DSP-POLICY-0001 - ADVERSE EVENT AND PRODUCT COMPLAINT POLICY

All Purdue Pharma L.P. (PPLP) and its Purdue subsidiaries in USA (Rhodes, Imbrium, Adlon and Avrio) employees and those acting on the Company's behalf (such as Vendors) are required per Company policy to report Adverse Events (AEs) associated with any of the Company's products, including any product that contains the **same active ingredient as a Company product when the brand and/or manufacturer of that product are unknown,** to the Drug Safety and Pharmacovigilance (DSP) Department. DSP is required to monitor and assess safety of Purdue products and the products of its subsidiaries (Adlon, Avrio, SVC Pharma, and Rhodes) and ensure information is reported to FDA per applicable regulations.

An **Adverse Event (AE)** is any unwanted or unintended experience associated with the use of a drug (prescription or over the counter (OTC)) or dietary supplement in humans, regardless of whether the experience is thought to be caused by the drug or supplement.

Examples of Adverse Events may include, but are not limited to: *Unintended benefits, lack of effect, increased effect, misuse or abuse, overdose (accidental or intentional), off-label use, drug withdrawal, exposure during pregnancy, occupational exposure, worsening of a pre-existing condition, interactions with other drugs, supplements, or foods, medication errors such as incorrect dosing or administration of the drug or supplement, hospitalization, inpatient or outpatient surgery, and death.*

All company employees and those acting on the Company's behalf (such as Vendors) are required per Company policy to report **Product Complaints (PCs)** associated with any of the Company's products to the Product Monitoring Group in the Quality Assurance Department. The DSP or Quality Assurance team will follow up with the reporter, as necessary.

A **Product Complaint (PC)** is any untoward occurrence with the physical characteristics of a product or with the product's packaging, labeling, immediate container, closure, or contents.

When reporting a potential PC, provide as much information as possible concerning the description of the potential PC:

- Product: Brand name, generic name, active ingredient, lot number,
- Report: Full name and contact information (phone number and current mailing address)

Should you become aware of a potential AE or PC, please follow the procedures in this document. **Please report the potential AE/PC as soon as possible, but no later than 24 hours after learning of it**.

- ***If you are uncertain if something is a potential AE or PC, please err on the side of caution and report the information as per this Policy.***

WAYS TO REPORT AN AE/PC:

It is only necessary to report via **one** of the following methods.

- **Phone:** Dial 1(888) 726-7535, Adverse Event= Press 2, Product Complaint= Press 3
- **Company Voicemail:** can be forwarded to the phone number above (follow the prompts)
- **Email: AEs:** AEReport2@pharma.com (Company employees can select the "**AE Report**" address in Outlook). **PCs:** productcomplaints@pharma.com (Company employees can select the "**Product Complaints**" address in Outlook).

The Health Insurance Portability and Accountability Act (HIPAA) specifically permits disclosure of protected health information without authorization in the context of AE reporting.

When reporting a potential AE, remember the acronym "**RIPE**," and provide as much information as possible:

- **R**eporter: Full name and contact information (phone number, email address and/or current mailing address)
- **I**ndividual(s) experiencing the potential AE: Age, date of birth, or age category (e.g., adolescent, adult, elderly), gender, name, initials, or patient identification number
- **P**roduct(s): Brand name, generic name, active ingredient, lot number
- **E**vent(s): Description of the event(s) the patient experienced

If the AE/PC was received as a hard copy (e.g., letter):

- Immediately date stamp any hard copy information
- Once hard copy information is date stamped, it should be scanned and forwarded to Drug Safety and/or Product Monitoring via email (see **Ways to Report an AE/PC above**)
- After emailing, forward the original hard copy to Drug Safety or Product Monitoring via interoffice mail and state that this was emailed on {date}. *Please do not address the hard copy to any specific individual*