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PHARMACOVIGILANCE - Spontaneous Reporting

Circular pursuant to art. 13 of the General Data Protection Regulation (UE Regulation 679/2016).

Pharmacovigilance includes a series of activities that involve the Supervisory Authorities, Marketing Authorization Holders (MAHs), Local Health Authorities and Healthcare Professionals. The contribution made by citizens is essential to ensure that the whole pharmacovigilance system works.

Within the field of pharmacovigilance, MAHs have the legal obligation of recording in detail all suspected adverse reactions observed in the European Union or in any another country.

Likewise, vigilance focused on the safety of medical devices, cosmetics and food supplements includes activities designed to collect reports of incidents, inconveniences or undesirable effects (hereafter referred to as undesirable effects), the assessment of same and their notification to the Supervisory Authorities in order to safeguard the health of consumers. A spontaneous report is the communication by a healthcare professional or a patient / consumer related to the onset of an adverse event or undesirable effect suspected to have occurred after the intake of a product. Such reports are the tool that enables pharmaceutical companies to detect potential alarming safety signals regarding the products that they market. The quality and completeness of the information collected within the context of spontaneous reporting are essential to ensure that the pharmacovigilance system works properly, as well as vigilance on the safety of other products. The quality of the information is determined by the consistency of the data, their completeness and the precision with which they are reported. An incomplete report might not enable the assessment of the causal relationship between the medication and the event, resulting in the emergence of a potential safety signal.

As far as medicinal products are concerned, spontaneous reports are made by healthcare professionals or patients by filling in the Suspected Adverse Reaction (ADR) Reporting Form (which applies to any medicinal product or vaccine) or the electronic version online (provided by the National Medicines Authority via web). All the ADR reports originating from European countries are entered into the European Network (Eudravigilance). Alternatively, the adverse reaction report can be communicated by the healthcare professional or patient to the MAH of the suspect medicinal product.

As far as other types of product are concerned, undesirable effects are reported by the consumer to the healthcare professional or the company that markets the product and subsequently communicated, by means of specific report forms, to the Supervisory Authority, according to the relevant legislation.

Pursuant to art. 13 of the General Personal Data Protection Regulation (EU Regulation 679/2016) and the relevant national legislation, Dompé Farmaceutici S.p.A. wishes to inform you about the processing of the personal data that you have freely provided via a spontaneous report within the context of the pharmacovigilance system as well as vigilance on the safety of other products..

PURPOSES OF THE PROCESSING

The personal data that you have provided will be collected and processed only for the purposes of pharmacovigilance and vigilance focused on the safety of other products, which the Company is obliged to implement by law.

The data will be collected and processed exclusively to perform activities related to and required for the achievement of the purposes of pharmacovigilance and vigilance on the safety of other products adequately, such as, e.g., (i) detecting any unexpected adverse reactions / undesirable effects (ii) improvement and strengthening of information on expected suspect adverse reactions / undesirable effects; (iii) notification to the Supervisory Authority; (iv) monitoring of the benefit / risk ratio, ensuring that it is favourable for the population.

MODALITIES OF PROCESSING AND PROVISION OF DATA, AND CONSEQUENCES OF FAILURE TO DO SO

The processing of personal data may occur manually, resorting to IT or telematic devices, with configurations closely related to the purposes for which the data have been collected. It will always be suited to guarantee their safety and confidentiality.

The provision of data is voluntary, but failure to provide data could jeopardize the proper functioning of the pharmacovigilance system.

RECIPIENTS OF YOUR PERSONAL DATA

The data provided will be processed by company pharmacovigilance staff and by staff belonging to departments where adverse events and the consequences resulting from the reports are managed.

Furthermore, for the entry and management of adverse event reports the Company resorts to external service suppliers, who maintain the IT platform and who offer services related to the management of data collection and processing systems, archiving of data in electronic formats and archiving of documentation, and who act on our behalf in the capacity of data processing controllers, based on specific contract obligations.

As laid down by legislation, the Company will make your personal data available for the purposes described above to subjects who access the European Pharmacovigilance Network (Eudravigilance), as well as to subjects obliged to carry out pharmacovigilance activities (Medicines Agency, MAHs, Regional Pharmacovigilance Centers) or vigilance on safety of other products (Supervisory Authority and manufacturers / distributors) who process data independently. In some circumstances, we share personal data also with (i) other companies belonging to the Dompé Group both in Italy and abroad, also outside the EU, in particular for the management of the pharmacovigilance reporting system and for notification to Regulatory Authorities in the various countries; (ii) subjects whose authority to access personal data is acknowledged by legislative provisions, secondary legislation or orders by public authorities (e.g. Judicial Authorities and/or Regulatory Authorities). These subjects will process your data in the capacity of independent processing controllers.

To the purposes of the reports as indicated above, your personal data may be transferred to another Member State of the European Union in the event of sharing information with other companies of the Dompé Group in Europe or to vigilance and judicial authorities, as appropriate, for the management of any reports. In the event that such subjects are located out of the European Union, their transfer will occur only when one of the legal legitimacy terms is met (after having stipulated typical contract clauses).

Your data will never be published or disseminated in any other way to indiscriminate addressees.

Should you be pregnant or breast-feeding, or in the event of particularly significant developments or if we believe that the acquisition of additional information is required to better safeguard your health and the health of the population, we shall ask you to allow Dompé staff to contact your attending physician to collect additional information and, on that occasion, to bring some details regarding the report to his/her attention.

This request will be made by sending you a consent form that you are to return duly signed together the contact information of your attending physician.

We wish to specify that the attending physician acts as an independent data processing controller.

DURATION OF DATA PROCESSING AND STORAGE

The personal data collected will be stored for the period of time required to achieve the objectives specified above, in compliance with the legislation in force, and in any case to meet any legal obligations. In particular, personal data will be anonymized no later than three months after closing the case and in any case no later than two years after the end of the exercise in which the first report occurred.

RIGHTS OF THE DATA SUBJECT

We wish to also inform you that, within the restrictions and terms laid down by articles 15 – 23 of the General Personal Data Protection Regulation (EU Regulation 679/2016) and in compliance with relevant national legislation, it will be possible to exercise the following rights:

- the right to access the personal data in your hard copy and/or electronic files;
- the right to ask for rectifications, updating or erasure, in the event that data are incomplete or erroneous, as well as to object to their processing for legitimate and specific reasons;
- the right to rectification of inaccurate personal data without undue delay. Bearing in mind the purposes of the processing, the data subject has the right to have incomplete personal data completed, also by providing a supplementary statement;
- the right to erasure of personal data without undue delay if one of the reasons laid down in art. 17, item 1 of Regulation EU 679/2016 applies;
- the right to restriction of processing when one of the hypotheses laid down in art. 18, item 1 of Regulation EU 679/2016; applies

- the right to data portability within the restrictions and modalities laid down by art. 20 of Regulation EU 679/2016 and by Guidelines related to data portability;
- the right to object to processing;
- the right to lodge a complaint with the Supervisory Authority.

Should treatment be based on your consent, we wish to remind you that you can revoke such consent at any time. Revoking consent does not jeopardize the lawfulness of the processing carried out up to that time. Any requests are to be sent to the e-mail address: privacy@dompe.com

Data processing controller: Dompé Farmaceutici S.p.A. with registered offices in Milano, via San Martino 12/12a.

The Data Protection Officer (DPO) may be contacted at the following email address: DPO@dompe.com