

NOTICE ON PERSONAL DATA PROCESSING REGARDING PHARMACOVIGILANCE/VIGILANCE AND COMPLAINTS ABOUT PRODUCT OR SERVICE QUALITY

1. INTRODUCTION

The company UNI-CHEM DOO BEOGRAD, with its registered office at Crnotravska 27, Belgrade - Savski Venac, Company Registration Number: 17167677, Tax Identification Number (TIN): 100052572 (hereinafter referred to as: **UNI-CHEM**), is committed to protecting personal data as the Controller of such data.

In accordance with the above, this Notice on Personal Data Processing regarding pharmacovigilance/vigilance and complaints about product or service quality aims to protect your personal data as well as special categories of personal data related to health status in cases where:

- We receive a report related to an adverse drug reaction or an adverse reaction to a medical device from our product range;
- We receive a complaint about product or service quality.

2. CONTACT INFORMATION OF THE CONTROLLER

In accordance with the Personal Data Protection Law, the controller is a natural or legal person who, independently or jointly with others, determines the purpose and manner of personal data processing, while the processor is a natural or legal person who processes personal data on behalf of the controller.

DATA CONTROLLER:

Business name: UNI-CHEM DOO BEOGRAD
Seat: Crnotravska br. 27, Belgrade - Savski Venac
Company Registration Number:17167677
TIN:100052572
Web-site: <https://www.uni-chem.rs/>
E-mail: zastitapodataka@uni-chem.rs

3. PHARMACOVIGILANCE AND VIGILANCE

Pharmacovigilance is a set of activities related to the collection, detection, assessment, understanding, and prevention of adverse drug reactions, as well as other drug-related issues. An adverse drug reaction (ADR) is any harmful and unintended response to a drug that occurs when used at normal doses in humans (for treatment, disease prevention, diagnosis, recovery, improvement, or modification of physiological functions) or at any dose during a clinical trial.

Medical device vigilance is a set of activities ensuring the collection, assessment, understanding, and response to information about risks arising from the use or application of a medical device, particularly regarding the reporting of incidents to improve and protect the health and safety of patients, users, and others. If necessary, it also includes providing information to reduce the likelihood of incident recurrence elsewhere or to mitigate its consequences.

An adverse reaction to a medical device refers to any harmful effect, interaction with other substances or products, contraindications, misuse, reduced effectiveness, malfunction, or technical defect related to the use of a medical device.

The goal of pharmacovigilance and vigilance is to improve and protect the health and safety of patients and others by reducing the likelihood of adverse reactions recurring.

The data we collect due to adverse reactions to a drug or medical device may be obtained from:

- The patient using the drug and/or medical device;
- The healthcare professional reporting the event;
- Third parties.

If we receive any information regarding an adverse event/adverse reaction to a drug related to our products, pharmacovigilance/vigilance regulations require us to collect case information and process it according to the established pharmacovigilance/vigilance procedure. Accordingly, once the data is provided to us, we are legally obligated to process it.

We emphasize that we are required to always process and register the contact details (name, surname, and other contact information) of the person submitting the report of an adverse event/adverse reaction to a drug.

Given the possible sources of information mentioned above, we do not always obtain personal data directly from the individual whose data is being processed (i.e., the person directly affected by the adverse event or requesting medical information about a medical product).

Informing the individual whose data is being processed is one of the fundamental principles of privacy protection. This obligation exists even when the personal data was not provided by the individual themselves. However, in some cases, we may not be able to contact the individual whose data is being processed and provide them with information about the processing after receiving their personal data from the data provider.

In cases where the source of the information (i.e., the data provider) is not the same as the individual whose data is being processed, we recommend and encourage the report submitter to provide the contact details of the affected individual. If this is not possible, we ask the report submitter to inform the affected individual about the existence and availability of this Data Processing Notice and the contact details of the Data Controller. It is advisable to provide a link to this Data Processing Notice or at least direct them to its content or location where it can be found.

Purposes for which we process personal data	Legal basis for personal data processing	Which personal data we may process	How long the collected data is retained
<ul style="list-style-type: none"> - processing and handling of the received report; - fulfilment of obligations prescribed by relevant laws 	<p>The processing of personal data is necessary for compliance with the legal obligations of the Controller,</p>	<p>Personal data that we may process are as follows:</p> <p>If you are a patient:</p> <ul style="list-style-type: none"> - initials; - date of birth; - age; - sex; 	<p>UNI-CHEM processes and stores pharmacovigilance/vigilance data as long as there is a marketing authorization for the product.</p>

<p>and other regulations;</p> <ul style="list-style-type: none"> - reporting an adverse reaction to a drug or other medical device in accordance with relevant regulations; - collecting necessary information related to the adverse effect of a drug or medical device; - in order to provide a response to the submitted inquiry. 	<p>for the performance of tasks in the public interest, or for the execution of Controller's legally prescribed authorities.</p>	<ul style="list-style-type: none"> - weight; - data and details about the therapy or medication(s) you are currently using or have used in the past; - information about health, including medical history and current health condition. <p>If you are a health workers:</p> <ul style="list-style-type: none"> - name; - specialty; - institution of employment; - address; - phone number; - email address. <p>If you are the data provider:</p> <ul style="list-style-type: none"> - name; - email address; - phone number; - address. 	<p>Given that patient safety is important, all the information we collect about you as part of the reports on adverse reactions to medicines/medical devices is kept so that we can properly assess the safety of the product over time. The data is stored for a minimum of 10 years from the date of receiving the report.</p> <p>For the processing of personal data for an additional 10-year period after the marketing authorization expires, UNI-CHEM will pseudonymize personal data and apply technical and organizational measures to ensure that personal data cannot be linked to an identified or identifiable individual.</p>
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4. METHODS OF REPORTING INFORMATION ON ADVERSE DRUG REACTIONS OR ADVERSE EFFECTS OF MEDICAL DEVICES

You can provide UNI-CHEM with information and necessary data related to adverse drug reactions or adverse effects of medical devices, as follows:

- in person;
- via email (electronic mail): info@uni-chem.rs or med-info@uni-chem.rs
- by phone: 011/3282-986
- through the website: <https://www.uni-chem.rs/>
- by mail to the address: UNI-CHEM, Crnotravska 27, 11000 Belgrade

5. DISCLOSURE AND TRANSFER OF DATA

To fulfil obligations in the area of pharmacovigilance/vigilance, we may share your data with the relevant regulatory authorities and with international partners with whom we have concluded Safety Data Exchange Agreements (SDEA) or other agreements that govern the activities related to pharmacovigilance/vigilance.

6. ACTIONS THAT UNI-CHEM PERFORMS WITH INFORMATION ABOUT ADVERSE DRUG REACTIONS/ADVERSE MEDICAL DEVICE REACTIONS

- Registering the report of adverse drug reactions/adverse reactions to medical devices;
- Processing the report of adverse drug reactions/adverse reactions to medical devices;
- Assessing the adverse drug reactions/adverse reactions to medical devices;
- Acting in accordance with the procedure in case of a report of adverse drug reactions/adverse reactions to medical devices;
- Sharing data with relevant regulatory authorities and international partners.

7. PRODUCT AND SERVICE QUALITY COMPLAINTS

Complaints about the quality of products or services may be received from:

- Patients using our drug and/or medical device;
- Healthcare professionals;
- Third parties.

If you wish to file a complaint about a product or service that does not relate to pharmacovigilance/vigilance, the personal data we will process are as follows:

Purposes for which we process personal data	Legal basis for personal data processing	Which personal data we may process	How long the collected data is retained
The purpose for which we process your personal data in the case of a product or service complaint is to process and handle your complaint	The legal basis for processing is your consent. You can withdraw your consent at any time. In the event of consent withdrawal, the withdrawal will not apply to data processed before the withdrawal.	Your contact details: <ul style="list-style-type: none">- name;- email address;- phone number;- address;- data contained in your message/report.	The data will be stored for a maximum of 10 years.

8. METHODS FOR FILING COMPLAINTS TO PRODUCT OR SERVICE

A complaint to product or service can be filed as follows:

- in person;
- via email (electronic mail): info@uni-chem.rs or med-info@uni-chem.rs
- by phone: 011/3281-205
- through the website: <https://www.uni-chem.rs/>
- by mail to the address: UNI-CHEM, Crnotravska 27, 11000 Belgrade

9. ACTIONS THAT UNI-CHEM PERFORMS WITH PRODUCT OR SERVICE COMPLAINT INFORMATION

- Registering the complaint;
- Processing the complaint;
- Assessing the complaint;
- Acting on the complaint.

10. SHARING DATA OF A COMPLAINANT IN REGARDS TO PRODUCT OR SERVICE

- sharing information with employees within UNI-CHEM who need the information to process the complaint;
- with entities affiliated with UNI-CHEM for providing specific services (e.g., lawyers);
- with national regulatory authorities (if necessary);
- with manufacturers and suppliers of the drug or medical device related to the complaint.

11. PERSONAL DATA PROTECTION

In order to protect the personal data being processed, we take all necessary technical and security measures in accordance with applicable regulations, including limiting access to data only to authorized persons, encrypting data where applicable, implementing protective systems to prevent unauthorized access, and following procedures to respond in case of security incidents.

12. WHAT ARE YOUR RIGHTS AND HOW TO EXERCISE THEM?

In relation to the processing of personal data, you have the following rights:

- the right to be informed about the processing of personal data, i.e., the right to request and receive additional information related to the processing of your personal data,
- the right to access, i.e., the right to view the personal data we process about you,
- the right to receive a copy of the personal data we process about you,
- the right to request correction, supplementation, and updating of the personal data we process about you,
- the right to request the deletion of your personal data,
- the right to restrict the processing of your personal data,
- the right to object,
- the right to portability of your personal data, which means your right to receive the data you have previously provided to us in a structured, commonly used, and electronically readable format, as well as to transfer this data to another person or request that the Data Controller directly provide this data to another person.

We would like to point out that some rights may be restricted in accordance with the relevant regulations of the Republic of Serbia in the field of personal data protection, particularly to the extent that the restriction of your rights is necessary to protect the rights and freedoms of others, or to ensure compliance with a legal obligation of the Data Controller that requires data processing, as well as the submission, exercise, or defense of a legal claim, and in cases where the processing is carried out for scientific or historical research purposes, as well as for statistical purposes.

To exercise the above rights, we may ask you to provide additional information necessary to verify your identity.

If you believe that the processing of data is being carried out in violation of the Personal Data Protection Act, you have the right to file a complaint with the Commissioner for Information of Public Importance and Personal Data Protection (www.poverenik.rs).