

Data Privacy Notice

This Privacy Notice (“**Notice**”), provides information about how Medison Group (“**we**”, “**our**” or “**Medison**”) collects and processes your Personal Data for the purpose of fulfilling its Pharmacovigilance obligations or providing its Services. We take your privacy seriously and this Notice describes our practices regarding our collection and use of your Personal Data – in particular what data we collect, why we collect it, what we do with it and sets forth your privacy rights.

“**Applicable Laws**” means any regional or state or country law, including but not limited to ordinances, decrees, decisions, rulings, ordinances, provisional measures, guidelines and similar, enacted, adopted, promulgated or applicable by the competent authorities, and self-regulating industry codes of conduct or ethics.

“**Health Data**” means all data pertaining to the health status of a living human being which reveal information relating to their past, current or future physical or mental health status.

“**Personal Data**” means any information that can be used, alone or together with other data, to identify, directly or indirectly, any living human being.

“**Pharmacovigilance**” entails all activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems.

“**Safety Information**” means all information regarding human health that is connected with the use of a medicinal product.

“**Medison Services**” and/or “**Services**” means any service offered by Medison to patients including Patient Support Programs, Named Patient Supply or Early Access Program, customer general support or any other service that Medison may provide to patients including through third parties to the extent allowed under Applicable Laws.

“**Special Categories of Personal Data**” means personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation.

This Notice applies to the information that Medison collects from patients, as well as healthcare professionals, patient’s relatives or other persons in relation to safety reporting.

Any information described under this Notice that you provide to Medison is strictly confidential. It is only intended for Medison’s competent personnel and for Medison to provide its Services and meet its legal and Pharmacovigilance obligations.

The Personal Data we process

When you report Safety Information, we collect the following Personal Data:

- patient's initials;
- patient's age or date of birth;
- patient's gender;
- patient’s weight and height;
- patient's medical history, current illnesses, laboratory test results, concomitant medicinal products, etc.);

- details on medicinal product involved (name, strength, indication, batch, expiry date, etc.);
- patient's dosing;
- details related to the adverse event;
- start date of the therapy and discontinuation date;
- onset date of the adverse event;
- treatment of the event;
- outcome of the event (recovered/not recovered) and resolved date.

Additionally, when the reporting of Safety Information takes place on behalf of the patient, e.g. by a healthcare professional, lawyer or other third party:

- reporter's full name or initials;
- reporter's qualification (e.g. physician, pharmacist, other healthcare professional, lawyer, or other non-healthcare professional);
- reporter's contact details (organization, department, street, city, state or province, postcode, country, email, phone/fax number).

When you apply or participate in Medison Services we may collect the following Personal Data:

- patient's full name;
- patient's ID number;
- patient's contact data including phone number, personal address and email address;
- patient's age or date of birth;
- patient's gender;
- patient's medical history, current illnesses, laboratory test results, concomitant medicinal products, etc.);
- details on medicinal product involved (name, strength, indication, batch, expiry date, etc.);
- patient's dosing;
- contact details of patient's personal healthcare professional;
- personal data of your relatives, if you choose to provide such data.

The Personal Data that you may need to disclose to Medison include Health Data and/or other Special Categories Personal Data. Medison adheres to all Applicable Laws with respect to the collection of such data.

Purpose for the processing

- (a) Medison will process your Personal Data for the following purposes:
- for public health reasons, e.g., ensuring patient safety and safe use of medicines;
 - to document and archive the information you provide, for the Pharmacovigilance department of Medison or the Marketing Authorization Holder (MAH) to communicate with you to receive additional information, monitor the reported case, or answer possible questions;
 - to fulfil and monitor our legal responsibilities, for example, under Pharmacovigilance legislation;
 - to collect, keep and organize your Personal Data in accordance with Applicable Laws and Medison's procedures;

- to further process your personal data for the purposes of cross-referencing and combining them with other safety reports.
- to respond to your specific request and provide you with the Services you wish to receive. Such collection of information will enable us to provide you with technical and professional assistance.

The legal basis of the processing

When we process your Personal Data, we do so:

- to comply with our legal obligations, industry regulations and guidelines related to our Pharmacovigilance obligations or legal obligations related to medicinal product safety;
- to safeguard our legitimate interests, including without limitation our interest to ensure high safety and quality standards for our products, maintain Pharmacovigilance information related data for legal, providing Medison Services, record keeping, compliance purposes, as well as for the exercise or defense of legal claims.
- to take steps at your request prior to entering into a contract.

With whom do we share your Personal Data

We share your Personal Data with our affiliates within Medison Group, with service providers assisting Medison Group with the specific Pharmacovigilance activity related to your report or Medison Services, with our business partners with whom we jointly offer the product related to your report, and, to the extent necessary, with regulators, courts or competent authorities, to comply with Applicable Laws, as well as with requests of law enforcement, regulatory and other governmental agencies. The processing of your Personal Data by the third Parties mentioned above shall be in accordance with their Personal Data protection policies and procedures, their policies and procedures pertaining to the applicable activities, as well as any agreements between Medison and the respective third party. Furthermore, Medison provides no guarantees regarding the processing of your Personal Data by law enforcement, regulatory and other governmental agencies.

How long are your data kept?

Your Personal Data will be stored in accordance with Applicable Laws and until we proactively delete them or you send a valid deletion request. We may retain your Personal Data for a longer period to comply with Applicable Laws, including but not limited to applicable Pharmacovigilance legislation, regulations and rules, or in the event of a complaint or if we reasonably believe there is a prospect of litigation or any complaints or challenges in respect to our relationship with you.

How are your data transferred and secured?

We process your personal data on dedicated IT systems and within our premises including, in EU, other non-EU countries (including Switzerland and/or Israel). We also may use software and service providers who host and/or process personal data for us in both the EU and non-EU countries, including US, Canada, Australia, Asia Pacific, Singapore, and Israel. We may also transfer your Personal Data to companies in the same corporate group as Medison that are covered by an internal processing arrangement of the Medison group which obliges each member to ensure that Personal Data receives an adequate and consistent level of protection

wherever it is transferred to. When we transfer your Personal Data outside of EU/EEA (for example to third parties who provide us with services), we will generally obtain adequate safeguards from them to protect your Personal Data. We have implemented appropriate technical, organizational and security measures designed to protect your Personal Data from accidental loss, unauthorized access, use, modification or disclosure.

The data of the patient and the reporter that are collected for the purposes of Pharmacovigilance are processed by Medison in a pseudonymized form and particularly stringent measures are implemented, including but not limited to the following:

- Medison has implemented detailed internal policies and procedures for the proper and timely recording of Safety Information and its processing.
- All Safety Information received by Medison even non-valid reports, is forwarded to Medison's local safety email inbox.
- All Safety Information received by Medison is documented in folders to which only the competent members of the PV department can access in order to perform their duties pertaining to Medison's PV obligations.
- In case any Safety Information is required to be sent to the MAH under Applicable Laws, including those pertaining to the PV responsibilities of the MAH:
 - (a) any patient personal data included in the Safety Information are transferred anonymized (via, inter alia, the reduction of any patient identifiers) and

(b) in case the MAH is responsible to conduct follow-up on the case, only the minimum required contact details of the reporter are transferred to the MAH, unless such transfer is prohibited under local Applicable Laws.

Your rights in relation to your data

In some jurisdictions, in particular those located within the European Union or within the EEA, you may be afforded the following general rights with respect to your Personal Data:

- the right to withdraw consent to use your Personal Data,
- the right to be informed about how we process your Personal data,
- the right to access, to rectify or to erase your Personal Data,
- the right to restrict the scope of the processing of your Personal Data,
- the right to data portability.

You also have the right to lodge a complaint to the relevant supervisory authority about the processing of your Personal Data. To exercise your rights, you may contact us at: privacy@medisonpharma.com.

Your rights regarding the use and processing of your personal data are fully respected, without prejudice to Medison's right to lawfully process it to the extent necessary for its compliance with its legal or legitimate obligations under Pharmacovigilance or other Applicable Laws.

Third Party Websites

Our platforms may provide links to third party websites. This Notice does not apply to those websites, please ensure that you verify all terms and conditions of use, including the privacy policies of any third-party website you use.

Last Updated: September 2023