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Information highlighted in yellow to be updated by each affiliate

Privacy Notice for pharmacovigilance and medical information enquiries

Last updated: August 2021

General Information

Astellas Pharma (Pty)Ltd ("**Astellas**", "**we**", "**us**" and "**our**") respects your right to privacy and treats your personal information in accordance with applicable laws and regulations, including the South African Protection of Personal Information Act, 2013 ("POPIA) and the European General Data Protection Regulation ("GDPR") and all the regulations thereunder, which regulate and control the processing of personal information. This Privacy Notice explains who we are, how we collect and process personal information about you to help us fulfil our duty to monitor the safety of all products including medicines we market or have in clinical development (also known as our pharmacovigilance obligations) and to ensure the quality and safety of all our products, and how you can exercise your privacy rights. If you have any questions or concerns about our use of your personal information, then please contact us using the contact details provided at the bottom of this Privacy Notice.

What does Astellas do?

Astellas Pharma is a global pharmaceutical business, whose ultimate parent company is headquartered in Tokyo, Japan. Our mission is to improve the lives of patients in the following key areas: transplantation, urology, oncology and anti-infectives.

For more information about Astellas, please see the "About" section of our Website at <https://www.astellas.eu/about/about/>.

What personal information does Astellas collect and for what purposes? We do not process personal information unless we have a proper legal basis. The processing of personal data described in this Privacy Notice is necessary for the legitimate interests of Astrellas in managing adverse events, medical information queries, and product complaints and in the public interest.

The types of information we may collect and process, and the reasons why we ask you to provide it, will depend on the category of data subjects and/or the data processing activity:

Pharmacovigilance purposes:

We may collect the following personal information depending on the individual contacting us (patient or reporter of an adverse event): name, surname, age, date/year of birth, gender, initials, contact details and profession. The personal Information that we may collect about you when you are the subject of an adverse event report is:

- name or initials;
- age and date of birth;

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- gender;
- weight and height;
- details of the product causing the reaction, including the dosage you have been taking or were prescribed, the reason you have been taking or were prescribed the product and any subsequent change to your usual regimen;
- details of other medicines or remedies you are taking or were taking at the time of the reaction, including the dosage you have been taking or were prescribed, the period of time you were taking that medicine, the reason you have been taking that medicine and any subsequent change to your regimen;
- details of the adverse reaction you suffered, the treatment you received for that reaction, and any long-term effects the reaction has caused to your health; and
- other medical history considered relevant by the reporter, including documents such as lab reports, medication histories and patient histories

Some of this personal information is considered “sensitive personal data” about you (including amongst others, health, ethnicity and religion) We may be required by law to use your information to assess the safety of our products and report the data to the regulatory authorities (e.g. the South African Health Products Regulatory Authority). For reporting data to the regulatory authorities your personal information will be shared in an anonymous manner. Your personal information will not be used for other purposes other than activities related to pharmacovigilance.

We may receive personal information about you from third party sources (such as the physician who treats you), but only where we have checked that these third parties either have your consent or are otherwise legally permitted or required to disclose your personal information to us. The types of information we may collect from third parties will include the above types of personal information and we use the information we receive from these third parties only to assess the safety of our products, report any adverse events to regulatory authorities and contact you for any follow up information or for confirmation purposes.

Medical Information enquiries purposes:

We may collect name, surname, initials, date/year of birth, gender, contact details and profession of the individual contacting us with a medical enquiry. We may collect health data or data relating to the medical history of an individual submitting an enquiry to us. We collect this personal information to respond to your enquiry and follow up with you if necessary in order to comply with our legal obligations. We may be required by law to report your personal information to the regulatory authorities, to the extent your enquiry is associated with an adverse event.

If we ask you to provide any other personal information not described above, then the personal information we will ask you to provide, and the reasons why we ask you to provide it, will be made clear to you at the point we collect your personal information.

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Product complaints purposes:

We may collect name, surname, initials, contact details and profession of individuals reporting a product complaint to us. If relevant for the evaluation of the product complaint, we may collect health data of the individual who suffered the complaint. We collect this personal information to assess and evaluate the product complaint in order to comply with our legal obligations. We may be required by law to report your personal information to the regulatory authorities or contact you for any follow up information.

Other purposes

Our pharmacovigilance obligations require us to review patterns across reports received from every country where we market our products. To meet these requirements, information provided as part of an adverse event report is shared within Astellas on a worldwide basis through the Astellas Global Database and other similar databases as may be required by law.

In general, we will use the personal information we collect from you only for the purposes described in this Privacy Notice or for purposes that we explain to you at the time we collect your personal information. However, we may also use your personal information for other purposes that are not incompatible with the purposes we have disclosed to you (such as archiving purposes in the public interest, scientific or historical research purposes, or statistical purposes) if and where this is permitted by applicable data protection laws.

Who does Astellas share my personal information with?

We may disclose your personal information to the following categories of recipients:

- to our **group companies and affiliates, third party services providers and partners**, who provide data processing services to us, or who otherwise process personal information for purposes that are described in this Privacy Notice, such as operating the relevant pharmacovigilance and medical information services & databases and assisting Astellas to fulfil reporting obligations. A list of our current group companies is available [here](#);
- to any **competent law enforcement body, regulatory, government agency, court or other third party** where we believe disclosure is necessary (i) as a matter of applicable law or regulation, (ii) to exercise, establish or defend our legal rights, or (iii) to protect your vital interests or those of any other person;
- to a **potential buyer** (and its agents and advisers) in connection with any proposed purchase, merger or acquisition of any part of our business, provided that we inform the buyer it must use your personal information only for the purposes disclosed in this Privacy Notice.

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Legal basis for processing personal information (for EU Countries and South Africa only)

To the extent that the GDPR and POPIA are applicable, our legal basis for our processing may differ depending on the nature of the medical information enquiry or complaint. For many enquiries our legal basis is that processing personal data is necessary for the purpose of our legitimate interests and the legitimate interests of a data subject, in order to respond to the enquiry, in accordance with Article 6(1)(f) of the GDPR and sections 11(d) and 11(f) of POPIA. If your enquiry is associated with an adverse event we may be required by law to report to the regulatory authorities, and processing health data is necessary for reasons of public interest in the area of public health in accordance with Articles 6 (1) (c) and Article 9 (2) (i) of the GDPR and section 27(d)(i) of POPIA. If you are a patient we may process your health data in relation to a medical enquiry which is not associated with an adverse event, we will ask for your explicit consent, but we will make this clear to you at the relevant time. In this particular case, our legal basis for processing your health data is Articles 6(1)(a) and 9(2)(a) of the GDPR. Our legal basis for pharmacovigilance purposes is Article 6 (1) (c) and Article 9 (2) (i) of the GDPR and section 27(d)(i) of POPIA.

If you have questions about or need further information concerning the legal basis on which we collect and use your personal information, please contact us using the contact details provided under the "How to contact us" heading below.

How does Astellas keep my personal information secure?

Astellas takes appropriate measures to secure personal information from the accidental loss and from unauthorised access, use, alteration and/or disclosure. We use appropriate technical and organisational measures to protect the personal information that we collect and process about you (e.g access controls, stringent physical security and robust information collection, storage & processing practices). The measures we use are designed to provide a level of security appropriate to the risk of processing your personal information.

International data transfers

Your personal information may be transferred to, and processed in, countries other than the country in which you are resident. These countries may have data protection laws that are different to the laws of your country and may not provide the same level of protection as your country.

However, we have taken appropriate safeguards to require that your personal information will remain protected in accordance with this Privacy Notice. These include implementing the European Commission's Standard Contractual Clauses for transfers of personal information between our group companies, which require all group companies to protect personal information they process from the EEA in accordance with European Union data protection law.

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Our Standard Contractual Clauses can be provided on request. In addition, we comply with section 72 of POPIA. Further, we have implemented similar and adequate safeguards with our third party service providers and partners and further details can be provided upon request.

Data retention of your personal information

We retain personal information we collect for pharmacovigilance purposes for the life of the company since such information is important for public health reasons.

For medical information enquiries purposes, personal data may be kept for 6 years since the date you contact Astellas with an enquiry.

Your data protection rights

You have the following data protection rights:

- If you wish to **access, correct or update** your personal information, you can do so at any time by contacting us using the process and the contact details provided under the "How to contact us" heading below.
- Your right to **object to processing** of your personal information, or to ask us to **restrict processing** of your personal information or to **delete** your personal information, or to **request portability** of your personal information, will be limited due to our legal obligations for on pharmacovigilance legislation. Astellas will not be able to erase or restrict processing of your data for legal reasons.
- Similarly, if we have collected and process your personal information with your consent, then you can **withdraw your consent** at any time. Withdrawing your consent will not affect the lawfulness of any processing we conducted prior to your withdrawal, nor will it affect processing of your personal information conducted in reliance on lawful processing grounds other than consent. Again, you can do so at any time by contacting us using the process and the contact details provided under the "How to contact us" heading below.
- You have the **right to complain to a data protection authority** about our collection and use of your personal information. For more information, please contact your local data protection authority. (Contact details for data protection authorities in the European Economic Area are available [here](#).)

We respond to all requests we receive from individuals wishing to exercise their data protection rights in accordance with applicable data protection laws.

Updates to this Privacy Notice

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We may update this Privacy Notice from time to time in response to changing legal, technical or business developments. When we update our Privacy Notice, we will take appropriate measures to inform you, consistent with the significance of the changes we make. We will obtain your consent to any material Privacy Notice changes if and where this is required by applicable data protection laws.

You can see when this Privacy Notice was last updated by checking the "last updated" date displayed at the top of this Privacy Notice.

How to contact us

The data controller of your personal information is [insert relevant Astellas entity] [which is registered with the [insert relevant data protection authority] with registration number [insert data protection authority registration number]].

To exercise any of your privacy rights, please submit your query [here](#).

If you have any questions or concerns about our use of your personal information, please contact our data protection officer using the following details: privacy@astellas.com.