

PRIVACY NOTICE PURSUANT TO ARTICLE 13 OF THE EU REG. NO. 679/2016 ON THE PROTECTION OF INDIVIDUALS WITH REGARD TO THE PROCESSING OF PERSONAL DATA AND ON THE FREE MOVEMENT OF SUCH DATA ("GDPR")

Pursuant to Article 13 of the GDPR, the company Dompé farmaceutici S.p.A. (hereafter referred to as "**Dompé**"), as Data Controller, being the marketing authorization holder for medicinal products as well as the manufacturer or distributor of medical devices, cosmetics, and nutritional supplements is required to provide certain information about the use of Personal Data collected in the event of spontaneous reports regarding the occurrence, of adverse drug reactions/experience and special situation, of unusual failure in efficacy, of incident and inconvenience, unwanted or undesirable event or effects, or however named according to the applicable local law (now referred to as "**Undesirable Effect(s)**"), occurring after taking a drug or after the use of medical device, cosmetic, or nutritional supplement.



Identity and contact details of the Data Controller and of the DPO

In this section we indicate our references

DATA CONTROLLER

Dompé farmaceutici S.p.A., with registered office at via San Martino 12, 20122, Milano, Italia, in the person of its pro-tempore legal

e-mail: privacy@dompe.com

DPO: dpo@dompe.com



Purpose and legal basis of the processing

In the section we explain why we collect Your data

Your Personal Data, which you have freely provided, will be collected and processed by Dompé:

➤ **without Your consent (ex Art. 6.1 (c), GDPR)**

for the execution of mandatory legal obligations in the field of pharmacovigilance and vigilance (by way of example but not limited to: EU Directive 2010/84, EU Regulation 1235/2010, EU Regulation 520/2012 and EU Regulation 2017/745, as well as any additional local regulations in force), and more specifically, for the purpose of identifying any unknown Undesirable Effects, improvement of information on already known Undesirable Effects, assessment of the causal link between administration of the drug as well as the use of the medical device, cosmetic or food supplement and the undesirable effect observed, as well as notification to the competent authorities of such information to ensure that the that the drugs, the medical devices, cosmetics or nutritional supplements are safely used and present a favorable benefit/ risk assessment for the population.

The provision of your Personal Data for the above purpose is necessary. Failure to provide it on your part will not allow Dompé to fully fulfill the above pharmacovigilance and vigilance obligations.



Categories of Personal Data

In this section we indicate what data we collect

As part of the purpose described above, Dompé will collect and process the following Personal Data:

for the reporter (ex Art. 4, no. 1 GDPR)

- Identifiable Data: initials or name and last name;
- Contact Details: postal address, e-mail address and telephone number (landline or mobile)

for the subject to whom the report refers (ex Art. 4, no. 1 and no. 15 and 9, GDPR)

- Identifiable Data: initials or name and last name, age or date of birth;
- Contact Details: City of residence, telephone number (landline or cellular), e-mail address;
- Particular Data: sex, data relating to the state of health as well as any other information contained in the report.



Methods of data processing

In this section we tell you how we use Your Personal Data

We process Your Personal Data in line with the legislative provisions in force, through the use of supports and / or IT, manual and / or telematic tools, in compliance with adequate technical and organizational security measures following logic strictly related to the purposes for which data is collected.



Recipients or categories of recipients of the data

In this section we indicate who uses Your Personal Data

In relation to the purposes indicated above, Your Personal Data are also processed by:

- as data controllers, by way of example but not limited to:
 - a) Regulatory Authorities (Italian and foreign): AIFA, FDA, EMA etc.,
 - b) Health control bodies, public administration bodies, public security authorities or judicial authorities
- as Data Processors and Sub-Processors of the processing, appointed pursuant to art. 28, GDPR:
 - a) Companies of the Dompé Group, located, including outside the European Union (or outside the country where the data are collected);
 - b) business partners in Italy and abroad;
 - c) professionals and / or companies appointed by the Data Controller to perform support activities for the purposes referred to in this privacy notice;

- d) IT service providers for the management of the technological infrastructure, information systems and telecommunications networks.

The complete and updated list of data recipients, as well as those authorized subjects pursuant to Art. 29, GDPR, can be requested at the addresses indicated above.

Your Personal Data will be shared, with the subjects indicated above, where necessary.



Dissemination of Data

In this section we indicate whether Your data is disclosed to indeterminate subjects

Your Personal Data are not disclosed to indeterminate subjects.



Data transfer abroad

Your Personal Data, where collected both in the territory of the European Union and in countries outside the European Union (including through the companies of the Dompé Group), may be disclosed to third parties, located in countries outside the European Union or the territory in which they are collected (including the companies of the Dompé Group). In any case, we guarantee that this transfer will only take place in accordance with the principles expressly established by the GDPR in order to adequately protect the data.



Duration of the conservation of data

In this section we indicate how long we will conserve Your data

Your Data will be processed for the time strictly necessary to pursue the purposes of pharmacovigilance and vigilance of the safety of other products, which Dompé is required by law. In relation to this purpose, Your Personal Data are stored in the security database for the time strictly necessary to manage the report and the related follow-up.

Specifically, Personal Data will be pseudonymized within three months of the closure of the case and in any case not later than two years from the end of the financial year in which the initial report took place.

All data relating to the reporting of Undesirable Effects will be conserved as long as the product is authorized and for a maximum period of 10 years starting from the expiration or revocation of the marketing authorization of the product in the last marketing country, except any defensive needs of the Data Controller. At the end of this period, the data will be deleted or made anonymous so as not to allow, even indirectly or by connecting other databases, the identification of the data subjects.



Rights of the Data Subjects

In this section we indicate what rights You have in relation to Your data

At any time, you may exercise the following rights:

- a) right of access, i.e., the right to obtain confirmation from Dompé that Personal Data is or is not being processed and, if so, to obtain access to it;
- b) right of rectification and erasure, i.e. the right to have inaccurate Data corrected and/or incomplete Personal Data supplemented or erased for legitimate reasons;
- c) right to restriction of processing, i.e., the right to request the suspension of processing if legitimate grounds exist;
- d) right to data portability, i.e., the right to receive Personal Data in a structured, commonly used and readable format, as well as the right to transmit the same to another data controller;
- e) right to object, i.e., the right to object to the processing of Personal Data if there are legitimate grounds.



Complaint to the authority

We highlight Your right to be able to appeal to the competent data protection authority

You also have the right to lodge a complaint with the competent data protection authority in the event of unlawful processing of Personal Data if you believe that Your rights have not been respected or that your requests have not been responded to in accordance with the law.

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