

PHARMASPHERE PRIVACY STATEMENT FOR PHARMACOVIGILANCE DATA

Pharmasphere, Inc., and its affiliates including, but not limited to WG Critical Care, LLC, and US VET Inc., (hereinafter “Pharmasphere, “us”, “our” and “we”) develop and/or market prescription drugs, OTCs, and related products, for human and animal use (“Pharmasphere Products”). Pharmasphere is legally obligated to monitor the safety of all Pharmasphere Products that are being developed or are being marketed in the United States.

Pharmasphere’s monitoring of the safety of the Pharmasphere Products includes capturing information about any adverse events or adverse reactions related to, or arising from, the use of these Products. The monitoring of adverse events, is critically important to the safe development and marketing of the Pharmasphere Products.

The monitoring of such adverse events is called Pharmacovigilance. Pharmacovigilance requirements exist to allow Pharmasphere and regulatory authorities to manage these adverse events in order to protect the health and safety of the public and to ensure that all Pharmasphere Products meet the highest standards of quality and safety.

Pharmasphere’s Pharmacovigilance obligations require us to gather and process information which may directly or indirectly identify a person, personal medical information of a patient and/or the reporter of an adverse event. We review this information in order to comply with our strict obligations to assess the safety of Pharmasphere Products and to report suspected adverse events to relevant regulatory authorities.

This Privacy Statement provides important information about how we process and protect the privacy of your personal data in compliance with our obligations under applicable data privacy laws. If you are a resident of California or Nevada in the United States, you may have additional rights regarding your personal data.

Definitions

“Adverse event” means any adverse drug experience associated with the use of a Pharmasphere product in humans or animals, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal, and any failure of expected pharmacological action.

“Affiliate(s)” shall mean any person, corporation, company, partnership, joint venture or other entity controlling, controlled by or under common control with Pharmasphere, Inc. For such purpose the term “control” means the holding of 50% or more of the common voting stock or ordinary shares in, or the right to appoint 50% or more of the directors of the said corporation, company, partnership, joint venture or entity.

“Personal Data” means information in any format that can be used, directly or indirectly, alone or in combination with any other information, to identify a person.

“Pharmasphere” means Pharmasphere, Inc. or its Affiliates including, but not limited to, WG Critical Care LLC and US Vet Inc. having their principal offices at 120 Route 17 North, Paramus, New Jersey 07652 also referred to in this Privacy Notice as “we”, “us” and “our”.

Pharmasphere and your privacy

Ensuring patient safety is extremely important to Pharmasphere and we take the safe use of all our products seriously. Pharmasphere needs to be able to get in touch with people who contact Pharmasphere about our products in order to follow-up and obtain further information, give answers to requests or to send requested material. This Privacy Notice describes how we collect and use Personal Data to help us fulfill 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.

Scope of this Privacy Notice

This Privacy Notice applies to information we collect from or about you online, by phone, fax, e-mail or post, or as part of the adverse event or quality reporting regulations applicable to Pharmasphere. We may also collect this information about you through specific forms submitted by you on a site that is owned or controlled by Pharmasphere.

If you are a patient, we may also be provided with information about you by a third party reporting an adverse event that affected you. Such third parties may include medical professionals, lawyers, relatives or other members of the public.

Information we collect and why we collect it

Pharmasphere is under a legal obligation to collect specific data for reasons of the public interest in protecting public health. We may need to collect, store or use Personal Data regarding patients who are the subject of adverse event reports and the reporters of such events.

Patient Information

We collect Personal Data about you when you or a third party provides us with information in relation to an adverse event that affected you or someone else. Where you are reporting the adverse event yourself, please also refer to the Reporters section.

Pharmacovigilance laws require us to take “detailed records” of every adverse event passed to us to allow the event to be evaluated and collated with other adverse events recorded about that product. The Personal Data that we may collect about you when you are the subject of an adverse event report includes the following:

- name or initials;
- age and date of birth;
- gender;
- weight and height;
- your medical history and status which may include details of the product suspected to cause the adverse event, 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 prescribed at the time of the reaction,
- information regarding 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 including such information as laboratory reports and patient histories.

Some of this information is considered by law to be “sensitive personal data” about you. This includes any information that tells us about your:

- health;
- ethnicity;
- religion; and
- sexual life.

This information is only collected or used to document your adverse reaction properly and for the purpose of meeting Pharmasphere’s pharmacovigilance and any other legal requirements.

Reporter Information

We collect information about persons who provide us with information in relation to an adverse event that has been reported.

Pharmacovigilance laws require us to ensure that adverse events are traceable and available for follow-up. As a result, we must keep sufficient information about reporters to allow us to contact you once we have received the report. The Personal Data that we may collect about you when you report an adverse event includes the following:

- the reporter's name;
- personal contact details (which may include your address, e-mail address, phone number or fax number); and
- relationship with the person who is the subject of the report.

Where you are also the subject of a report, this information may be combined with the information you provide in relation to your reaction.

How we use your Personal Data

As part of meeting our pharmacovigilance obligations, we may use and share Personal Data only to investigate the adverse event, to contact the patient or reporter for further relevant information, to analyze the safety of our products and to provide legally required data and reports to regulatory authorities in the United States so that the safety of our products can be evaluated.

Personal Data collected from you in accordance with this Privacy Notice may also be transferred to a third party in the event of a sale, assignment, transfer, or acquisition of the company or a specific product or therapeutic area, in which case we would require the buyer, assignee or transferee to treat that Personal Data in accordance with applicable data protection laws.

We may also share Personal Data with other pharmaceutical companies who are our co-marketing, co-distribution, or other license partners, where pharmacovigilance obligations for a product require such exchange of safety information.

We share information with national or local regulatory authorities as required by applicable pharmacovigilance laws. We are unable to control their use of any information we share, however, note that in these circumstances, we do not share any information that directly identifies any individual (such as names or contact information).

Maintaining Security of your Personal Data

We have implemented appropriate technical and organizational measures to safeguard the data gathered or stored for pharmacovigilance purposes. We take appropriate physical and electronic steps to protect the data from unauthorized use or disclosure or accidental loss or destruction.

We use and store the data in accordance with applicable laws and regulations governing the storage and use of pharmacovigilance data. These requirements mandate the retention of the data for the life cycle of the product and for any additional period that may be required by applicable government regulations.

Personal Data is submitted to Pharnasphere and is hosted and stored in databases on servers situated in Paramus, New Jersey, which are owned and maintained by Pharnasphere and its affiliates.

Your rights

You have the right to request information regarding your Personal Data including the right to correct your Personal Data if incorrect or incomplete, the right to request transfer of your Personal Data to you or another person, and the right to request deletion of your Personal Data if no longer needed for pharmacovigilance purposes. These rights may be limited, however, by legal or regulatory requirements regarding the storage and use of pharmacovigilance data. For example, we cannot delete data that has been collected for an adverse event report unless it is inaccurate.

We hope that we can satisfy any queries you may have about the way in which we process your Personal Data. If you have any concerns about how we process your Personal Data, you can contact Pharmasphere at adverseevents@interchem.com. We shall require you to provide proper identification before we can respond to any request to access or correct your Personal Data.

Contact Information

If at any time, you have questions or concerns about this Privacy Notice, please e-mail us at adverseevents@interchem.com. We will use reasonable endeavors to answer your question promptly or resolve your problem.