SPONTANEOUS REPORTING - PRIVACY NOTICE related to pharmacovigilance

In accordance with Articles 13 and 14 of the Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data ("GDPR")

Pursuant to Articles 13 and 14 of the GDPR, Chiesi Pharmaceuticals GmbH ("Chiesi"), as drugs marketing authorization holder, wishes to provide you with detailed information on how it will process personal data which may be processed in case of spontaneous reporting with reference to any adverse reaction that is suspected to have occurred after taking the drug. Therefore, we kindly ask you to carefully read the following privacy notice.

1) CATEGORIES AND SOURCE OF PERSONAL DATA AND PURPOSES FOR THE PROCESSING

The personal data you have provided on an optional basis will be collected and processed exclusively to fulfil the legal obligations related to pharmacovigilance and, more specifically, for the purposes of the identification of any unknown adverse reactions, improvement and enhancement of the information on already known adverse reactions, assessment of the causal link between the administration of the medicine and the adverse reaction that was observed, as well as communication of the information to the competent authorities to ensure that the medicines used have a benefit/risk ratio that is beneficial to the population.

The data processed for this purpose will involve:

a) as to the subject reporting the event: name, surname, contact details;

b) as to the subject to whom the report refers, at least one of the following categories of data: initials, age, gender. Special categories of data concerning health status may also be processed if part of the report.

The provision of the data is optional, but failure to provide the data under a) could compromise the proper management of your report, while failure to provide the data under b) will prevent Chiesi from fulfilling the legal obligations related to pharmacovigilance.

2) PROCEDURES FOR THE PROCESSING

The personal data you have provided or otherwise acquired by us within our activity may be processed in hardcopy, by automated or electronic means in compliance with the applicable laws and regulations, with procedures strictly related to the purposes set out above and may involve all the operations provided for in Article 4.2 of the GDPR, e.g. collection, storage, processing, cancellation, updating, etc..

3) LEGAL BASIS FOR THE PROCESSING

The processing of your personal data is required by law (EU Directive 2010/84, EU Directive 2012/26 and relevant national implementing legislation regarding pharmacovigilance; Article 6 para 1 lit c GDPR).

4) DATA CONTROLLER & CONTACT

The controller for the processing activities listed here is.

Chiesi Pharmaceuticals GmbH

Gonzagagasse 16/16 | 1010 Vienna

If you have any questions regarding the collection, processing or use of your personal data, or want to exercise any of your data subject rights, you can contact us at any time without formalities, e.g. via dataprotection.cee(at)chiesi.com.

5) CATEGORIES OF RECIPIENTS

For the purposes described above, i.e. to comply with applicable laws and regulations in the area of pharmacovigilance and drug safety, we may transfer your personal data to the following categories of recipients to the extent necessary:

- to authorities and other public bodies to the extent required by law (e.g. national and European authorities responsible for monitoring the marketing of medicines, in particular AGES - Agentur für Gesundheit und Ernährungssicherheit GmbH and EMA - European Medicines Agency);

- to IT service providers and/or providers of data hosting, tools and software solutions, data processing or similar services and other service providers who support us in the provision of our services and act on our behalf;

- to our parent company Chiesi Farmaceutici S.p.A. and other Chiesi Group companies (available at https://www.chiesi.com/en/about-us/our-affiliates/).

We only work with third parties who take appropriate technical and organizational measures to ensure the protection of your data. Companies that perform services for us and could thereby gain knowledge of your personal data are contractually bound to secrecy. If processors are used to support and fulfil the intended purposes, your data will only be disclosed to processors that have been carefully selected in advance and with which appropriate data processing agreements are in place.

6) DATA RETENTION

The personal data relating to adverse reactions reports will be retained as long as the product is authorized and for ten years starting from the expiration or the withdrawal of the marketing authorization of the product in the last country of marketing, except for any defensive needs of the marketing authorization holder. At the end of this period, the data will be deleted or rendered anonymous so as not to allow, even indirectly or by linking other databases, the identification of the data subjects.

7) DATA SUBJECT RIGHTS

During any stage of personal data processing, you will be entitled to exercise, where applicable, the following rights:

1. right to access;
2. right to rectification and right to erasure;
3. right to restriction of processing;
4. right to data portability;
5. right to object to processing based on Chiesi's legitimate interests, public interest or profiling;
6. right to withdraw your consent with future effect (in cases where data processing is based on your consent);
7. right to lodge a complaint with a supervisory authority in case of unlawful processing of personal data.

You may exercise the above rights without formalities by contacting Chiesi Pharmaceuticals GmbH.Your request will be processed without undue delay and in any case within 30 days of receipt of the request, except for more complex cases or due to a large number of requests received, where said period may be extended by two further months.

8) UPDATES

This notice may be updated from time to time. Any update to this notice will become effective at the time of its publication on the Website.

Status: November 2022