

## PRIVACY NOTICE

### ENQUIRIES AND REPORTS OF SUSPECTED SIDE EFFECTS

#### 1. The personal information we use

##### 1.1 Information we collect directly from you

##### 1.2 Information we collect about you from other sources

##### 1.3 Special categories of personal information

#### 2. How we use your personal information and the basis on which we use it

#### 3. Your rights over your personal information

#### 4. Information Sharing

#### 5. Information Security and Storage

#### 6. International Data Transfer

#### 7. Contact Us

#### 8. Changes to the Policy

This privacy notice describes how **Servier Laboratories Ltd** whose registered offices are located at Block 2, West Pier Business Campus, Old Dunleary Road, Dun Laoghaire, Co. Dublin, Ireland and **Servier (Ireland) Industries Ltd.** whose offices are located at Gorey Road, Arklow, Co. Wicklow, Ireland ("**Servier**", "**we**" or "**us**"), collect and process personal information about you, how we use and protect this information, and your rights in relation to this information.

This privacy notice applies to all personal information we collect or process about you when you contact us in relation to medical enquiries, suspected side effects (adverse drug reactions ("**ADRs**")) and other relevant information linked to use of our products ("**Special Situations**" e.g. medication errors, off-label use), product quality complaints, customer enquiries, recruitment enquiries, press enquiries and all other enquiries we receive via:

- the 'Contact Us' forms on our website: [www.servier.ie](http://www.servier.ie) (the "**Website**");
- telephone;
- email;
- post at our office address above; or
- in person to employees or representatives of Servier.

This privacy notice also applies to personal information relating to other individuals that is provided to us by those submitting enquiries or reports of suspected ADRs and Special Situations, in particular:

- patients who have experienced a possible ADR or Special Situation when a report is made by their doctor or other healthcare professional; and
- healthcare professionals when a report or enquiry is submitted by their patients.

**When providing us with personal information relating to another person, you must ensure that you have provided them with the information set out in this privacy notice and have obtained their consent where necessary.**

We will not routinely ask for personal information relating to other individuals except when a patient has contacted us and we need to speak to their doctor or in the case of reports of suspected ADRs and Special Situations.

Personal information is information, or a combination of pieces of information that could reasonably allow someone to be identified.

## **1. PERSONAL INFORMATION WE USE**

We collect personal information from you directly (e.g. when you contact us) as well as from other sources as described below.

### **1.1 Personal information we collect directly from you**

The categories of personal information that we collect directly from you are:

- (a) personal details (e.g. name, title);
- (b) contact details (e.g. phone number, email address, postal address or mobile number, business address);
- (c) whether you are a healthcare professional, patient or a member of the public; and
- (d) details related to your enquiry (e.g. information relating to your use of our products or services)
- (e) Where a suspected ADR or Special Situation has been reported by a non-health care professional (HCP), written consent will be requested in order to contact their Doctor or other HCP to obtain medical confirmation of the case.

### **1.2 Information we collect about you from other sources**

If you are a healthcare professional and we receive an enquiry from a patient of yours, we may request the following categories of personal information about you:

- (a) personal details (e.g. name, title);
- (b) contact details (e.g. phone number, email address, postal address or mobile number, business address); and
- (c) your occupation and where you work.

If you are a patient and we receive a report of a suspected ADR or Special Situation relating to you from your doctor, relative or another person, we will collect your initials, gender and date of birth (please also see section 1.3 below).

### **1.3 Special categories of personal information**

Some of the categories of personal information that we collect are special categories of personal data (also known as sensitive personal information).

In particular, if you are a patient we will collect and process the following personal information that you provide to us or that is provided to us by your doctor, relative or other third party when reporting a suspected ADR or Special Situation relating to you, including:

- (a) Your height and weight;
- (b) Information about your medical history and treatment if this is relevant to the report or enquiry;
- (c) The results of laboratory tests and investigations that are relevant to the report or enquiry; and
- (d) Details of the suspected ADR or Special Situation and any other relevant information.

## 2. **HOW WE USE YOUR PERSONAL INFORMATION AND THE BASIS ON WHICH WE USE IT**

We use your personal information to:

- (a) comply with our legal obligations to investigate ADRs and patterns of use of our products, product quality complaints and suspected falsified medicines (fake medicines passing off as one of our products) and to report these to appropriate medicines regulatory authorities;
- (b) comply with our legal obligation to provide a scientific service to compile and collect all information relating to our products;
- (c) comply with our legal obligations to undertake a batch recall where necessary or in relation to a discontinuation of one of our products; and
- (d) contact you if we require further details from you about your enquiry or report and to appropriately respond to your enquiries.

If you or your employer are engaged by us to provide certain services, you may have a contractual obligation to provide certain personal information to us for the purposes of reporting and investigating ADRs, Special Situations and product quality complaints. If you do not comply with this obligation we have the right to terminate our agreement with you. If you would like further information, please contact us using the details below.

We must have a legal basis to process your personal information. In most cases the legal basis will be one of the following:

- (a) to comply with our regulatory and legal obligations as described above; and
- (b) to meet our legitimate interests, for example to answer your enquiries, contact you if we require further information about your enquiries and to ensure appropriate use of our products. When we process personal information to meet our legitimate interests, we put in place robust safeguards to ensure that your privacy is protected and to ensure that our legitimate interests are not overridden by your interests or fundamental rights and freedoms.

- (c) In addition, when we process sensitive personal data as set out in section 1.3 above, we rely on the legal basis that this is necessary to ensure high standards of quality and safety of our medicinal products.

### **3. YOUR RIGHTS OVER YOUR PERSONAL INFORMATION**

You have certain rights regarding your personal information, subject to certain exceptions in accordance with applicable law. These include the following rights to:

- access your personal information. There may be some exceptions, which means you may not always receive all the information we process about you;
- rectify any inaccurate information we hold about you;
- erase your personal information except in certain circumstances for example if it is necessary for us to process your personal information to comply with a legal obligation (as described in section 2 above) or for the establishment, exercise or defence of a legal claim;
- restrict our use of your personal information in certain circumstances;
- object to our use of your personal information in certain circumstances where we use your personal information for our legitimate interests (as described in section 2 above); and
- lodge a complaint with your local data protection authority (the Data Protection Commission in Ireland: <https://www.dataprotection.ie>).

If you would like to discuss or exercise such rights, please contact us at the details below.

We encourage you to contact us to update or correct your information if it changes or if the personal information we hold about you is inaccurate.

We will contact you if we need additional information from you in order to honour your requests.

### **4. INFORMATION SHARING**

We may, under certain circumstances, share your personal information with third parties below:

- Our medical information agency who act on our behalf to respond to certain medical information enquiries.
- Servier group companies. Servier Laboratories Ltd is ultimately owned by Les Laboratoires Servier, so we work closely with other businesses and companies that fall under the Servier Group. We may share certain information about your enquiry with Les Laboratoires Servier and other Servier Group companies to enable us to appropriately deal with your enquiry for example with your local Servier Group company if you are not based in Ireland. We also share certain personal information relating to suspected ADRs and Special Situations with Les Laboratoires Servier to comply with the Servier Group's legal obligations with respect to pharmacovigilance and to ensure high standards of quality and safety of our medicinal products. Information on the global presence of the Servier group can be found here: <https://servier.com/en/company/global-presence/>.

- Law enforcement agencies, courts, regulators (including appropriate medicines regulatory authorities in the European Union), government authorities or other third party. We will share your personal information with these parties where we believe this is necessary to comply with a legal or regulatory obligation (such in relation to ADR reporting), or to support a legal or criminal investigation or otherwise to protect our rights or the rights of any third party.
- Asset purchasers. We may share your personal information with any third party that purchases, or to which we transfer, all or substantially all of our assets and business. Should such a sale or transfer occur, we will use reasonable efforts to try to ensure that the entity to which we transfer your personal information uses it in a manner that is consistent with this privacy notice.

Because we operate as part of a global business, the recipients referred to above may be located outside the jurisdiction in which you are located (or in which we provide the services). See the section on "International Data Transfer" below for more information.

## 5. **INFORMATION SECURITY AND STORAGE**

We implement technical and organisational measures to ensure a level of security appropriate to the risk to the personal information we process. These measures are aimed at ensuring the ongoing integrity and confidentiality of personal information. We evaluate these measures on a regular basis to ensure the security of the processing.

We will keep your personal information for as long as is required to answer your request or enquiry. Once we have responded to your request or enquiry, we will retain your personal information for a period of time that enables us to:

- Maintain business records for analysis and/or audit purposes including to evidence that we have complied with our legal obligations described in section 2 above;
- Comply with record retention requirements under the law;
- Defend or bring any existing or potential legal claims; and
- Deal with any complaints regarding our products or services.

We will delete your personal information when it is no longer required for these purposes. If there is any information that we are unable, for technical reasons, to delete entirely from our systems, we will put in place appropriate measures to prevent any further processing or use of the data.

## 6. **INTERNATIONAL DATA TRANSFER**

Given the global nature of the Servier Group, we may transfer personal information including sensitive personal information to other entities of the Servier Group based outside Ireland to appropriately deal with your enquiry. A list of Servier Group entities and where they are based is available here: <https://servier.com/en/company/global-presence/>.

In addition to Servier Group entities overseas, your personal information may be transferred to, stored, and processed by an international organisation or a third party located in a country that is not regarded as ensuring an adequate level of protection for personal information under European Union law or by the European Commission.

We have put in place appropriate safeguards (such as contractual commitments) in accordance with applicable legal requirements to ensure that your data is adequately protected. For more information on the appropriate safeguards in place, please contact us at the details below.

## 7. CONTACT US

**Servier Laboratories Ltd / Servier (Industries) Ireland Ltd.** is the controller responsible for the personal information we collect and process in accordance with this privacy notice.

If you have questions or concerns regarding the way in which your personal information has been used, please contact us using the contact details below:

### **Servier Laboratories Ltd.**

- Email: [dataprivacy-dublin@servier.com](mailto:dataprivacy-dublin@servier.com)
- Telephone: 01 663 8110
- Post: Servier Laboratories Ltd, Block 2, West Pier Business Campus, Old Dunleary Road, Dun Laoghaire, Co. Dublin, Ireland
- Our Data Protection Relay can be contacted at: [dataprivacy-dublin@servier.com](mailto:dataprivacy-dublin@servier.com).

### **Servier (Ireland) Industries Ltd.**

- Email: [dataprivacy-arklow@servier.com](mailto:dataprivacy-arklow@servier.com)
- Telephone: 0402 20800
- Post: Servier (Ireland) Industries Ltd, Gorey Road, Arklow, Co. Wicklow, Ireland
- Our Data Protection Relay can be contacted at : [dataprivacy-arklow@servier.com](mailto:dataprivacy-arklow@servier.com).

We are committed to working with you to obtain a fair resolution of any complaint or concern about privacy. If, however, you believe that we have not been able to assist with your complaint or concern, you have the right to make a complaint to the Data Protection Commission in Ireland (<https://www.dataprotection.ie>) or your local data protection authority if you are based outside Ireland

## 8. CHANGES TO THE POLICY

You may request a copy of this privacy notice from us using the contact details set out above. We may modify or update this privacy notice from time to time.

If we change this privacy notice, we will notify you of the changes by way of a banner on our Website.

**[NOVEMBER 2018]**