DATA PROTECTION NOTICE
PHARMACOVIGILANCE

Section 1 - Introduction

Tillotts Pharma France S.A.S. ("**Tillotts**", "**we", "us**" - R.C.S. Paris n° 817.483.134, established at 40-48 rue Cambon, 75001 Paris, France) and its affiliates respect the privacy rights of individuals and are committed to processing personal data responsibly and in accordance with applicable laws. This data protection notice (the "**Notice**") details the personal data that we collect and process about you for pharmacovigilance purposes. Tillotts is the data controller in relation to this personal data.

This Notice is intended for:

- people exposed to an adverse health event linked to a Tillotts product,
- people who have reported an adverse health event linked to a Tillotts product,
- healthcare professionals following a person exposed to an adverse health event linked to a Tillotts product.

If you have any questions about this Notice, please contact us using the details provided in Section 8 below.

Section 2 - What types of personal data are collected?

As part of pharmacovigilance management, we may need to process personal data about you. This data is only collected if it is strictly necessary to achieve the purpose for which it was collected.

Tillotts may process various types of personal data, including:

(i) data relating to the person exposed to the adverse event:

- indirect identification data: example age, year or date of birth, sex, weight, height, initials, etc.;
- an identification number: e.g. alphanumeric code, alphabetic code.

(ii) health data: for example, treatments administered, test results, nature of the adverse drug reaction, personal or family medical history, associated diseases or events, risk factors, information relating to the method of prescribing and use of medicines and the therapeutic conduct of the prescriber or health professionals involved in the management of the disease or adverse event.

(iii) the contact details of the person who reported the adverse event or of any healthcare professional who may be able to provide further information: name, first name, postal address, e-mail address, telephone number and, if applicable, the specialty of the healthcare professional (and his/her identification number, if any, as allocated in the country concerned).

(iv) provided that they are strictly necessary for the assessment of the adverse event, data relating to professional life, tobacco, alcohol or drug consumption, lifestyle habits and behaviour.

(v) data relating to ethnic origin, to the extent permitted under national law and provided that a document presenting the characteristics of the product validated by a competent authority (in France, the RCP for example) mentions, on the basis of scientific work, the fact that the ethnic origin of persons may have an impact on its efficacy or safety.

When, as an exposed person, you notify Tillotts directly and on your own initiative of the adverse event to which you have been exposed, this has the effect of lifting the confidentiality of your identity. In such a case, the collection of data by Tillotts is limited to what we need to know in order to meet our legal obligations in terms of pharmacovigilance (in this respect, see Section 5).

Section 3 - What are the purposes of processing your personal data?

We process your personal data for the purposes of pharmacovigilance in order to prevent, monitor, assess and manage adverse events. The purpose of the processing is to allow:

(i) collecting, recording, analysing, monitoring, documenting, transmitting and storing data relating to all adverse events;

(ii) management of contacts with the person notifying the adverse event or with the healthcare professional following the exposed person in order to obtain details of the adverse event, while respecting medical confidentiality.

Section 4 - With whom do we share your data?

We grant access to your personal data only to those persons who are authorised and need to have access to it in order to carry out their duties:

- The person in charge of vigilance and the staff and agents involved in the pharmacovigilance process: Chief Pharmaceutical Officer and Deputy, Head of Pharmaceutical Affairs, Regulatory Affairs Manager, Quality Assurance Manager;
- Tillotts employees involved in the pharmacovigilance report process: all employees;
- Audit department staff, on an ad hoc and motivated basis, to check compliance with regulatory requirements: Chief Pharmaceutical Officer and Deputy, Head of Pharmaceutical Affairs, Quality Assurance Manager;
- Authorised personnel in charge of complaints management, depending on the cases they handle: Chief Pharmaceutical Officer and Deputy, Head of Pharmaceutical Affairs, Quality Assurance Manager.

Certain third parties may also have access to your personal data exclusively in the context of their pharmacovigilance activities:

- Tillotts' subcontractors for pharmacovigilance activities;
- Companies affiliated with Tillotts, in particular its parent company Tillotts Pharma AG, insofar as they are involved in the operation or marketing of the product;
- Third parties whose products may be implicated;
- Health professionals involved in the medical care of the exposed person and any other health professional who can provide additional information;
- Notified bodies responsible for product assessment;
- National or foreign public bodies responsible for pharmacovigilance in the exercise of their missions as defined by legal and/or regulatory texts, foreign national

health authorities or agencies and international health authorities or agencies.

Whenever we allow a third party to access your personal data we implement appropriate measures to ensure that (i) the personal data is used in accordance with this Notice and (ii) the security and confidentiality of the data is maintained.

Your personal data may also be accessed by, or transferred to, any regulatory body, state authority, court or national and/or international public body, where we are required to do so by law or regulation, or at their request.

The personal data we collect about you may also be processed, accessed or stored in a country outside the country where Tillotts is located, which may not offer the same level of protection for personal data.

If we transfer your personal data to companies located in other jurisdictions outside the European Economic Area, we will ensure that we protect your personal data by i) applying the level of protection required by the applicable data protection law to which Tillotts is subject, ii) acting in accordance with our internal policies and standards and, iii) only transferring your personal data on the basis of an adequacy decision adopted by the European Commission (where such a decision exists) or standard contractual clauses approved by the European Commission (available on request), unless otherwise specified. With regard to transfers of personal data to other companies in the group, the Tillotts group has adopted internal rules designed to guarantee effective levels of personal data protection in the event of data transfers, notably outside the European Economic Area.

Section 5 - What is the legal basis for processing your personal data?

In the context of pharmacovigilance, compliance with the legal obligations imposed on Tillotts by the applicable legal provisions relating to pharmacovigilance (namely, in France, as provided for in particular in the Public Health Code (“Code de la santé publique”), in Belgium, as provided for in particular in the Act of 25 March 1964 on medicinal products for human use and in the Royal Decree of 14 December 2006 on medicinal products for human use and, in the Netherlands, as provided for in particular in the Medicines Act (“Geneesmiddelenwet”) and the Regulation on the Medicines Act (“Regeling Geneesmiddelenwet”)) is used as the legal basis for the processing of personal data.

The collection of health data (and, subject to what is indicated in Section 2 of this Notice, data relating to ethnic origin) in the context of pharmacovigilance is necessary for reasons of public interest in the field of public health and is intended, in particular, to ensure compliance with high standards of quality and safety of healthcare and products in accordance with the provisions of Article 9 of the Regulation (EU) 2016/679 of the European Parliament and of the Council 27 April 2016 (and also, as far as France is concerned, of Article 66 of the amended Act of 6 January 1978, known as the "Loi informatique et libertés").

Section 6 - How long will your data be kept?

Your personal data is kept in the active database for the time required to manage the report of the undesirable health event. It is then kept in intermediate storage for a maximum period of seventy (70) years (in France) or ten (10) years (in Belgium and in the Netherlands), from the date of withdrawal of the product from the market, unless there is a legal exception. At the end of these periods, the data is deleted or archived in anonymised form.

Section 7 - How is the security and confidentiality of your personal data ensured?

Tillotts takes all necessary precautions with regard to the risks presented by its processing to ensure the security of personal data and, in particular, at the time of collection, during transmission and storage, to prevent it from being distorted, damaged or accessed by unauthorised third parties. Tillotts also ensures that authorised third parties with access to personal data provide security guarantees equivalent to those of Tillotts.

Section 8 - What are your rights and how can you exercise them?

Data subjects have the following rights:

- The right to access your personal data
- The right to rectify your personal data
- The right to limit the processing your personal data

Insofar as processing is based on compliance with a legal obligation, data subjects do not have the right to object, the right to erasure of data or the right to data portability. Nor do data subjects have the right to withdraw their consent to the processing, as the legal basis for the processing is not consent.

When exercising your rights, Tillotts may, if necessary, ask you to provide proof of identity to verify your identity. This information will only be kept for as long as is necessary for this purpose. If you have any questions about the protection of your data or wish to exercise your rights, you can contact us at the following address: dataprivacy@tillotts.com. In the event of a complaint, each individual is free to make a request to the supervisory authority in his or her country of residence:

- In France, this is the Commission nationale de l'informatique et des libertés ("CNIL" - http://www.cnil.fr/ - Place de Fontenoy 3, TSA 80715, 75334 PARIS CEDEX 07).

- In Belgium, this is the Autorité de Protection des Données ("APD" - https://www.autoriteprotectiondonnees.be/ - Rue de la Presse, 35, 1000 Brussels).

- In the Netherlands, this is the Autoriteit Persoonsgegevens ("AP" - https://www.autoriteitpersoonsgegevens.nl/ - Hoge Nieuwstraat 8, 2514 EL Den Haag).

Section 9 – Update of the Notice

This Notice may be updated periodically to reflect necessary changes in our privacy practices. In this case, where necessary, we will inform you and indicate the most recent update date at the top of the Notice.