

PRIVACY STATEMENT

regarding the processing of personal data to carry out the pharmacovigilance activity

The Pharmacovigilance Service of BIOFARM SA responds to a public health problem, having an important role for patient safety and a significant contribution to the transmission of correct information to consumers, to the promotion of rational use and to the permanent analysis of the benefit-risk ratio for the medicines from our company's portfolio.

This information regarding data processing applies to all reporters and/or patients using Biofarm products.

INVOLVED PROCESSING ACTIVITIES

PROCESSING ACTIVITY	Explanations
A1 – Collection by RA/RAG, completion and transmission of individual reporting sheets	Biofarm is responsible for receiving, collecting and sending the individual Biofarm's product reporting sheets.
A2 – Case processing and medical evaluation	Biofarm is responsible for case processing and medical evaluation.
A3 – Transmission of individual reporting sheets to the competent national/European authorities	Biofarm will report the information from the individual reporting sheets to the national/European authorities.
A4 – Requesting medical information and technical complaints regarding products	Biofarm is responsible for the transmission of all medical information and complaints/requests regarding Biofarm products.
A4 - Archiving	BIOFARM is responsible for data archiving, in accordance with legal provisions.

Targeted personal data

Patient identification data	Patient medical data	Reporter identification data
<input checked="" type="checkbox"/> Patient number <input checked="" type="checkbox"/> Patient initials <input checked="" type="checkbox"/> Age / Age category <input checked="" type="checkbox"/> Birth date <input checked="" type="checkbox"/> Gender <input checked="" type="checkbox"/> Weight <input checked="" type="checkbox"/> Height	<input checked="" type="checkbox"/> Patient medical history <input checked="" type="checkbox"/> Concomitant treatments <input checked="" type="checkbox"/> Side effects <input checked="" type="checkbox"/> Medication interactions <input checked="" type="checkbox"/> Symptoms <input checked="" type="checkbox"/> Pre-existing conditions and allergies <input checked="" type="checkbox"/> Treatment of side effects	<input checked="" type="checkbox"/> Name, Surname <input checked="" type="checkbox"/> Address <input checked="" type="checkbox"/> Phone <input checked="" type="checkbox"/> Email <input checked="" type="checkbox"/> Qualification <input checked="" type="checkbox"/> Signature

Legal basis for processing

Pursuing the company's legitimate interest in protecting the health of its patients and ensuring the continuity of the company's business.

The pharmacovigilance activity is carried out in accordance with the provisions of Law no. 95/2006 regarding health reform.

Storage period

Medical documents regarding the patient's state of health and medical history are kept for a period of 100 years, according to the National Archives Law no. 16/1996.

Data recipients

Biofarm will not share/transfer this data to other processors without the consent of the data subject. The data mentioned in the individual reporting sheets will be communicated to the competent authorities, in accordance with the applicable legislative provisions.

Personal data will not be subject to an international data transfer.

Data subjects' rights

You have the right to request from the processors, regarding the personal data relating to the data subject, access to them, their rectification or deletion or restriction of processing or the right to object to processing, as well as the right to data portability.

Additionally, the data subject may exercise, at any time, concerning Biofarm, the right to withdraw its explicit consent.

Further information

We invite you to study our privacy policy to learn more about Biofarm S.A.'s commitment to the protection of personal data and to learn more about your rights and how you can exercise them, using the following contact addresses:

dpo.biofarm@biofarm.ro