
Privacy Information for Pharmacovigilance reports

ITEL Telecomunicazioni S.r.l., with headquarters in Via A. Labriola Z.I. snc, 70037 Ruvo di Puglia (BA) (hereinafter "ITEL"), pursuant to art. 13 of EU Reg. 2016/679, as Data Controller wants to inform you of the following.

The data and information that we want to communicate will be used by us for pharmacovigilance purposes, that is to say the set of activities aimed at continuously evaluating all information relating to the safety of drugs and to ensuring, for all medicinal products on the market, a report favorable benefit / risk for the population. Furthermore, the information that you communicate to us will be used to fulfill the obligations imposed on us by Italian and European legislation concerning the safety and efficacy of medicines. This legislation requires us to send health authorities information on possible adverse reactions following use or exposure to one of our medicines and to respond to any requests from the competent authorities; the reports are transmitted - normally - indicating only the initials and the year of birth of the subject, and with your specific consent, to contact you in case of need and to respond to your further requests. The provision of data is free, but failure to provide it could jeopardize the correct functioning of the pharmacovigilance system and will not allow us to fulfill the obligations imposed on us by current legislation with the competent authorities.

The personal data communicated by you will be collected and processed by ITEL's authorized and trained pharmacovigilance staff and by the suppliers who collaborate in the area of pharmacovigilance activities designated as data controllers to fulfill the obligations imposed on us by Italian and European legislation regarding the safety and efficacy of medicines, to provide feedback, to contact them in case of need and to respond to their further requests. The legal bases for the processing of your personal data can be found in the fulfillment of legal obligations to which ITEL is subject, in safeguarding its vital interests and other natural persons and for reasons of significant public interest.

The data provided will also be made available, for the purposes indicated above, to those accessing the National Pharmacovigilance Network as well as to subjects obliged to perform pharmacovigilance activities (AIFA, holders of the marketing authorization for medicinal products, Italian Regions, Local Health Units, Pharmacovigilance Office of hospitals or Scientific Research and Treatment Institutes). The data provided may also be communicated, for the purposes indicated above, to the following categories of subjects: (i) parent companies, subsidiaries or affiliates of ITEL; (ii) Company in charge of managing pharmacovigilance activities on behalf of ITEL; (iii) Persons, companies, associations that provide services or activities of assistance and advice in legal, IT and control matters with regard to ITEL; (iv) Subjects whose right to access personal data is recognized by provisions of law and / or secondary legislation or orders of public authorities; v) to your doctor if you allow us to contact you.

Your data will not be disseminated, nor will it be subject to automated or profiling processing.

Your data will be stored in our archives in accordance with the conservation criteria and terms set forth in the applicable legislation. In particular, the data will be kept for the strictly necessary period and by implementing the security measures provided by law, in our archives or at our pharmacovigilance service provider.

We inform you that at any time you have the right to request confirmation of the existence of personal data concerning you, obtain access to personal data, rectification, cancellation, limitation of processing, portability of data to another owner, oppose to processing for legitimate reasons, revoke the consent,

ITEL TELECOMUNICAZIONI S.r.l.

forwarding a specific request to the Owner, also via e-mail or fax or by registered letter to the addresses indicated also available on the website www.itelte.it. Finally, we remind you that you always have the right to file a complaint with the Guarantor Authority for the protection of personal data for the exercise of your rights or for any other matter relating to the processing of your personal data.

The pharmacovigilance report must be made by an adult, or in the event that the report concerns a minor from the person exercising parental authority or from the guardian. If the report concerns a subject other than the reporting party, the latter must be entitled to make the report and must first make the interested party aware of the contents of this information.

If you do not wish to provide personal data, the report can be made using the methods available on the Italian Drug Agency's website using the forms available on the Agency's website www.agenziafarmaco.gov.it.

Consent Form to treatment for spontaneous reports Pharmacovigilance

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70037 Ruvo di Puglia (BA) Italy

by mail by fax at no. +39 080 3611114 by email itel@itelte.it

ACKNOWLEDGMENT OF INFORMATION AND CONSENT TO THE PROCESSING OF PERSONAL DATA

The undersigned _____ (name and surname) declares to have received the information pursuant to art. 13 of EU Reg. 2016/679 regarding the processing of personal data and

consent **not to consent**

to the processing of personal data relating to the state of health by ITEL Telecomunicazioni S.r.l. to contact you in case of need and to respond to your further requests

consent **not to consent**

to the communication of personal data to the subjects indicated in the information regarding the report made

(legible signature)

Date: _____

The above consent is expressed:

for the undersigned

for _____ (indicate the personal details of the minor or of the person unable to give consent)

(legible signature)

Date: _____