

Data protection information in connection with the reporting of side effects, quality complaints and medical enquiries

Dear product user,

This letter is intended to inform you about how we process your data and your rights when you contact us in connection with a side effect (undesired effect of a pharmaceutical product), a quality complaint or a medical enquiry about our products.

Data controller and contact in data protection matters

We are the controller of the data processing,

CO.DON GmbH
Deutscher Platz 5d
04103 Leipzig, Germany

You can reach us and our data protection officer, Mr Jens Krügermann (kpp group GmbH), with all your questions about data protection as follows:

CO.DON GmbH
Attn: Data Protection Officer
Deutscher Platz 5d
04103 Leipzig, Germany
Telephone: +49 341 991 90 200
Fax: +49 341 991 90 309
Email: datenschutz@codon.de

Which personal data do we collect?

Personal data means all information that can be assigned directly or indirectly to a particular individual. This includes information that can only be attributed to a person indirectly, e.g. by means of attribution to an identifier like a name, an identification number (e.g. patient number) or to site data.

In order to comply with our statutory obligations to trace side effects and quality complaints as well as possible, we particularly collect the following data:

Data about the patient:

- Patient's initials
- Date of birth/age group, sex, weight, height
- Health information, particularly

- ➔ Patient's medical history and current medical condition
- ➔ Treatment indication
- ➔ Details of the side effect, including symptoms, and their therapy and on any potential long-term effects that the side effect may have on the patient's health; if relevant, documents such as laboratory reports and medication taken
- ➔ Details of medication and treatment taken concurrently by the patient or taken at the time the side effect occurred, including the dosage, the length of time taken, the reason for the medication and all subsequent changes to your therapy

Data about the person reporting or making the enquiry:

- Name
- Address data (particularly country)
- Contact data (phone number and email address)
- If relevant, profession, position, specialisation, department
- If applicable, relationship to the person concerned by the report

Purpose of collection, use and disclosure of your data

We only use your data to process your request. This may relate to the processing of reports of side effects and quality complaints about our products and their use, or to the answering of medical enquiries, which may subsequently give rise to reports of side effects. To the extent necessary, the processing of reports on side effects may also include comparisons with other reports of side effects. It may also be necessary for us to contact you to obtain further information about the side effect or the quality complaint. Your data are only used and processed within the company for the purposes mentioned above. Your data are recorded in our safety database in pseudonymous form. The data are pseudonymized for the statutory reporting of side effects to the competent authorities. Your personal data are otherwise not disclosed to anyone.

Legal basis for the data processing

Processing of personal data generally takes place on the basis of Art. 6(1)(c) GDPR, to the extent that the data are collected in the context of reports on side effects. This states that personal data may be processed, if necessary, to meet a legal obligation. We have such a legal obligation to process pharmaceutical safety data under the German Pharmaceutical Products Act (AMG).

Processing of personal data also generally takes place on the basis of Art. 6(1)(f) GDPR, to the extent that the data are collected in the context of medical enquiries. This states that we may process personal data in pursuit of our legitimate interests.

What rights do you have?

You have a right to demand **access** to your personal data stored by CO.DON GmbH at any time.

In addition, you have a right to the **rectification** of incorrect data, to the **restriction** of processing of excessively processed data and to the **erasure** of personal data that have been processed illegitimately or stored for too long (unless they are subject to statutory retention periods or other reasons mentioned in Art. 17(3) GDPR). Furthermore, you have the right to **transfer** all the data you have provided to us in a common data format (right of data portability), to the extent that you have provided us with data in the context of a consent declaration or the performance of a contract.

If you also have a right to object to individual processing methods, you are notified when the individual methods are described.

To assert your rights you can approach us by post at the above address and by phone, email or fax.

You also have the right to complain to a data protection authority about our processing of your personal data.

Data is provided freely

Generally speaking, you provide your personal data voluntarily. However, it is necessary to process certain data about you in order to respond to reports and requests and to make further enquiries. These data include your name and phone number, email address, if available, and other information connected with the respective report or enquiry.

Erasure of data

We erase the collected data when the purpose for their storage no longer exists or restrict their processing if the data are subject to statutory retention obligations. Special provisions of pharmaceutical product law require that data reported/received about side effects is retained for 10 years after the authorisation for the corresponding product expires, or 30 years after the expiry data for the pharmaceutical product, whichever is longer. Many types of personal data are also relevant for tax purposes or constitute commercial documents and so are retained for ten years after the close of the year in which the invoice was sent or the accounting entry made, in accordance with the commercial and tax provisions of Section 147 German Tax Code (AO) and Section 257 German Commercial Code (HGB).