Privacy Policy for Pharmacovigilance data - Notice on data processing for Pharmacovigilance

ACS Dobfar S.p.A. is a producer and marketing authorisation holder (”A. I. C. holder") of medicinal products and a producer of pharmacologically active substances.

ACS Dobfar S.p.A. continues to monitor the safety of medicinal products even after placing them on the market through the Pharmacovigilance tool, which consists of all activities aimed at identifying, evaluating, understanding and preventing adverse effects or any other problem related to the use of medicinal products, to ensure the protection of Public Health and guarantee the highest quality and safety standards of ACS Dobfar S.p.A. products.

This document - also intended as a privacy statement pursuant to art. 13 of the European Regulation 2016/679 GDPR - aims to describe the procedures for the collection and use of personal and health data in the event of spontaneous reports relating to the onset of adverse reactions or problems that are suspected to have occurred after taking a drug.

Data controller of personal and health data is ACS Dobfar S. p. a. Tax code and VAT number 05847860151, with Registered office in Tribiano, Viale Addetta 4/12.

Data processor of personal and health data is the Pharmacovigilance Office of ACS Dobfar S.p.A., domiciled at the administrative offices of the company in Agrate Brianza (MI), Palazzo Pegaso Entrance 2, Viale Colleoni n. 23, and available at the following e-mail address: pharmacovigilance@acsdobfar.it

We also inform you that in Italy the authority responsible for Pharmacovigilance is the **Italian Medicines Agency (AIFA)**. Reports of adverse reactions, from doctors, health workers and citizens, can be made directly to the AIFA, following the instructions at this link: Adverse reactions reports / Agenzia Italiana del Medico (aifa.gov.it).

Finally, we remind you that any health problems must be communicated in the first instance to your doctor or the nearest health facility.

A) reporting of suspected adverse reactions/side effects

Reports of suspected adverse reactions / side effects are an important source of information for Pharmacovigilance activities, as they allow the detection of potential warning and/or alarm signals.

Adverse Event: it is any unfavorable episode that occurs after the administration of a drug, but that is not necessarily caused by taking the drug;

Adverse Reaction- it is a harmful and unintentional response to a drug for which a causal relationship with the drug itself can be established. To distinguish, therefore, whether we are facing an adverse event or an adverse reaction, we must assess whether it is possible to trace a cause related to the medicinal product. It is not enough that the event occurred within a short distance of vaccination or taking the drug. Adverse reactions may result from consistent or improper use of the product with respect to the terms of the marketing authorisation (AIC), or as a result of occupational exposure. Misuse includes the use of the drug in all conditions not provided for by the AIC, overdose, misuse, abuse and medication errors. Other conditions requiring specific reporting are transmission of infectious agents via the drug, use in pregnancy and lactation, lack of efficacy, drug interactions, drug addiction.

Side effect: it is an unintended effect related to the properties of the drug that is not necessarily harmful and has been observed in a number of people. This is therefore a possible known effect, which has occurred over time and is considered acceptable.

B) Scope of data processing, types of data processed and consequences in case of refusal to provide your personal and health data

The personal and health data you freely provide will be collected and processed solely to comply with legal obligations relating to Pharmacovigilance and, more specifically, for the purposes of identifying any unknown adverse reactions, improving information on suspected adverse reactions already known, assessing the causal link between the administration of the drug and the observed adverse reaction, and notifying the Competent Authority of such information to ensure that the drugs used present a favorable benefit/risk ratio for the population.

For the purposes of the aforementioned pharmacovigilance activity, ACS Dobfar S.p.A. will process the following data:

1) for the whistleblower: name; contact details (address, e-mail, telephone number); profession (this information can determine the questions that will be asked about the suspected adverse event, based on the alleged level of medical knowledge of the whistleblower); and relationship with the subject of the report (eg. the whistleblower is the patient's attending physician or a relative or the patient himself);

2) for the subject to whom the alert refers (“patient”): name and/or initials of the patient; date of birth/age group, gender, weight, height; information on health, racial or ethnic origin and sex life; medical history and medical conditions, which may include for example: details of the medicine suspected of causing the adverse event, including the dosage that was taken or was prescribed, the reason why the medicine was taken or was prescribed and any subsequent changes to the usual regimen of taking such Medicine; details of other medicines or remedies that the patient was taking or that you were taking at the time of the adverse event, including the dosage you

were taking or were prescribed, the period of time that medicine was taken, the reason for taking or prescribing that medicine and any subsequent changes to the regimen of taking that medicine; details of the adverse event suffered by the patient, the treatment you received for that event and any potential long-term effects that the adverse event caused to your health; and any other elements or details considered relevant for reporting.

We inform you that the provision of the above data takes place on a voluntary basis; however, the failure to provide the data referred to in point 1) could prejudice the correct management of your report, while the failure to provide at least one of the identification data indicated in point 2) (ie, name and/or initials of the patient and date of birth or age group) will imply the impossibility to comply with legal obligations in the field of Pharmacovigilance.

The data indicated in points 1 and 2 are exemplary and not exhaustive. For the purpose of Pharmacovigilance activity it is not necessary to provide all of them, however, it should be taken into account that the more information and details provided, the more thorough the pharmacovigilance activity can be.

C) Processing methods

The processing of personal data provided by you or otherwise acquired in the context of our activity in compliance with the legal and contractual provisions in force, takes place through manual, computer and telematic tools, with logics strictly related to the purposes themselves and may involve all the operations provided for by Article 4, paragraph 2, of the GDPR (eg. collection, storage, processing, cancellation, updating, etc.) in compliance with the law and the confidentiality obligations imposed by it.

D) Legal basis of processing and legitimate interest

ACS Dobfar S.p.A. process your personal data, including sensitive data, including health data, in accordance with the GDPR in order to comply with the obligations arising from the laws and regulations on pharmacovigilance and your legitimate interests in ensuring the purposes of Pharmacovigilance (art. 6 GDPR), as well as in consideration of the legal obligations imposed on ACS Dobfar S.p.A. for reasons of significant public interest in the field of Public Health and the safety of medicinal products (art. 9 GDPR).

E) Communication to third parties

The data you provide will be made available, for the purposes indicated above, to subjects who access the National Pharmacovigilance network, as well as to subjects obliged to carry out pharmacovigilance activities (AIFA, EMA, holders of marketing authorization for medicines, Italian regions, Local Health Units, pharmacovigilance Office of hospitals or scientific research and treatment Institutes). The personal data provided may also be communicated, for the purposes indicated above, to the following categories of subjects: (i) other companies of the ACS Dobfar S.p.A. group. or business partners both in Italy and abroad, even outside the EU in the manner specified below; (ii) subjects who may have access to such data by law or order of the Public Authority; (iii) public and/or private subjects, natural and/or legal persons with respect to whom communication is necessary for the pursuit of the purposes of Pharmacovigilance specified above. The subjects belonging to the categories listed above will use the data as independent data controllers and in relation to the specific activity carried out, or, in relation to the activity carried out, as external data processors pursuant to art. 28 of the GDPR, specifically appointed with specific appointment agreement containing the indication of the processing methods and

security measures that they must adopt for the management and storage of personal data of which ACS Dobfar S.p.A. is the owner.

In case of data transfer outside the European Union, ACS Dobfar S.p.A. will take all appropriate and necessary contractual measures to ensure an adequate level of data protection, including - among others - agreements based on standard contractual clauses for the transfer of data outside the European Economic Area, approved by the European Commission.

You can request information on the transfer of your personal data abroad at any time by contacting the data controller or the data processor at the addresses indicated above.

F) Place of processing

Personal data will be processed within the territory of the European Union. If for technical and/or operational reasons it is necessary to use subjects located outside the European Union, it is hereby guaranteed that the transfer to these subjects, limited to the performance of specific processing activities, will be carried out in accordance with the provisions of the GDPR.

G) Data retention period

Pharmacovigilance reporting data shall be kept for as long as the product is authorised and for ten (10) years from the expiry or revocation of the marketing authorisation of the product in the last country of marketing, except for any defence requirements of the holder. At the end of this period, the data will be made anonymous so as not to allow, even indirectly or by linking other databases, the identification of the interested parties.

H) Rights of interested parties

Pursuant to art. 13, 15-22 of the GDPR, the interested party has the right to exercise the following rights: (i) right of access, i.e. the right to obtain from ACS Dobfar S.p.A. (II) the right to rectification and erasure, i.e. the right to obtain the rectification of inaccurate data and/or the integration of incomplete data or the erasure of data for legitimate reasons; (iii) the right to restriction of processing, i.e. the right to request the suspension of processing if there are legitimate reasons; (iv) the right to data portability, i.e. the right to receive data in a structured, commonly used and readable format, as well as the right to transmit the data to another data controller processing; (V) right to object, i.e. the right to object to the processing of data if there are legitimate reasons; (VI) right to contact the guarantor authority for the protection of personal data in case of unlawful processing of data.

The above rights may be exercised at any time by the interested party with a request addressed without formalities to the data processor by writing to ACS DOBFAR S.p.A., Palazzo Pegaso, Entrance 2, Viale Colleoni n. 23, 20864 Agrate Brianza (MI), to the attention of the data processor or to the e-mail address pharmacovigilance@acsdobfar.it. Such request will be provided with appropriate response, without delay and in any case no later than 30 days from receipt of the same, except for cases of greater complexity or in the case of a large number of requests received, in which this period may be extended by a further 2 months.

We inform you that, however, the aforementioned rights may be limited in order to fulfill pharmacovigilance obligations. Your rights are limited where there is a legal basis for processing your personal data, for example we cannot delete information that has been collected as part of

an adverse event report unless it is inaccurate. We may require you to provide adequate personal identification before fulfilling any request to access or correct your personal data.

(I) Amendments to this policy

The data controller reserves the right to update this information at any time. It is therefore advisable to carry out periodic checks, in order to be updated on the company's Privacy Policy. In the event of material changes to the policy, a notice will be posted on the site, along with the updated privacy policy.