PHARMACO DISTRIBUTION (PTY) LTD

PHARMACOVIGILANCE PRIVACY NOTIFICATION

1. INTRODUCTION

1.1 Pharmaco Distribution (Pty) Ltd and its group companies (hereinafter referred to as Pharmaco/we/us) market and distribute medical products and devices (hereinafter referred to as "our Products").

1.2 Although our products and devices are developed to ensure that they remain safe for use, complete safety is not always possible and situations may arise when a person may experience an adverse or undesirable reaction to one of our Products, which has not previously been detected during development or clinical trials.

1.3 Should you notify us of any undesirable or adverse events, we are under a legal obligation to manage your notification and to report same to our international partners and regulatory authorities (such as the South African Health Products Regulatory Authority).

1.4 Monitoring and reporting adverse events, no matter how rare they may be, is therefore extremely important and allows us and regulatory authorities to effectively manage such events and ensure that the public health is, and remains, protected and to ensure that the high standards of quality and safety of our Products is maintained.

1.5 The process of monitoring and reporting adverse events is known as Pharmacovigilance and requires us to process personal information of the patient and/or reporter of an adverse event in order to comply with our legal obligations.

1.6 This notification will inform you about how we process your personal information for Pharmacovigilance purposes in accordance with our legal obligations under the Protection of Personal Information Act 4 of 2013 (hereinafter referred to as "POPI").

1.7 Should you have any questions about this notification, or about how we process your personal information, please feel free to contact us using the contact information provided below.

2. CATEGORIES OF PERSONAL INFORMATION

In compliance with our obligations, we may be required to process the following personal information: -

2.1 Patient

2.1.1 Patient name and/or initials;

2.1.2 Date of birth;

2.1.3 Age group;

2.1.4 Sex;

2.1.5 Weight;

2.1.6 Height;

2.1.7 Information about health, racial or ethnic origin and sexual life;

2.1.8 Medical history and status, which may include, but are not limited to: -

2.1.8.1 Details of our Product and/or the active ingredient contained therein, which is suspected to have caused the adverse event, including the dosage being taken and/or prescribed;

2.1.8.2 Details of any other medicine or remedy which you have been taking, or were taking at the time of the adverse event, including the dosage being taken and/or prescribed;

2.1.8.3 Details of the adverse event suffered, the treatment you have received in respect thereof and any potential long and/or short-term effects the adverse event has caused, and other medical history related information which may be considered relevant by the reporter, including documents such as lab reports, medication histories and patient histories.

2.2 Reporter:

2.2.1 Full name(s);

2.2.2 contact information (which may include your address, e-mail address, phone number or fax number);

2.2.3 profession; and

2.2.4 relationship with the patient whose adverse event is being reported (where the reporter is not the patient itself).

3. PURPOSE OF PROCESSING

3.1 We will process the personal information we collect for Pharmacovigilance compliance for the following purposes: -

3.1.1 investigate the adverse event, as well as its possible causes;

3.1.2 contact you for further information about the adverse event that was reported;

3.1.3 collate the information about the adverse event with information about other adverse events received by us to evaluate the safety of our Product, or the active ingredient; and

3.1.4 provide mandatory reports to national and/or regional competent regulatory authorities so that they can evaluate the safety of our Product, or active ingredient.

3.2 The personal information which is processed pursuant to our Pharmacovigilance obligations is based on compliance with obligations which are imposed on us by law in accordance with section 11(1)(c) of POPI, the protection of your legitimate interests to manage any adverse events which you may report in accordance with section 11(1)(d) of POPI and the pursuit of our legitimate interests in ensuring the continued safety of our Products in accordance with section 11(1)(f) of POPI

4. SUPPLY OF INFORMATION AND THE CONSEQUENCES OF A FAILURE TO PROVIDE SAME

The supply of the information is entirely voluntary. However, should you wish to report an adverse event, we will require the information, which is required to identify the patient and the reporter, failing which we are unable to report the adverse event in question.

5. **LAWS AUTHORISING THE COLLECTION OF THE INFORMATION**

We are required to collect this information in terms of the National Health Act 61 of 2003, the Medicines and Related Substances Act 101 of 1965, as amended, and any regulations promulgated in respect thereof.

6. **CROSS BORDER TRANSFER OF PERSONAL INFORMATION**

6.1 In certain cases, we may need to transfer your personal information to other members of Pharmaco or to third party business partners and regulatory bodies. These may be based outside of the Republic of South Africa.

6.2 In circumstances where such transfer is required, we shall always ensure that a contractual relationship is in place between us and the recipient which provides an adequate level of protection that—

6.2.1 effectively upholds principles for reasonable processing of your personal information which are substantially similar to the conditions for the lawful processing of personal information as contained in POPI; and

6.2.2 includes provisions limiting the further transfer of personal information from the recipient to third parties who are in a foreign country in substantially the same manner as the provisions of section 72 of POPI,

unless we have obtained your consent to the transfer or other valid legal grounds apply, which authorise us to effect transfer of your personal information.

6.3 Save as aforesaid, we shall not transfer your personal information outside of the Republic of South Africa for any other purpose.

7. **RECIPIENTS OF YOUR PERSONAL INFORMATION**

In compliance with our Pharmacovigilance obligations, be in terms of law or otherwise, we may share and/or disclose your personal information to the following persons: -

7.1 within Pharmaco, in order to log, analyse and investigate a reported adverse event;

7.2 to competent regulatory authorities (such as the South African Health Products Regulatory Authority), to comply with our legal obligations, in terms of which we ensure

that all patient information is pseudonymised to ensure that personal information remains confidential and secure;

7.3 to our third-party business partners, who are responsible for manufacturing our Product;

7.4 when publishing information about adverse events (such as case studies and summaries); in terms of which, we will remove identifiers from any publication to keep your identity anonymous.

8. SECURITY OF YOUR PERSONAL INFORMATION

8.1 All information stored by us, is stored in compliance with POPI and on specially secured servers. Only authorized persons are able to access your personal information.

8.2 The storage thereof is a technical and organizational measure employed by us to protect against loss, destruction, access, alteration, or dissemination of your personal information by unauthorized persons.

8.3 Despite regular inspections, complete protection against all risks is not possible and we in no way guarantees complete protection in this regard.

8.4 For more information in respect of our security practices, please refer to our Manual which has been prepared in accordance with section 51 of the Promotion of Access to Information Act 2 of 2000, as amended, which Manual is available on our website.

9. RETENTION PERIODS

We will store your personal information which may be collected for any Pharmacovigilance purposes in accordance with the retention periods prescribed by law and/or in terms of the contractual Safety Data Exchange Agreements we are bound by. In terms of law, we are required to store your personal information for a period of 6 (Six) years after the relevant Pharmacovigilance records goes dormant, as prescribed by the Health Professionals Council of South Africa. However, we may store personal information for longer periods, where such periods of retention are prescribed in terms of the relevant Safety Data Exchange Agreements.

10. **YOUR RIGHTS**

We wish to inform you that you have the following rights in respect of your personal information: -

10.1 **Right of Access to, Correction and/or Deletion of Personal Information**

10.1.1 Provided you are able to prove your identity, you have the right to request confirmation, free of charge, whether we hold personal information about you, as well as information about the categories of third parties who have, or have had, access to your personal information.

10.1.2 Should you wish to establish whether we hold any personal information about you, you are invited to send us an email with your request using the information set forth above.

10.1.3 Should personal information be disclosed to the data subject in response to any requests as aforesaid, the data subject is hereby notified of its right to request correction, deletion and/or blocking of the personal information, in line with section 24 of the Protection of Personal Information Act 4 of 2013, as amended.

10.1.4 Should you wish to request the correction or deletion of your personal information or the destruction or deletion of a record of personal information, please submit a request to us on Form 2, which may be accessed at https://www.justice.gov.za/legislation/notices/2018/20181214-gg42110-rg10897-gon1383-POPIregister.pdf. We will render such reasonable assistance, as may be necessary and free of charge, to enable you to complete Form 2.

10.2 **Right to Object to processing of Personal Information**

10.2.1 Please take note that you may object, at any time in terms of section 11(3) of POPI, to the processing of your personal information, where processing takes place on the following grounds: -

10.2.1.1 In order to protect your legitimate interest; or

10.2.1.2 Where processing is necessary for pursuing our legitimate interest, or those of a third party; and

10.2.1.3 Where your information is processed for the purposes of direct marketing, other than by way of electronic communication.

10.2.2 Should you wish to object to the processing of your personal information in terms of section 11(3)(a) of POPI, please submit your objection to us on Form 1, in accordance with the Regulations relating to POPI.

10.2.3 The Form 1 document may be accessed through the following link: https://www.justice.gov.za/legislation/notices/2018/20181214-gg42110-rg10897-gon1383-POPIregister.pdf

10.2.4 We will render such reasonable assistance as is necessary, free of charge, to enable you to make an objection on Form 1.

10.2.5 Any objections must be based on reasonable grounds relating to your particular situation, unless legislation provides for such processing, in which case we shall continue to process such personal information in compliance with our statutory obligations.

10.2.6 In the absence of such legislative obligations, we will review and, if necessary, cease the processing of such personal information.

10.2.7 We will inform you of the results of the review and if the data processing is to continue nevertheless, we will provide you with detailed information about why the continued processing is permitted and/or required.

10.3 **Right to Lodge a Complaint**

10.3.1 Should you feel as though we have used your personal information contrary to POPI, please send us an email in order for us to attempt to address any of your concerns. If we are unable to resolve the issue to your satisfaction, you have the right to lodge a complaint with the Information Regulator.

10.3.2 In terms of the Regulations relating to POPI, any person who wishes to submit a complaint must submit such a complaint to the Information Regulator on Part I of Form 5.

10.3.3 The relevant form is accessible via the following link: https://www.justice.gov.za/legislation/notices/2018/20181214-gg42110-rg10897-gon1383-POPIregister.pdf

10.3.4 The available contact details of the Information Regulator are recorded as follows:

10.3.4.1 Address: JD House, 27 Stiemens Street, Braamfontein, Johannesburg, 2001;

10.3.4.2 Postal Address: PO Box 31533, Braamfontein, Johannesburg, 2017.

10.3.4.3 Email: complaints.IR@justice.gov.za.

11. OUR CONTACT INFORMATION

11.1 Feel free to contact us with any questions related to handling of personal information for Pharmacovigilance purposes using the details provided below:

11.1.1	Information Officer:	Mr. Roberto Agustoni.
11.1.2	Postal Address:	P.O. Box 786522, Sandton 2146.
11.1.3	Street Address:	3 Sandown Valley Crescent, South Tower, 1st Floor, Sandton, 2196.
11.1.4	Telephone Number:	011 784 0077.
11.1.5	Fax Number:	011 784 6994
11.1.6	Email Address:	privacy@pharmaco.co.za.

11.2 For more information regarding the way Pharmaco protects your personal information, we invite you to read our privacy policy, accessible here.

Last updated: 22 November 2021