PRIVACY POLICY STATEMENT PURSUANT TO ARTICLES 13 AND 14 OF EU REGULATION 2016/679 (GDPR)
Pharmacovigilance reports

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Processing operations relating to the spontaneous submission of reports sent by mail to the address pharmacovigilance@sit-farmaceutici.com or by phone to the number +39 0677209020

To Mr/Ms

Pursuant to article 13 and 14 of the GDPR, the Company Laboratorio Farmaceutico SIT S.r.l. (hereinafter "***SIT***" or the "**Company**") having its registered office in Via Cavour, n. 70 - 27035 Mede (PV) VAT number 01467050181, email address privacy@sit-farmaceutici.com tax code 01108720598, in its capacity as Data Controller, with regard to personal data collected when reports are submitted, wishes to advise you of the following information.

SIT shall process general personal data in addition to personal data falling into the special categories as per article 9 of the GDPR, relating specifically to the data subject's health or sex life, where possible anonymously, in order to comply with obligations relating to pharmacovigilance, notably activities of public interest organised by the Italian Pharmacy Agency (AIFA).

The data may originate from spontaneous reports submitted by the data subject or otherwise due to legal obligations by relevant authorities or otherwise professionals in the health sector who have independently provided the data subject with information within the scope of their activities.

For further clarification, the Data Controller may be contacted by using the email address privacy@sit-farmaceutici.com

Purpose and legal basis of data-processing

the data sent, through the site, by email, telephone or using any other means, shall be processed

a) in compliance with obligations governing pharmacovigilance, in other words assessing, understanding and preventing adverse reactions or any other problem, related to the use of pharmaceutical products;
b) for the necessary scientific research purposes.

The legal basis for the processing of general information is an obligation to which the Data Controller is subject (article 6.1.c GDPR); whenever special/sensitive information is processed this shall be done solely in accordance with reasons of public interest in the public health sector (article 9.2.i and e GDPR and generally, for any significant general interest (article 9.2.g GDPR) in accordance with national and international law (Law Decree 30 April 2015, EU directive 2010/84, EU directive 2012/26).

The Company may also process data in order to assert or defend a right in a court of law and in order to deal with any litigation, for example in the event of any legal disputes. The legal basis of such processing derives from the Company's legitimate interest to safeguard its own rights in addition to third-party rights.

2. Manner of provision of data

The provision of data relating to pharmacovigilance may serve to ensure the best possible security for all parties. For this reason, health professionals and companies operating in the health sector are under a legal obligation whilst for others it is optional but represents an act of responsibility. In the event of failure to provide data, it will not be possible to pursue the aforementioned aims.

3. Categories of parties to whom data may be forwarded.

Only authorised parties who are duly instructed pursuant to articles 29 GDPR and 2 *quaterdecies* of the Personal Data Protection Code may have access to data (also with regard to compliance with security measures and confidentiality obligations), by way of example: the Company's salaried employees receiving reports submitted on pharmacovigilance).

Such parties, the number of which shall as far as possible be limited, shall be suitably instructed in order to avoid any loss, destruction or unauthorised access of data or any processing of data when consent has not been granted.

In order to perform these activities relating to the processing of personal data, SIT may forward personal data to the following categories:

a) the public and private bodies which are responsible for performing tasks relating to pharmacological vigilance - the national pharmacological vigilance network, AIFA, Italian regions, local health authorities, the pharmacological vigilance office in hospitals and scientific research and healthcare institutes;
b) partner companies, consultants or professionals engaged by the data controller to verify and manage in the best way possible, all reports submitted relating to audits, legal services, IT services and organisational consultancy services;
c) entities managing databases collecting information pertaining to pharmacological vigilance;
d) after being anonymized, such data shall subsequently be shared with the scientific community and all those interested in pharmacological vigilance.

All recipients of the personal data process such data in their capacity as "Data Controllers", in full autonomy, or otherwise as "Data Processor" on the basis of a data-processing agreement entered into with SIT. The complete updated list of the Data Processors and independent Data Controllers can be obtained by sending a written request to SIT.

The data shall not be disclosed or transferred to any third country (or site outside the European Economic Area) or to any international organisation. Should it become necessary to transfer the data to a third country outside the European Economic Area, the Company guarantees that such transfer shall be made solely when an adequacy decision has been adopted by the European Commission or other appropriate guarantees have been provided in accordance with legislation governing the protection of personal data (such as for example stipulating standard contractual clauses with the recipient of the data).

4. Data retention period.

The data shall be retained for administrative purposes and for managing pharmacological vigilance duties for a period of 10 years and in accordance with applicable regulations for scientific purposes.

5. Data Subject's Rights

Exercising the rights indicated in this section is not subject to any formal restrictions and is free of charge, except in the case of patently groundless or excessive requests pursuant to article 12 (5) of the GDPR. With regard to the data processing operations described in this policy statement and pursuant to the GDPR, the Person exercises the following rights:

−the right to access one's own personal data and all the information as per article 15 of the GDPR,

−the right to rectify one's own incorrect personal data and to supplement data which is incomplete,

−the right to delete one's own data, with the exception of data placed on file which must necessarily be stored by the Company and unless there are legitimate overriding grounds for proceeding with processing operations;

−the right to limit processing operations in the eventuality of one of the cases contemplated by article 18 of the GDPR.

−the right to object to the processing of one's own personal data, without prejudice to provisions governing the need and requirement to conduct processing operations for purposes of initiating relations

−the right to withdraw any consent previously granted to non-mandatory data processing, without this adversely affecting the legality of processing conducted on the basis of consent granted prior to such withdrawal.

The data subject is also entitled to file a complaint with the Data Protection Authority (www.garanteprivacy.it) or to the Data Protection Authorities in EU Member States where the data subject habitually resides or works, or otherwise the place where the alleged breach occurred, with regard to any data processing operation deemed non-compliant.

For all these requests, the data subject may contact the Company Laboratorio Farmaceutico SIT S.r.l. having its registered office in Via Cavour, n. 70 - 27035 Mede (PV) VAT number 01467050181, email address privacy@sit-farmaceutici.com.