**Information Notice pursuant to and for the purposes of art.13 of EU Reg. 2016/679 – GDPR**
**Information notice on the processing of personal data collected from the data subject direct reporter**

Pursuant to EU Reg. 2016/679 (General Data Protection Regulation), we hereby provide you with the necessary information regarding the processing of your personal data**.** This is an information notice given to you according to art. 13 of EU Reg. 2016/679. The processing will be based on principles of correctness, lawfulness, transparency, protection of privacy and of your rights.

**1. DATA CONTROLLER**
Pursuant to articles 4 and 24 of the EU Reg. 2016/679 the Data Controller is **Sanofi S.r.l.**, with registered offices in Viale Bodio 37/b – 20158 Milano, represented by its *pro tempore* Legal Representative.

**2. DATA PROTECTION OFFICER (DPO),** pursuant to art. 37-39 of the EU Reg. 2016/679. Within Sanofi Group, pursuant to the EU Reg. 2016/679, the Data Protection Officer has been appointed and can be contacted at the following email address: privacy-office-global@sanofi.com

**3. CATEGORIES OF DATA PROCESSED**
The Data Controller processes your personal data (e.g. name, surname, address, telephone number, email address) as well as sensitive data (e.g. data concerning your health and ethnicity).

**4. PURPOSES OF THE PROCESSING AND LEGAL BASIS FOR THE PROCESSING**
The personal and sensitive data, voluntarily provided, will be processed only and exclusively in order to manage - in compliance with current pharmacovigilance legislation which imposes to monitor the safety of authorized medicinal products and detects any changes in their risk/benefit ratio - the pharmacovigilance report provided by you to Sanofi and related to medicinal products, vaccines, food supplements, cosmetics and medical devices marketed by Sanofi as applicable, as well as for the purpose of reporting these reports to the competent public authorities and any related reply.
The legal basis of the data processing is the need to comply with legal obligations relating to pharmacovigilance – art.6, paragraph 1 letter c) of the EU Reg. 2016/679 – which the Data Controller is subject to and include the need to collect and manage pharmacovigilance reports for the products marketed by Sanofi.

**5. MODALITIES OF PROCESSING – DATA RETENTION**
The data processing will be carried out in an automated and/or manual way, with modalities and instruments aimed at guaranteeing maximum security and confidentiality, by subjects specifically appointed to do so.
The patient's initials and date of birth are necessary to identify duplicates, moreover the name and contact details of who provided the report are necessary to conduct effective follow-up activities and ensure that the data collected are accurate and complete.
In compliance with the provisions of art. 5 paragraph 1 letter e) of the EU Reg. 2016/679, the personal and sensitive data collected will be retained in a form that allows the identification of data subjects for a period of time not exceeding the achievement of the purposes for which the personal and sensitive data are processed. In particular your personal data and pharmacovigilance documents relating to the authorized medicines reported will be retained until a marketing authorization for these medicines is existing and for at least 10 years after the marketing authorization ceased to exist;

this is in accordance with the Good Pharmacovigilance Practices and in accordance with the current pharmacovigilance legislation. Upon the expiry of the retention time, Sanofi will securely destroy your personal data in accordance with applicable laws and regulations.

**6. SCOPE OF COMMUNICATION AND DISSEMINATION**

Your data, which are subject to processing, will not be disclosed and can be communicated to companies contractually bound to Sanofi, in order to fulfill the contracts or for connected purposes. This data communication will be done in a secure mode (e.g. encryption) in order to ensure an adequate security and confidentiality of your data.

Your personal and sensitive data will be communicated to recipients, who will process the data as Data Processors (art. 28 of EU Reg. 2016/679) and / or as natural persons acting under the authority of the Data Controller and the Data Processor (Art. 29 of EU Reg. 2016/679), for the purposes listed under previous point 4.

The data may be communicated to third parties belonging to the following categories:

- Corporate and companies belonging to Sanofi Group;
- subjects that provide services for the management of the information system used by Sanofi and of the telecommunications networks (including email);
- studies or companies in the field of assistance and consultancy services as well as provision of services in any sectors;
- competent authorities for compliance with legal obligations (e.g. Malta Medicines Authority) and/or provisions of public bodies, upon request.

The subjects belonging to the aforesaid categories act as Data Processor, or they operate as autonomous and separate Data Controllers. The list of Data Processors is constantly updated and available at the Sanofi offices.

**7. DATA TRANSFER TO A THIRD COUNTRY AND/OR AN INTERNATIONAL ORGANIZATION**

Your data, which are subject to processing, could be transferred also abroad in countries belonging to the European Union and/or in extra-UE countries in order to pursue the aforementioned purposes but always respecting the limits and conditions set forth in EU Reg. 2016/679 to protect your personal data. In case of transfer, the data will be transferred in compliance with and according to the limits set forth by articles 44 (General principle for transfers), 45 (Transfer on the basis of an adequacy decision) and 46 (Transfer subject to appropriate safeguards) of EU Reg. 2016/679.

Sanofi specifies that your personal data will be transferred to Corporate and Affiliated Companies also abroad, in countries belonging to the European Union and/or in extra-UE Countries. Even if an Affiliate of the Sanofi Group is based in a country where personal data are not protected by a law or where the level of protection is lower than the one required by European Legislation, the Sanofi Group has developed processes and procedures (called Binding Corporate Rules) which, also in those countries, ensure the security and limit the access to databases according to the highest standards of protection applicable in the European Union.

**8. NATURE OF DATA PROVISION AND REFUSAL TO PROVIDE THEM**

The data subject is free to provide his/her personal and sensitive data. The provision of your data, necessary for the management of the pharmacovigilance report only, is therefore optional but necessary. The failure to provide your personal data could lead to the loss of important information for monitoring the safety and for detecting any changes in the risk/benefit ratio of Sanofi products and/or for processing adequately your report.

**9. DATA SUBJECTS RIGHTS**

You are entitled to exercise the rights set forth in articles from 15 to 22 of EU Reg. 2016/679 by sending, at any time, an email to PharmacovigilanceMalta@sanofi.com

You have the right, therefore, to ask the Data Controller to access your personal data, rectify, delete them, and limitate their processing. Furthermore you have the right to lodge a complaint with the Authority for the Protection of Personal Data if you deem that the processing of your personal data is in breach of the laws in force. Your personal data are not subject to an automated decision-making process. If you contact the Data Controller, please provide the e-mail address, name, address and/or telephone numbers, in order to allow the correct handling of the request.

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