

## PRIVACY NOTICE PRODUCT QUALITY COMPLAINTS

In accordance with Article 13 of the General Regulation on the Protection of Personal Data of the European Union 2016/679 (GDPR) and any applicable Data Protection Law

Following your notification of the problem associated with the product quality [Enter the Name of the product] you have encountered, we inform you that Dompé, as the holder of the Commercial Authorization (AIC), will process the Personal Data provided by you, in order to ensure the safety and effectiveness of all products. For this reason, the Company has provided information pursuant to art. 13 GDPR specific for the processing of personal data and any applicable Data Protection Law.

### DATA CONTROLLER

Pursuant to articles 4 and 24 of EU Reg. 2016/679, Dompé farmaceutici S.p.A. has its registered office in Via San Martino 12-12a, - 20122 - Milan (MI) and operating headquarters in Via Campo di Pile s.n.c. - 67100 L'Aquila;

The contact details of the Owner are as follows: e-mail: [privacy@dompe.com](mailto:privacy@dompe.com) tel.: 02583831

### DATA PROTECTION OFFICER

In compliance with the provisions of Articles 37 - 39 of EU Reg. 2016/679, the Company has also appointed a Data Protection Officer (DPO), whose contacts are listed below: e-mail: [dpo@dompe.com](mailto:dpo@dompe.com)

### TYPE OF DATA PROCESSED

With reference to the processing subject of this information, Dompé will collect and process the following personal data, including particular data (so-called sensitive data): - name and surname, telephone, e-mail of the reporter and the data related to the quality problem encountered:

<b>Treatment Purposes</b>	Taking charge of and managing the quality alert and, if requested, sending any feedback to the reporter. Any reports associated with requests for in-depth medical examination or concerning adverse events will be forwarded to the relevant departments that will manage the data for the purposes provided for by law based on the applicable regulations and in line with the GDPR.
<b>Legal Basis</b>	The legal basis of the treatment is identified in the pursuit of the legitimate interest, aimed in particular, to carry out the above mentioned activity in compliance with the provisions of the laws and regulations in force at Global level, in Europe and in Italy regarding the supervision of product quality, to which Dompé farmaceutici S.p.A. is subject as producer and only for Italy by art. 70 of Legislative Decree 219/06, Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009, Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States.
<b>Data Retention</b>	Personal data will be processed for the time strictly necessary to pursue the abovementioned purpose of quality management. And in any case no longer than 15 days from the closing of the product complaint). Personal data will be subsequently deleted
<b>Nature of Provision</b>	The provision of data is necessary for the management of the quality claim. Failure to provide the data will preclude the Data Controller from taking charge of the report.

### DATA COMMUNICATION

The personal data processed will be communicated to authorized and/or responsible persons in any case duly trained and instructed.

### DATA TRANSFER TO EXTRA UE

Personal data will not be transferred to countries outside the European Union.

In the event of product quality complaints associated with adverse reactions, refer to the Privacy Notice on the website [www.dompe.com](http://www.dompe.com) in the dedicated section.

### RIGHTS OF THE DATA SUBJECT

You may assert your rights as expressed in Articles 15 et seq. of EU Regulation 2016/679, by contacting the Data Controller or the DPO directly at the contacts listed above. In particular, you have the right, at any time, to obtain, from the Data Controller, access to your personal data and request information on the processing and to limit its processing. If you believe that the processing of personal data carried out by the Data Controller is in breach of the provisions of Regulation (EU) 2016/679, you have the right to lodge a complaint with the Supervisory Authority - Garante Italiano (<https://www.garanteprivacy.it/>)