

Privacy Policy for Personal Data Associated with Adverse Events Notifications

No. POL-CNO-010-00

DEPARTMENT: COMPLIANCE

PRIVACY POLICY FOR PERSONAL DATA ASSOCIATED WITH ADVERSE EVENTS NOTIFICATIONS				POLICY N° POL-CNO-010-00
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1. PURPOSE

The purpose of this Privacy Policy for personal data associated with adverse event notifications (hereinafter the "Privacy Policy" or "the Policy") is to establish the guidelines for the proper processing of personal data collected, recorded, organized, stored, retained, prepared, modified, extracted, consulted, used, transferred and deleted in the context of the Pharmacovigilance, Technovigilance and Cosmetovigilance activities carried out by Medifarma S.A. (hereinafter "**humanova**").

The processing of the personal data contained in the pharmacovigilance data bank has as its main purpose **the detection, assessment, understanding and prevention of adverse events and any other safety problem related to the use of humanova products**, in compliance with the regulatory obligations established by health authorities, including the General Directorate of Medicines, Supplies and Drugs - DIGEMID.

Likewise, this policy seeks to ensure that the processing of personal data is carried out in accordance with the principles established in current regulations, such as specific purpose, proportionality, quality, security and availability of recourse, ensuring the confidentiality, integrity and availability of the information.

2. SCOPE

This Privacy Policy applies to all processing of personal data carried out by **humanova** in the context of its Pharmacovigilance, Technovigilance and Cosmetovigilance activities, regardless of the medium in which they are stored, whether physical, digital or any other medium.

3. OBJECTIVES

Guarantee the proper, lawful and secure processing of the personal data contained in the pharmacovigilance and technovigilance data bank, ensuring compliance with current Peruvian regulations and the protection of the rights of data subjects.

4. CONTENT

4.1. IDENTIFICATION OF THE DATA BANK OWNER

MEDIFARMA S.A., with RUC No. 20100018625, domiciled at Jr. Ecuador No. 787 – Lima, Lima, in its capacity as holder of the sanitary registration and/or the sanitary registration certificate, is responsible for the processing of the personal data collected in the context of its Pharmacovigilance, Technovigilance and Cosmetovigilance activities.

4.2. LEGAL BASIS FOR THE PROCESSING

This policy is governed by:

- Law No. 29733 – Personal Data Protection Law and its Regulations approved by Supreme Decree No. 016-2024-JUS.
- Ministerial Resolution No. 1053-2020/MISA approving the technical document: Good Pharmacovigilance Practices Manual (BPFV), and its amendments.
- Directorial Resolution No. 144-2016-DIGEMID-DD-MINSA approving the mandatory fields of the format for reporting suspected adverse reactions.

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4.3. PURPOSE OF THE PROCESSING

Personal data are processed exclusively for:

- The detection, assessment, understanding and prevention of adverse events and problems related to the safety of humanova products.
- The management of reports of suspected adverse reactions, adverse incidents and undesirable effects.
- Compliance with regulatory obligations before DIGEMID and other health authorities.
- The preparation of periodic safety reports (PSRs).
- The performance of active Pharmacovigilance, Technovigilance and Cosmetovigilance activities, case follow-up and risk management.
- Audits, regulatory inspections and quality control of the Pharmacovigilance, Technovigilance and Cosmetovigilance system

4.4. PERSONAL DATA PROCESSED

a) Patient data:

- Patient initials or code
- Age or age range
- Sex
- Relevant clinical information (diagnosis, treatment, adverse events)

b) Reporter data

- First and last names
- Profession (e.g., physician, pharmacist, patient)
- Contact data (telephone, email)

c) Sensitive data

- Health-related data are processed, and therefore their processing is exclusively for Pharmacovigilance, Technovigilance and Cosmetovigilance purposes.

4.5. DATA COLLECTION CHANNELS

The data may be obtained from:

- Healthcare professionals
- Employees of **humanova**
- Patients or consumers
- Scientific literature monitoring
- Health authorities.
- Patient support programs
- Post-authorization studies

4.6. DATA TRANSFERS

Personal data may be transferred to:

- General Directorate of Medicines, Supplies and Drugs - DIGEMID

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- Other international regulatory authorities related to Pharmacovigilance, Technovigilance and Cosmetovigilance and when so provided by our local authority.

➤ International transfers:

They will be carried out under mechanisms that guarantee an adequate level of personal data protection.

4.7. DATA RETENTION PERIOD

humanova will retain the data for the period required by pharmacovigilance regulations, that is, up to five (05) years after the cancellation of the product's sanitary registration.

4.8. SECURITY MEASURES

humanova implements:

- Pseudonymization of patient data
- Role-based access control
- Audit log (traceability of changes and access)
- Systems validated in accordance with regulatory requirements
- Confidentiality agreements with personnel
- Periodic training in Pharmacovigilance, Technovigilance and Cosmetovigilance and in personal data protection

4.9. ARCOP RIGHTS

Data subjects may exercise their rights of:

- Access
- Rectification
- Cancellation
- Opposition
- Portability

However, the exercise of these rights may be limited when the data are necessary to comply with legal obligations of Pharmacovigilance, Technovigilance and Cosmetovigilance.

Requests to exercise ARCOP rights must be submitted through the following channels:

- Corporate email: datospersonalesperu@humanovalab.com
- Web form for the exercise of ARCOP rights
- Physical filing office:
 - Jirón Ecuador 787, Cercado de Lima, Lima – Peru

- For further details, the *Privacy Policy* and the *Procedure for handling requests for the exercise of ARCOP rights* should be reviewed.

4.10. PERSONAL DATA BANK

The data will be stored in the data bank named: "PHARMACOVIGILANCE AND

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TECHNOVIGILANCE", registered with the National Personal Data Protection Authority (ANPDP) under No. PJ-2026-405.

4.11. PHARMACOVIGILANCE, TECHNOVIGILANCE AND COSMETOVIGILANCE SYSTEM GOVERNANCE

humanova guarantees that:

- It has a person responsible for Pharmacovigilance, Technovigilance and Cosmetovigilance.
- It maintains a documented Pharmacovigilance, Technovigilance and Cosmetovigilance System in accordance with the regulations on the matter.
- It ensures the integrity, traceability and availability of the information.

5. REFERENCES

Document 1: Business code of conduct

Document 2: Privacy policy

Document 3: Procedure for handling requests for the exercise of ARCOP rights

6. REVISION HISTORY

Revision No.	Description of Change
00	This policy is issued as part of compliance with Law No. 29733 – Personal Data Protection Law and its regulations approved by Supreme Decree No. 016-2024-JUS

7. GLOSSARY

- **Pharmacovigilance Activities:** Set of activities aimed at the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem.
- **Cosmetovigilance Activities:** Set of activities related to the monitoring and safety of cosmetic products after their marketing, collecting and assessing undesirable effects in order to protect public health.
- **Technovigilance Activities:** Set of activities aimed at the prevention, detection, investigation, assessment and dissemination of information on adverse incidents or potentially adverse incidents related to medical devices during their use that may cause harm to the patient, user, operator or the environment around them.
- **National Personal Data Protection Authority (ANPDP):** State body responsible for ensuring compliance with personal data protection regulations in Peru.

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- **Competent health authority:** Entity responsible for the regulation and oversight of medicines and pharmacovigilance, such as the General Directorate of Medicines, Supplies and Drugs.
- **Personal data bank:** Organized set of personal data, automated or not, regardless of its medium, managed by a natural or legal person.
- **Personal data:** Information about a natural person that identifies them or makes them identifiable through reasonably usable means.
- **Sensitive data:** Personal data consisting of information on health, racial or ethnic origin, economic income, political opinions, religious beliefs, among others. In pharmacovigilance, health-related data stand out.
- **Undesirable effect (UE):** alteration or non-harmful clinical manifestation in the human body that occurs after the application of a cosmetic product under normal conditions of use. In other words, it is an adverse reaction to human health attributable to the normal or reasonably foreseeable use of a cosmetic product.
- **Adverse event:** Any unfavorable medical occurrence that may arise during the use of a **humanova** product (pharmaceutical products, without necessarily having a causal relationship with it).
- **Adverse incident (AI):** Any undesirable event that causes harm to the patient, user, operator or others, or that poses a risk of harm, which may or may not be causally associated with one or more medical devices. It is related to their identity, quality, durability and safety. It includes errors, preventable adverse events and risks.
- **Adverse drug reaction (ADR):** Noxious and unintended response to a medicine that occurs at doses normally used in humans.
- **Data controller:** Natural or legal person who, alone or jointly with others, processes personal data on behalf of the owner of the data bank.
- **Pseudonymization:** Processing of personal data that prevents direct identification of the data subject without additional information, which must be kept separate and protected.
- **Personal data subject:** Natural person to whom the personal data being processed belong.

8. ANNEXES

Not applicable.

