

Privacy Notice for Medical Information Enquiries

Name and address of the controller

Berlin-Chemie / A. Menarini Macedonia LLC, Metodija Šatorov Šarlo St. No. 1/2-15, Skopje – Kisela Voda (hereinafter “**Berlin-Chemie**” or „Controller“). The Data Protection Officer responsible for Berlin-Chemie (“**DPO**”) can be reached at: dpo.macedonia@berlin-chemie.com.

Purpose of this Privacy Notice

Berlin-Chemie respects your right to privacy and treats your personal information in accordance with applicable laws and regulations, including the European General Data Protection Regulation (“**GDPR**”) and North Macedonian Law on Personal Data Protection („Law“). This Privacy Notice is intended to HCPs, patients, consumers, as well as to other persons who contact us with medical information enquiries and explains who we are, how we collect and process personal information about you for medical information purposes, and how you can exercise your privacy rights. If you have any questions or concerns about our use of your personal information, then please contact us using the contact details provided above.

We are affiliated with A. Menarini Industrie Farmaceutiche Riunite S.r.l (head office), Via Sette Santi 1/3, 50131 Florence, Italy, which may also be involved in the collection and processing of the personal data.

What personal information does Berlin-Chemie collect when handling medical Information enquiries and for what purpose?

We may collect name, surname, initials, date/year of birth, gender, contact details and profession of the individual as well as title, name, surname, business address, contact details, the field of activity or position, level of expertise in a certain diagnostic or therapeutic field in the case of HCPs contacting us with a medical enquiry. We may collect health data or data relating to the medical history of an individual submitting an enquiry to us, in case they are relevant for understanding, processing and correctly replying the enquiry in object. We collect this information to respond to your enquiry and keep your personal data in our medical information database for future reference. We may be required by law to report your data to the regulatory authorities, to the extent your enquiry is associated with an adverse event.

Legal basis for processing personal information regarding medical enquiries

We process your personal data based on our legitimate interests (Article 6(1)(f) GDPR, i.e. Article 10(1)(6) of the Law) to respond to your enquiries and to keep a medical information database for future responses. We may also use your data to follow up on them, and keep them in a medical information database for future reference. If you are a patient having health related questions, we may process your health data based on your explicit consent, given by email confirmation (Articles 6(1)(a) and 9(2)(a) GDPR, i.e. Articles 10(1)(1) and 13(2)(1) of the Law).

Additionally, we may be required by law (e.g., pharmacovigilance and drug safety) to report your data to regulatory authorities, i.e. Medicines and Medical Devices Agency of North Macedonia. In such cases, the legal basis for processing is Articles 6(1)(c) and 9(2)(i) GDPR, i.e. Articles 10(1)(3) and 13 (2)(9) of the Law.

Recipients of personal data, transfer of data to third countries

Authorized employees of Berlin-Chemie receive your data for processing for the purposes described above. We cooperate with service providers. These service providers process your data on our behalf, in accordance with our instructions and under our supervision, solely for the purposes described in this Information Notice.

In case you request medical information through our website, your personal data is transferred to BERLIN-CHEMIE AG, Glienicker Weg 125 , Berlin, Germany, where the server of our company's website is located.

If your enquiry is associated with an adverse event, we disclose your personal data to the Medicines and Medical Devices Agency of North Macedonia.

We also disclose your personal data to Berlin-Chemie's affiliated company A. Menarini Industrie Farmaceutiche Riunite S.r.l (head office), Via Sette Santi 1/3, 50131 Florence, Italy, when we need assistance with the response (your enquiry is related to global/corporate products etc.).

We will take all necessary steps to ensure that the information you provide is adequately protected in accordance with the requirements of European Union, i.e. North Macedonian data protection legislation. Where necessary, we ensure a legally adequate level of data protection through EU standard contractual clauses, i.e. standard contractual clauses adopted by the Personal Data Protection Agency.

Duration of data storage

As a matter of principle, we only store your data for as long as is necessary to answer to your enquires or as long as the legitimate interest exists. If the data are no longer required for the fulfillment of the latter, they will be deleted. There are exceptions, e.g., insofar as legal storage obligations are to be fulfilled or for the preservation of evidence within the framework of the statutory statute of limitations. For medical information enquiries purposes, personal data may be kept for 10 years from the date you contact Berlin-Chemie with an enquiry.

Data security

We use technical and organizational security measures to protect your personal data against misuse, loss, destruction, or access by unauthorized persons. Our security measures correspond to the current state of the art.

Privacy Rights

You are entitled to request information about your data stored by us at any time. Furthermore, you have the right to request the correction of incorrect data or, under the legal requirements, deletion, blocking, and restriction of processing and transfer of your data. You also have the right to object to the processing your data based on our legitimate interest at any time. If you have given us your consent, you can revoke this at any time with effect for the future. Please contact our Data Protection Officer under: dpo.macedonia@berlin-chemie.com. In addition, you have the right to file a complaint with the responsible supervisory authority, i.e. the Commissioner for Information of Personal Data Protection Agency, Boulevard Goce Delchev No. 18, (Macedonian Radio and Television MRTV building – 14th floor), 1000 Skopje, phone: +389 (2) 3230 635, email: info@privacy.mk

Obligation to provide data

There are no statutory or contractual requirement to provide personal data, or requirement necessary to enter into a contract. However, if your enquiry is associated with an adverse event we

may be required by law to report your data to Medicines and Medical Devices Agency of North Macedonia.

Status: April 2024