



PHARMACOVIGILANCE PRIVACY NOTICE

PHARMACOVIGILANCE PRIVACY NOTICE	Document Number	PV-PRN-001
	Version number	1.0
	Effective Date:	01.07.2026
	Review Date:	01.07.2028

1. Purpose

Meditech SH.P.K. is committed to protecting the privacy and confidentiality of personal data processed during Pharmacovigilance (PV) activities. This Privacy Notice explains how personal data are collected, processed, used, retained and protected when adverse events, product quality complaints associated with adverse events, or other safety information are reported to Meditech SH.P.K.

2. Scope

This Privacy Notice applies to all individuals who report safety information relating to medicinal products represented by Meditech SH.P.K., including:

- Patients
- Healthcare Professionals
- Pharmacists
- Caregivers
- Distributors
- Other reporters

3. Purpose of Processing

Personal data are processed exclusively for Pharmacovigilance purposes, including:

- Collection of adverse event reports;
- Assessment of product safety;
- Regulatory reporting to competent authorities;
- Reporting to the relevant Marketing Authorisation Holder (MAH);
- Follow-up activities where additional information is required;
- Compliance with applicable pharmacovigilance legislation.

Personal data are **not** processed for marketing purposes.

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4. Legal Basis for Processing

Processing of personal data is necessary to comply with legal obligations related to Pharmacovigilance and medicinal product safety, including applicable Pharmacovigilance legislation and data protection requirements.

5. Categories of Personal Data

Depending on the reported case, Meditech SH.P.K. may process:

Patient Information

- Initials (where available)
- Age or age group
- Sex
- Date of birth (if relevant)
- Medical history relevant to the case

Safety Information

- Description of the adverse event
- Suspected medicinal product
- Concomitant medication
- Relevant laboratory or medical information

Reporter Information

- Name
- Professional qualification (where applicable)
- Contact details
- Healthcare institution (if applicable)

Only the minimum information necessary for Pharmacovigilance purposes will be collected.

6. Recipients of Personal Data

Personal data may be shared only where necessary with:

- Marketing Authorisation Holder (MAH);
- Competent Regulatory Authorities;

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- Other parties where required by applicable legislation.

7. International Data Transfers

Where required for Pharmacovigilance purposes, personal data may be transferred to countries outside Kosovo. Appropriate safeguards are applied in accordance with applicable data protection legislation.

8. Data Retention

Pharmacovigilance records shall be retained in accordance with applicable Pharmacovigilance legislation and contractual obligations with the Marketing Authorisation Holder.

9. Confidentiality and Security

Meditech SH.P.K. implements appropriate technical and organizational measures to protect personal data against:

- unauthorized access;
- accidental disclosure;
- alteration;
- loss;
- destruction.

Access to Pharmacovigilance information is restricted to authorized personnel only.

10. Your Rights

Where applicable under data protection legislation, individuals may request:

- access to their personal data;
- correction of inaccurate information;
- restriction of processing where legally applicable.

Please note that certain Pharmacovigilance obligations may limit the deletion of personal data because retention is required by law.

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11. Reporting an Adverse Event

To report an adverse event or other safety information, please contact:

Meditech SH.P.K.

Pharmacovigilance Department

Email: pv.safety@meditech-ks.com

Telephone: +383 38 752 277 / +383 49 895 700

Safety information may be reported **24 hours a day, 7 days a week.**

12. Changes to this Privacy Notice

This Privacy Notice may be updated whenever required by changes in legislation, Pharmacovigilance requirements or internal procedures.

The latest approved version will be available on the Meditech SH.P.K. website.

13. Document History

Version	Date	Description
1.0	01.07.2026	Initial issue

Approved by:

CEO

Printed name: Arianit Jakupi

Signature: _____

Date: _____



01.07.2026

Prepared by:

Head of Pharmaceutical Department

Printed name: Tringa Kurti

Signature: _____

01.07.2026

