is important for public health, reports should be kept for a minimum of 10 years after the drug is withdrawn from the market in the last country where it was marketed.

6. Rights of Data Subjects

Your personal data is protected by technical and administrative measures in its physical and electronic archives by **Avixa İlaç San. A.Ş.**

As the Personal Data Owner, we inform you that you have the following rights in accordance with Article 11 of the Law:

- To learn whether your personal data is processed or not,
- If your personal data has been processed, requesting information about it,
- To learn the purpose of processing your personal data and whether they are used in accordance with their purpose,
 - To know the third parties to whom your personal data is transferred at home or abroad,
- Requesting correction of your personal data in case of incomplete or incorrect processing and requesting notification of the transaction made within this scope to third parties to whom your personal data has been transferred,
- Requesting the deletion or destruction of personal data in the event that the reasons requiring its processing disappear, although it has been processed in accordance with the Law and other relevant provisions of the law, and requesting notification of the transaction made within this scope to the third parties to whom your personal data has been transferred,
- Objecting to this in the event that a result arises against you by analyzing the processed data exclusively through automated systems,
- Requesting the compensation of the damage in case you suffer damage due to the unlawful processing of your personal data.

However, in accordance with pharmacovigilance legislation, it may not be possible to delete or restrict processed data in all cases.

Your applications can be made by sending an e-mail to gizlilik@avixa.com.tr. Applications are finalized within 30 days at the latest. If the transaction requires an additional cost, a fee may be charged according to the tariff determined by the Personal Data Protection Board.

Avixa İlaç San. A.Ş. undertakes to take all necessary measures to ensure that your personal data is processed in accordance with the principles of security and transparency.