Adress
MD-2032, Republica Moldova,
mun. Chișinău, str. Burebista, 23

E-mail & WEB
farmacovigilenta@dita.md
www.dita.md

Phone
(+373 22) 52 74 74

Fiscal code
1002600046359

INFORMATION NOTICE

regarding the processing of personal data

in the context of pharmacovigilance activities

DITA ESTFARM LLC. | IDNO: 1002600046359 | 23 Burebista St., Chisinau, Republic of Moldova

Version	**v1.0**
Prepared by	Lucian Chete, DPO Consultant — may, 2026
Approved by	Grigore Moraru, General Director/ July 1, 2026
Recipients	Safety information reporters (adverse reactions): healthcare professionals (physicians, nurses, pharmacists), medical representatives, patients and caregivers, contractual partners, regulatory authorities
Distribution Channels	Published on the website www.dita.md | Included as an Annex in LSOP PhV 03 | Available at the reception desk of the DITA ESTFARM headquarters | Communicated verbally and/or in writing at the time the report is collected
Legal reference	Law No. 195/2024 on the Protection of Personal Data | Law No. 133/2011 (in force) | Ministry of Health Order No. 358/2017 on Pharmacovigilance | Regulation (EU) No. 2016/679 (GDPR) — applicable to transfers to partners in the EU/EEA | GVP Guide Module VI (EMA) | ICH E2B(R3) Standards
Scheduled review	Annually or upon changes to the applicable legal framework (whichever occurs first)

This Information Notice is prepared in accordance with Articles 13 and 14 of Law No. 195/2024 on the protection of personal data and constitutes the mandatory information provided to individuals whose data is processed in the context of the pharmacovigilance activities of DITA ESTFARM LLC Please read it carefully. If you have any questions, please contact us using the contact information below.

SECTION I — GENERAL INFORMATION

1. Who is the data controller?

DITA ESTFARM LLC (hereinafter referred to as “DITA ESTFARM” or “the controller”) is the controller of the personal data processed in the context of pharmacovigilance activities. This means that DITA ESTFARM determines the purposes and means by which your data is processed.

Name	**DITA ESTFARM LLC**
IDNO	1002600046359
Registered Office	23 Burebista St., Chisinau, Republic of Moldova
Main Phone	+373 22 405 419
General email	office@dita.md

Pharmacovigilance phone number	**+373 22 52 74 74** **farmacovigilenta@dita.md — for reporting adverse reactions**
DPO Consultant (Data Protection Officer)	Lucian Chete, DPO Consultant | [dpc@ditaestfarm.md] | Contract QSDTA01
Internal DPO (internal contact)	*Friptu Evgheni, DPO email dpo@dita.md— point of contact for DITA employees and for requests from data subjects*

2. In what context does this Privacy Notice apply?

DITA ESTFARM conducts pharmacovigilance activities based on contracts entered into with the marketing authorization holders (MAHs) of medicinal products marketed in the Republic of Moldova. In this context, DITA ESTFARM has a legal obligation to collect, evaluate, and report safety information regarding adverse drug reactions.

This Information Notice applies whenever DITA ESTFARM collects safety information that may contain personal data, regardless of the reporting channel used:

* Reports received via the online form on the website www.dita.md
* Reports received online via Facebook or LinkedIn
* Reports received by phone—via the pharmacovigilance phone or the automated phone system
* Reports received via email at farmacovigilenta@dita.md or office@dita.md
* Reports received directly from DITA ESTFARM's field medical representatives
* Reports received from contractual partners or regulatory authorities
* Reports received following literature monitoring
* Reports received spontaneously, verbally, during visits to the office

SECTION II — DATA COLLECTED AND PURPOSES OF PROCESSING

3. What personal data do we process?

The types of data processed vary depending on the role of the person involved. Below we present the complete categories of data, with a mandatory distinction between the reporter's data and the patient's data.

3.1. Reporter's data (the person reporting the adverse reaction)

The reporter is the person who submits safety information to DITA ESTFARM. This may be a healthcare professional, a patient, a caregiver, or any other person.
This distinction has a clear legal basis and is a requirement of the data minimization principle (Art. 5(1)(c) of Law 195/2024), applied differently depending on necessity: The healthcare professional has a legal obligation to report (Ministry of Health Order 358/2017), and their full identity is necessary for the MMDA to validate the ICSR and for follow-up contact in the event that medical clarifications are needed. Without the physician's full name, the report cannot be validated in accordance with pharmacovigilance standards.
The patient, on the other hand, is under NO obligation to report—participation is voluntary. The patient's full identity is NOT required for the medical evaluation of the adverse reaction: the international standard ICH E2B(R3), used by all regulatory authorities including the MMDA, identifies the patient exclusively by initials, age, gender, and medical data. Collecting the patient's full name would constitute processing that is excessive in relation to the purpose.

Reporter Type	Required data collected	Optional data (if provided)	Data NOT COLLECTED (data minimization)
Physician / Healthcare professional	* First and last name * Medical specialty * Contact phone number or email (for follow-up)	* Medical license number * Address and name of the institution/clinic	* Personal IDNP * Home address * Financial information
DITA Medical Representative	* Employee's name * Contact phone number or email address (for follow-up)	* personal cell phone number (if you have a work contact number) * Personal email address	* Personal IDNP * Home address
Patient (self-reporter)	* Initials (not full name) * Age or year of birth * Gender * Phone number or email (if provided and necessary for follow-up)	* Occupation (if relevant)	* Full name * IDNP * Full address * Financial information
Caregiver / Relative	* Relationship to the patient (e.g., mother, husband) * Contact Information for Follow-up (if provided)	* Name (if voluntarily provided)	* IDNP * Full address

3.2. Patient data (the person who experienced the adverse reaction)

In accordance with the international ICH E2B(R3) standards and the principle of data minimization, patient data is collected in pseudonymized form—identification is based on initials, not full identifying information.

Data Category	Collected (YES/NO/Partially)	Notes / Restrictions
Patient initials	**YES — required**	Initials only (e.g., M.P.) — NEVER the full name
Gender	**YES — required**	M / F / Unknown
Age or date of birth	**YES — at least one of the three options: (i) approximate age, (ii) year of birth, (iii) full date of birth**	Preferably age or year of birth. Exact date of birth only if medically relevant

Data Category	Collected (YES/NO/Partially)	Notes / Restrictions
Health status data (diagnosis, symptoms, adverse reaction, concomitant treatment, relevant medical history)	**YES — special category, Art. 9**	Health data = special categories. Specific legal basis: Art. 9(2)(i) Law 195/2024 — public interest in the field of public health/PV
Weight and height (medically relevant)	**PARTIAL — if medically relevant**	Only if relevant to the assessment of an adverse reaction (e.g., overdose calculated per kg)
Medically relevant habits (smoking, alcohol, other medications)	**PARTIAL — if medically relevant**	Only if relevant to assessing the causality of the adverse reaction
Information on the patient's family members	**LIMITED**	Only the relationship (e.g., mother, spouse) and contact information of the family member if they are the reporter. Family medical history only if relevant to the case assessment (e.g., family and collateral history)
Voice of the patient/reporter (telephone recording)	**YES — if the report is received by phone and recorded**	The voice is personal. The reporter is informed via the automated voice message that the call is being recorded
Photos, medical images (e.g., skin rashes, visible effects)	**CONDITIONAL**	Only if voluntarily submitted and medically relevant. Not actively requested. After documentation, they are anonymized or stored in the secure case file
Complete patient identification information (full name, IDNP, address)	**NO — in principle**	Collected ONLY if explicitly requested by the regulatory authority (MMDA) or if the patient voluntarily provides them and they are strictly necessary for the case evaluation. The decision is documented.

4. Why do we process this data? (Purposes and legal basis by category)

DITA ESTFARM processes personal data in the context of PV exclusively on the basis of one of the following legal grounds, applied differently depending on the purpose:

Purpose of processing	Legal basis (Law 195/2024)	Categories of data involved	Mandatory or optional for the reporter?
Collection of safety information regarding adverse reactions (ICSR—Individual Case Safety Report)	Art. 6(1)(c) — legal obligation (Ministry of Health Order 358/2017) + Art. 9(2)(i) — public interest in public health	Patient medical data + reporter data	Mandatory for healthcare professionals. Voluntary for patients/caregivers.
Reporting ICSRs to the Medicines and Medical Devices e (MMDA) of the Republic of Moldova	Art. 6(1)(c) — legal obligation (Ministry of Health Order No. 358/2017)	ICSR fully compliant with the MMDA format	Mandatory — regulated reporting
Submission of the ICSR to the contractual partner (MAH/manufacturer) for a comprehensive safety assessment	Art. 6(1)(b) — performance of the clinical trial contract + Art. 9(2)(i) — public interest in public health	Pseudonymized ICSR (patient initials, not full data)	Mandatory under the clinical trial agreement
Follow-up (contacting the reporter for additional information needed to fully evaluate the case)	Art. 6(1)(f) — legitimate interest of the controller (completeness of safety reporting in the interest of patient safety)	Reporter's contact information	The reporter may refuse follow-up—the right to object is exercised in accordance with Section VII
Archiving of adverse event records for audit and regulatory compliance (including audits by contractual partners)	Art. 6(1)(c) — legal obligation (Ministry of Health Order 358/2017 + partner requirements)	Complete ICSR case file	Mandatory — regulated archiving requirement
Assessment of Safety Trends and Signals (Aggregate Analysis of Adverse Reaction Reports)	Art. 6(1)(c) — legal obligation + Art. 9(2)(i) — public interest in public health	Aggregated anonymized/pseudonymized data	Individual data are not used in this analysis — aggregated data are used
Recording of telephone calls received on the adverse reaction hotline (automated response system)	Art. 6(1)(c) — legal obligation (documentation of the received report) + Art. 6(1)(f) — legitimate interest (ensuring the completeness of the report)	The voice of the reporter and/or the patient	The reporter is informed via the automated voice message

IMPORTANT NOTE regarding the legal basis:
For patient health data (a special category under Article 9 of Law 195/2024), processing is permitted without consent pursuant to Article 9(2)(i)—processing necessary for reasons of public interest in the field of public health, including pharmacovigilance. This legal basis is supported by the legal reporting obligation imposed by Ministry of Health Order 358/2017 (Article 6(1)(c)). The reason why consent CANNOT be the legal basis here is a practical one and essential for auditors: if consent were the legal basis, the patient would have the right to withdraw it at any time and request the deletion of the data—which would make it impossible to comply with the legal obligation to report and archive pharmacovigilance reports (for a minimum of 10 years). A pharmacovigilance system based on revocable consent would be structurally incompatible with the traceability requirements imposed by the EMA and the MMDA.

SECTION III — DATA RECIPIENTS AND INTERNATIONAL TRANSFERS

5. To whom do we disclose data?

DITA ESTFARM discloses personal data from the pharmacovigilance system exclusively to the following categories of recipients, under the conditions described below:

5.1. Medicines and Medical Devices Agency (MMDA) — Republic of Moldova

Legal Basis for the Transfer	Legal obligation — Ministry of Health Order No. 358/2017 on pharmacovigilance
Data transmitted	Individual Case Safety Reports (ICSRs) in the format required by the MMDA, including the reporter's data (healthcare professional—full details) and the patient's data (pseudonymized—initials, age, sex)
Frequency	In accordance with legal deadlines: 15 calendar days for serious adverse reactions; 90 days for non-serious adverse reactions (or in accordance with deadlines updated by the MMDA)
Guarantees	MMDA is a national public authority—the transfer is carried out based on a legal obligation, without the need for additional DPA-type safeguards

5.2. Contractual Partners (MAH/Manufacturer)

DITA ESTFARM reports adverse reactions to the marketing authorization holders (MAHs) or to the manufacturers of the affected medicines, based on the pharmacovigilance contracts entered into. Current partners include, but are not limited to: all partners in the DITA ESTFARM portfolio.

Basis for the transfer	Performance of the pharmacovigilance contract (Art. 6(1)(b) of Law 195/2024) + public interest in public health (Art. 9(2)(i))
Data transmitted	ICSR pseudonymized in accordance with ICH E2B(R3) standards: patient data—only initials, age/sex, and relevant medical information. Reporter data—included only if necessary for follow-up and if the reporter has not requested anonymization
Partners in the EU/EEA	The transfer is covered by the Standard Contractual Clauses (SCCs) adopted by the European Commission through Implementing Decision (EU) 2021/914, included in the pharmacovigilance agreements. Data is transmitted via [secure channel—to be confirmed by IT: secure portal/encrypted email/SFTP]
Additional Guarantees	Contractual partners are obligated under the pharmacovigilance agreement not to use the data for any purpose other than global pharmacovigilance and to implement appropriate security measures in accordance with ICH and GVP standards

5.3. DITA ESTFARM IT Team (internal technical access)

Quality	The person authorized by the data processor — pursuant to the signed intra-Group DPA
Data accessed	Technical access to storage systems (Excel PV and 1C spreadsheets) exclusively during maintenance and support sessions, not for processing for their own purposes
Guarantees	Intra-Group DPA (Document 1 — DPO as a Service draft); individual confidentiality agreements for IT staff; logged maintenance sessions.

5.4. Supervisory Authorities and Other Competent Authorities

CNPDCP (in the event of a data breach)	If a security breach affecting data in the PV system is identified, DITA ESTFARM is required to notify the CNPDCP within 72 hours of discovery, in accordance with Article 33 of Law 195/2024
Judicial or criminal investigation authorities	Only on the basis of a specific legal ground (judicial decision, criminal investigation order)—not on the basis of an ordinary administrative request

DITA ESTFARM does not sell, rent, or market personal data from the pharmacovigilance system. We do not share data with advertising agencies, marketing companies, or any other entity for commercial purposes.

SECTION IV — DATA RETENTION PERIOD

6. How long do we retain data?

The data retention period is determined based on the legal obligations applicable to pharmacovigilance activities and the contractual terms agreed upon with our partners. DITA ESTFARM does not retain data for longer than is necessary for the stated purposes.

Data Category	Retention Period	Basis for the Retention Period	Method of deletion upon expiration
Complete ICSR case file (medical data + reporter data + follow-up correspondence)	For the duration of the product's marketing authorization + at least 10 years after its expiration	Ministry of Health Order No. 358/2017 + GVP Module VI (EMA) requirements + contract with the partner	Certified deletion/destruction or irreversible anonymization upon expiration of the retention period
Contact information for the rapporteur (for follow-up—after the case is closed)	For the duration of the product's marketing authorization + at least 10 years after its expiration	For the duration of the product's marketing authorization + at least 10 years after its expiration; to be deleted along with the complete file for the respective ICSR case	Automatic or manual deletion in accordance with the PV archiving procedure
Audio recordings of telephone calls (automated voice system)	For the duration of the product's marketing authorization + at least 10 years after its expiration,	During the term of the product's marketing authorization plus a minimum of 10 years after its expiration, it shall be deleted along with the complete file for the respective ICSR case	Automatic or manual deletion in accordance with the PV archiving procedure
PV system access logs (audit log—who accessed which file, when)	12 months in the active system + 24 months in the archive	Security requirement (Art. 32 of Law 195/2024) + auditability	Automatic deletion upon expiration of the retention period from the IT archive
Emails containing safety information received at the PV address farmacovigilenta@dita.md	For the duration of the product's marketing authorization + a minimum of 10 years after its expiration,	For the duration of the product's marketing authorization plus a minimum of 10 years after its expiration, It will be deleted along with the complete file for	Secure archiving in the dedicated PV folder, with restricted access

		the respective ICSR case	

SECTION V — DATA SECURITY

7. How do we protect your data?

DITA ESTFARM implements technical and organizational measures appropriate to the risks associated with the processing of pharmacovigilance data, given that such data includes special categories of data (health data) pursuant to Article 9 of Law 195/2024.

7.1. Organizational Measures

* Access to the adverse reaction record-keeping system (the PV Excel tracker and the corresponding 1C database) is limited exclusively to pharmacovigilance department staff and authorized IT personnel for maintenance—based on the “need-to-know” principle
* All employees with access to adverse reaction data have signed confidentiality agreements and received GDPR training specific to the adverse reaction context
* IT staff access to PV systems is permitted exclusively during documented, logged sessions with a specific technical justification
* The offboarding procedure provides for the immediate revocation of access to PV systems upon the termination of any employee’s employment
* Physical documents containing PV data (printouts, faxes) are stored in locked cabinets with restricted access and are destroyed via certified shredding upon expiration of the retention period

7.2. Technical Measures

* Access to the PV system (1C + Excel files) is granted exclusively through individual authentication (personal account + password)—there are no generic or shared accounts
* Encryption in transit: Electronic transmissions of PV data to MMDA and partners are carried out via [a secure channel: TLS
* Backups of the PV database are performed periodically and stored in secure locations
* DITA ESTFARM’s IT systems are protected by a perimeter firewall, up-to-date antivirus software, and active monitoring of security events

SECTION VI — RIGHTS OF DATA SUBJECTS

8. What rights do you have, and how can you exercise them?

Law No. 195/2024 on the protection of personal data grants you the following rights regarding your data processed by DITA ESTFARM in the context of pharmacovigilance. Please carefully read the explanations specific to the pharmacovigilance context, which may limit the exercise of certain rights.

8.1. Right of Access (Art. 15 of Law 195/2024)

You have the right to obtain confirmation that DITA ESTFARM is processing personal data concerning you and to request a copy of such data, accompanied by information regarding: the purposes of the processing, the categories of data concerned, the recipients or categories of recipients, the estimated retention period, and your rights.How to submit a request: Send a written request to dpo@dita.md with the subject line “Request for Access to PV Data.” Specify a time period or a medicinal product if you wish to limit the scope of your request. We will respond within 30 calendar days.

PV-specific limitation: If your data is included in an ICSR report that has already been submitted to the MMDA or to a contractual partner, we will inform you of this, but we cannot withdraw the report that has already been submitted due to our legal obligation.

8.2. Right to Rectification (Art. 16 of Law 195/2024)

If your data in the PV system is inaccurate (e.g., an adverse reaction described incorrectly, incorrect contact information), you can request that it be corrected. Correcting data in an ICSR that has already been submitted to MMDA or a partner will generate an updated version of the report (ICSR follow-up), which will be submitted through the same channels.

How to exercise this right: Send a request to dpo@dita.md with a precise description of the incorrect data and the correct version. We will make the correction in the PV system and, if necessary, submit a follow-up ICSR to the relevant recipients.

8.3. Right to erasure (Art. 17 of Law 195/2024) — LIMITED in the context of PV

ATTENTION — IMPORTANT LIMITATION: The right to erasure ("right to be forgotten") is SEVERELY LIMITED in the context of pharmacovigilance. DITA ESTFARM cannot delete your data from an ICSR if: (a) The processing is necessary to comply with a legal obligation (Ministry of Health Order 358/2017 — archiving pharmacovigilance reports for a minimum of 10 years is mandatory); (b) The processing is necessary for reasons of public interest in the field of public health; (c) The processing is necessary for archiving purposes in the public interest. In these cases, you may request that the processing be RESTRICTED (Section 8.4) as an alternative to erasure.

When deletion is possible: (i) the reporter's contact information stored solely for follow-up purposes may be deleted upon request after the case is closed; (ii) data collected in error or that is not necessary for the assessment of the case may be deleted; (iii) in the PV system.

8.4. Right to Restriction of Processing (Art. 18 of Law 195/2024)

You may request the restriction of the processing of your data in the following situations: (i) you contest the accuracy of the data—for the duration of the verification; (ii) the processing is unlawful, but you prefer restriction rather than erasure; (iii) the data is no longer necessary for the controller, but you need it to establish, exercise, or defend a legal claim in court. *During the restriction period, DITA ESTFARM will retain the data but will not actively process it (except for storage). The restriction does not apply to processing based on a legal obligation (reporting of PV to MMDA cannot be restricted).*

8.5. Right to Data Portability (Art. 20 of Law 195/2024)

You may request to receive the data you have provided directly to DITA ESTFARM (e.g., data from the online reporting form) in a structured, commonly used, and machine-readable format (e.g., CSV, JSON). This right does not apply to data processed based on a legal obligation or in the public interest.

8.6. Right to Object (Art. 21 of Law 195/2024)

You may object to the processing of your data based on the controller's legitimate interest—in particular, the processing of contact information for follow-up activities after the case has been closed. DITA ESTFARM will cease such processing unless it demonstrates compelling legitimate grounds that override your interests, rights, and freedoms.

Objection is NOT possible for processing based on a legal obligation (reporting adverse reactions to the MMDA) or on the public interest in public health.

8.7. Procedure for Exercising Your Rights — Specific Steps

Step	Your Action	Action by DITA ESTFARM	Deadline
1	Please send your written request to dpo@dita.md or to our office address. Please specify: the right you wish to exercise, the details to which the request relates (if known—e.g., medicinal product, time period), and your contact information for a response.	Acknowledgment of receipt + request registration number	Within 3 business days
2	If necessary: provide a form of identification to verify your identity (only if there are reasonable doubts regarding the applicant's identity)	Verification of the applicant's identity and identification of the data in the system	Within 5 business days
3	If the request is complex or requires clarification: The DPO may contact you for additional details	Application processing + assessment of applicable limitations in the context of PV	Within 30 calendar days of receipt (extendable by an additional 60 days for complex requests, with notice to you)
4	You will receive a written response to your request. If the request cannot be fully granted (e.g., the right to erasure is limited by a legal obligation), the response will explain the reasons and available alternatives.	Written response sent (via email or mail, according to your indicated preference)	Within 30 calendar days
5	If you are not satisfied with the response: you may file a complaint with the CNPDCP or appeal to the competent court	Cooperation with the CNPDCP in the event of an investigation initiated by the authority	—

9. The right to file a complaint with the supervisory authority

If you believe that your personal data has been processed in violation of the provisions of Law No. 195/2024 or other applicable legal provisions regarding data protection, you have the right to file a complaint with:

Authority	**National Center for the Protection of Personal Data (CNPDCP) of the Republic of Moldova**
Address	180 Stefan cel Mare si Sfant Blvd., Chisinau, Republic of Moldova
Email	info@datepersonale.md
Phone	022 820 801
Website	www.datepersonale.md

SECTION VII — GLOSSARY OF TERMS

10. Definitions

To facilitate understanding of this Information Memorandum, we provide definitions of the main terms used:

Term	Definition
Adverse Drug Reaction (ADR)	Any harmful and unintended response to a drug, occurring at doses normally used for prophylaxis, diagnosis, or treatment
Adverse Event (AE)	Any adverse medical event that occurs in a patient or a participant in a clinical trial who has received a medicinal product, and that is not necessarily causally related to that treatment
ICSR (Individual Case Safety Report)	Individual Safety Report — the standardized document used to report an individual case of an adverse reaction to regulatory authorities and/or manufacturers
MAH (Marketing Authorization Holder)	Marketing Authorization Holder — the company that holds the authorization to market a drug in a specific territory and is responsible for its pharmacovigilance
MMDA	Agency for Medicines and Medical Devices — the national regulatory authority for medicines in the Republic of Moldova
ICH E2B(R3)	International standard for the electronic submission of individual safety case reports, developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use
Term	**Definition**
GVP Module VI	Good Pharmacovigilance Practices — Module VI of the EMA Guidance on the Management and Reporting of Adverse Drug Reactions
SCC (Standard Contractual Clauses)	Standard Contractual Clauses adopted by the European Commission — a legal instrument that ensures an adequate level of protection for transfers of personal data to countries outside the EU/EEA
Pseudonymization	The processing of personal data in such a way that it can no longer be attributed to an identified or identifiable natural person without the use of additional information (e.g., replacing a name with initials in an ICSR)
Special Categories of Data (Art. 9 of Law 195/2024)	Data requiring enhanced protection, including: health data, genetic data, biometric data, data concerning sexual life or sexual orientation, data concerning racial or ethnic origin, political opinions, religious beliefs, etc.
DPO (Data Protection Officer)	Data Protection Officer — the person designated by the controller to monitor compliance with data protection laws, advise the controller, and serve as the point of contact for data subjects and the supervisory authority

SECTION VIII — FINAL PROVISIONS

11. Updates to This Privacy Notice

This Privacy Notice may be updated periodically to reflect legislative, operational, or organizational changes at DITA ESTFARM. The date of the last revision is indicated in the document header and in the metadata table at the beginning of the document.

In the event of significant changes that affect your rights, we will notify you in advance via website posting. We encourage you to periodically review the updated version of this Privacy Notice, available at www.dita.md.

12. Language of the Document

This Privacy Notice is drafted in Romanian (the primary version) and in English (the version for international partners and foreign reporters—see Section II of this document). In the event of any discrepancies in interpretation between the two versions, the Romanian version shall prevail.