Data Protection Statement for reports to Pharmacovigilance (PV), Medical Inquiries (MI) and Product Quality Complaints

Status: August 2023

Information pursuant to Article 13 of Regulation (EU) 2016/679 of the European Parliament and of the Council of the European Union as of 27 April 2016 «General Data Protection Regulation (GDPR)» on the protection of individuals with regard to the processing of personal data – **Drug Safety.**

Compliance with data protection regulations is a high priority for our company. In the following, we would like to inform you about the collection of your personal data by us.

Responsible:
Materia Medica Maibach AG
Birkenstrasse 49
CH-6343 Risch/Rotkreuz
This data privacy policy also applies to the subsidiary «**MEDARIS GmbH»**.

Security notice
If you wish to send confidential information to us by e-mail, please do so in encrypted form. Use the free web browser extension «Mailvelope» for Firefox and Chrome, for example.

Processed data
As a matter of principle, we only collect the data that is necessary for the optimal processing of the adverse event or product quality report and that enable this report to be properly clarified. On the one hand, this can be data of the person affected by the adverse event or quality defect or, if the report is made by a third party (medical person, family member), also include his or her data.

This applies in particular to the following information from you:

- Name and contact details of the reporter (for queries), whether you (the reporter) are a health professional and, if so, which profession (with this information we can ask you subject-specific questions if necessary)
- Your relationship as a reporter to the data subject
- Information about the person concerned (e.g. initials, age or age groups or year of birth, gender)
- Information on medicinal products (e.g. name, active ingredient, batch number, expiry date, dosage, period of use)
- Information on underlying and concomitant diseases of the person concerned
- Information on adverse drug reactions
- Information on the quality defect found
- Information on the medical inquiry

The provision of your contact details (for queries) is voluntary. There are no negative consequences associated with not providing this data. However, failure to provide it in individual cases may complicate or delay subsequent communication and, under certain circumstances, may result in the data not meeting the minimum criteria for data processing for reasons of public interest in the field of public health (see section below). If you are a patient, it is possible that we may receive a third-party adverse reaction report about you. Such third parties may include physicians or other health professionals, lawyers, family members, or other third parties.

Data processing in the public interest as a contribution to public health
We process your data exclusively for reasons of public interest in the field of health in order to be

able to guarantee a high standard of quality and safety of our medicines. The legal basis can be found in Article 9(2)(i) of the General Data Protection Regulation (GDPR) in conjunction with Article 6(2) (d) and (g) of the Data Protection Act (DPA) and Article 59(4) of the Therapeutic Products Act (TPA).

We retain the collected data for the period of the product's marketing authorisation and at least 10 years beyond, this also applies to personal data.

Disclosure of data

We only transmit your data to third parties (e.g. to the competent authority for drug safety, other pharmaceutical companies, credit institutions for payment processing, to lawyers for the enforcement of outstanding claims) if there is an authorisation to transmit data under data protection law (e.g. according to the above-mentioned legal provisions). The transfer of personal data to the competent authority for drug safety takes place exclusively in pseudonymised form. This means that we do not transmit such data (e.g. name, address data, telephone number, full date of birth) or (if such information should be technically necessary) change it before transmission within the framework of existing guidelines in such a way that a direct reference to the data subject is not possible.

If necessary, personal data will be transferred to other pharmaceutical companies acting as our partners, provided that the underlying agreements for the medicinal product in question provide for an exchange of such information.

Your data may also be passed on by us to external service providers (e.g. IT service providers, companies that destroy or archive data) who support us in data processing within the framework of order processing strictly bound by instructions.

We will not sell or otherwise market your personal data to third parties.

Contact Data Protection Officer

You can contact our data protection officer by email: privacy@mteriamedica.ch

Rights of the person concerned

Data subjects have the right to obtain information from the controller about the personal data concerning them as well as to the correction of inaccurate data or to deletion if one of the reasons mentioned in Article 17 GDPR applies, e.g. if the data is no longer required for the purposes pursued. There is also the right to restriction of processing if one of the conditions set out in Article 18 GDPR is met and, in the cases of Article 20 GDPR, the right to data portability.

If data are collected on the basis of Article 6 (1) (f) (data processing for the protection of legitimate interests), the data subject has the right to object to the processing at any time for reasons arising from his or her particular situation. We will then no longer process the personal data unless there are demonstrably compelling legitimate grounds for the processing which override his or her interests, rights and freedoms, or the processing serves the purpose of asserting, exercising or defending legal claims.

Right to lodge a complaint with a supervisory authority

Every data subject has the right to lodge a complaint with a supervisory authority if he or she considers that the processing of data concerning him or her violates data protection regulations. Complaints should be addressed to the state or local competent authorities.