Biotest AG: Data protection notice for drug safety

Thank you for reporting adverse drug effects or other information regarding a Biotest product relevant for drug safety.

This declaration provides information on how Biotest AG (hereinafter referred to as “Biotest”) together with its subsidiaries, including Biotest Pharma GmbH, collects, stores, processes, uses and shares your personal data.

Why we collect your personal data

Biotest processes your personal data for the purpose of monitoring drug safety through the collection, recognition, assessment and prevention of adverse effects or other problems related to medicines.

Biotest processes your personal data on the following basis:

(1) If you report an adverse event pertaining to another person: on the basis that the processing is necessary to comply with our legal obligations regarding drug safety.

(2) If you report the adverse event yourself as the patient: on the basis that the processing is necessary for reasons of public interest relating to public health.

Your personal data are provided on a voluntary basis (provided that you are not a health professional, who is obligated to report adverse events).

We use this information for no other purpose and your personal data will not be provided to any third parties, unless we are obliged to do so by law (e.g. to supervisory authorities) or if these third parties act as data processors on behalf of Biotest.

How long we retain your personal data

Your personal data are retained for only as long as deemed necessary for the purposes described above under reasonable standards and for reasons of public health and as required or permitted in accordance with relevant legislation, but for a minimum of 10 years after the product is no longer on the market in any country.

Who we share your personal data with and who we transfer data to internationally

For the purposes described above, Biotest may share your personal data with other companies in the Biotest Group as well as service providers operating on behalf of Biotest, such as to service providers in IT system administration and user support and providers that process reports related to adverse events.

Biotest is also obliged to report information relevant for pharmacovigilance to health authorities worldwide (including to countries whose level of data protection differs from that of the EU). The reports include detailed information on the occurrence, but only within certain personal data constraints:

- With regard to patients, the report – depending on the information available – will only include age and sex, but never the name of the patient.
- With regard to the reporting persons, the report – depending on the information available – will contain their professional activity (e.g. doctor, pharmacist).

Contact details are required to be able to respond to reporting persons and therefore receive high-quality and complete information on adverse events. If your data are shared with other Biotest companies, business partners, or service providers outside of the EU, we ensure the adequate protection of your personal data. To this end, we are concluding appropriate agreements, such as on data transfer.

You can request information about these third parties as well as copies of the agreements by sending an email to datenschutz@biotest.com.

Your rights

You have the following rights:

- You may check whether we keep personal data on your person and in such case, for what purposes this is done and what type of data this involves, and you can request copies of these data.
- In reasoned cases, you may request the rectification, restriction or deletion of your personal data, insofar as these data are incorrect or are processed for purposes other than the purposes referred to above.
- You can request for us to limit the processing of your personal data.
- There are certain circumstances under which you may object to the processing of your personal data.
- You can request information regarding the identity and/or category of third parties to which your personal data are transmitted.
- You may submit a complaint to the data protection authority in your country.

Controller responsible for data processing

The controller responsible for processing your personal data is the business unit of Biotest that, according to the information in the use instructions (package insert), is registered as the marketing authorisation holder for the medicinal product concerned – here, Biotest Pharma GmbH.

If you have questions regarding the processing of your personal data or this data protection declaration, or if you would like to exercise your rights, you can contact us at any time at datenschutz@biotest.com or get in direct contact with our data protection officer:

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