NOTICE
Adverse Event and Product Complaint Reporting
July 22, 2019

The Company has obligations to monitor Adverse Events (AEs) and Product Complaints (PCs) that are associated with any Company product, including any product that contains the same active ingredient when the brand and/or manufacturer of that product are unknown. Please refer to pages 4, 5, and 6 of this document for the list of products.

Should you become aware of a potential AE or PC, please follow the procedures in this document and in the corresponding section of Purdue's Healthcare Law Compliance Policies. **Please report the potential AE/PC as soon as possible, but no later than 48 hours after learning of it**.

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 or not it is caused by the drug/supplement.

Examples of Adverse Events include, but are not limited to:

- Unintended benefits
- Lack of effect
- Increased effect
- Drug misuse or abuse
- Overdose (accidental or intentional)
- Drug withdrawal
- Drug exposure during pregnancy
- Worsening of a pre-existing condition
- Drug interactions
- Medication errors
- Hospitalization
- Inpatient or outpatient surgery
- Death

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, please provide as much information as possible concerning the:

1. Adverse Event (AE): description of the event(s) the patient experienced
2. Patient(s): age, (or age category, e.g. adolescent, adult, elderly), gender, initials, date of birth, name, or patient identification number
3. Product(s): Brand name, generic name, active ingredient, lot number
4. Reporter: Full name and contact information (phone number and current mailing address)

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.

Please provide as much information as possible concerning the:

1. Description of the potential PC
2. Product: Brand name, generic name, active ingredient, lot number
3. Reporter: Full name and contact information (phone number and current mailing address)

If you are uncertain if something should be reported as an AE or PC, please err on the side of caution and report the information. We will follow up with the reporter, as necessary.

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, scan and forward the document to Drug Safety and/or Product Monitoring via e-mail (see **Ways to Report an AE/PC** below).
- After e-mailing, forward the original hard copy to Drug Safety or Product Monitoring via interoffice mail. Please do not address the hard copy to any specific individual.

Ways to Report an AE/PC:

Report via **one** of the following:

Phone/Voicemail:

Phone: (888) 726-7535, prompt 2 (to report an Adverse Event) or prompt 3 (to report a Product Complaint)

Voicemail can be forwarded to the phone number above (follow the prompts).

E-mail:

- **AEs:** Select the "Drug Safety and Pharmacovigilance" or "AE Report" address in Outlook (or email: AEReport2@pharma.com).
- **PCs:** Select the "Product Complaints" address in Outlook (or email: productcomplaints@pharma.com).

Adverse Events in Aggregate Data:

Adverse events concerning **individual patients** can be found in aggregate data.

An **individual patient** can be identified by one of the following:

- age
- age category (e.g. adolescent, adult, elderly)
- gender
- initials
- date of birth
- name
- patient identification number.

The following **do not qualify** as patient identifiers:

- Groups of unknown size, such as "some" or "a few"
- Age range (e.g. 35-50 years old) unless additional personal information is provided (e.g. "a man between 35-45 years," "a middle-aged woman," or "three adolescents").

Solicited reports are those derived from organized data collection systems, which include clinical trials, post-approval named patient use programs, other patient support and disease management programs, surveys of patients or healthcare providers, or information gathering on efficacy or patient compliance.

Examples of aggregate data include, but are not limited to:

- meta-analyses
- observational studies
- claims data review
- patient registries
- medical chart reviews (including following-up on data with healthcare professionals)
- analysis of electronic health records
- PMR (Post-Marketing Requirement)
- market research

Anyone reviewing aggregate data is responsible for being familiar with the US Package insert(s) pertaining to the products(s) involved.

- Any **serious, unexpected adverse events associated with an individual patient** found during periodic (quarterly, bi-annual, etc.) review of aggregate data must be reported to Drug Safety **within 48 hours**.
- Any **serious, expected or non-serious adverse events must be reported to Drug Safety within 15 days after the end of the study analysis**.

Thank you for your attention to this important matter.

Drug Safety & Pharmacovigilance
Corporate Quality Assurance

Purdue Pharma L.P.

Butrans® (buprenorphine) Transdermal System CIII and authorized generic
Hysingla® **ER** (hydrocodone bitartrate) Extended-Release Tablets CII
MS Contin® (morphine sulfate extended-release tablets) CII
OxyContin® (oxycodone hydrochloride) Extended-Release Tablets CII and authorized generic

Adlon Therapeutics L.P.

Adhansia XR™ (methylphenidate hydrochloride) extended-release capsules CII

Avrio Health L.P.

Betadine first aid antiseptic products-Consumer Use

Betadine® **Cream**
Betadine® **Solution**
Betadine® **Spray**
Povidone Iodine (all of the above)

Betadine antiseptic products-Professional Use

Betadine® Solution
Betadine® **Surgical Scrub**
Betadine® **Swabsticks**
Povidone iodine (all of the above)

Betadine antispetic products-Veterinary Use

Betadine® Solution
Betadine® Surgical Scrub
Povidone Iodine (all of the above)

Betasept® antispetic products-Professional Use

Betasept® **Surgical Scrub**
Chlorhexidine gluconate 4%

Colace stool softeners and laxatives

Colace® **Capsules**
Docusate sodium
Colace Clear® **Soft Gels**
Docusate sodium
Colace® **2-IN-1 Tablets**
Docusate sodium and sennosides

Senokot laxatives

Senokot® Tablets
Standardized senna concentrate
Senokot® Extra Strength Tablets
Standardized senna concentrate
Senokot-S® Tablets
Standardized senna concentrate
and docusate sodium

Dietary Supplements

Senokot™ Ginger Care™ Tablets
Ginger root extract

Senokot™ Kiwi Balance™ Chewable Tablets
Kiwi Zyaction™ (freeze dried
kiwifruit pulp)

SlowMag™ Mg Muscle + Heart Tablets
Magnesium Chloride + Calcium

SlowMag™ Mg Brain Caplets
Magnesium Citrate + Riboflavin

Rhodes Pharmaceuticals L.P.

Acetaminophen and Codeine Phosphate Tablets, USP

Aptensio XR® (methyphenidate hydrochloride extended release) Capsules CII

Buprenorphine Sublingual Tablets CIII

Dilaudid® Oral Solution
Dilaudid® Tablets
(hydromorphone hydrochloride) CII

Dexmethylphenidate Hydrochloride Tablets CII

Dextroamphetamine Saccharate, Amphetamine Aspartate Monohydrate, Dextroamphetamine Sulfate, and Amphetamine Sulfate Extended-Release Capsules CII

Fenofibrate Capsules, USP (micronized)
Fenofibrate Tablets, USP

Hydromorphone Hydrochloride Oral Solution CII Authorized generic
Hydromorphone Hydrochloride Tablets CII Authorized generic

Hydrocodone Bitartrate and Acetaminophen Tablets, USP CII

Morphine Sulfate Extended-Release Tablets CII
Morphine Sulfate Oral Solution CII

Oxycodone and Acetaminophen Tablets, USP CII

Oxycodone Hydrochloride Tablets, USP CII

Theophylline (Anhydrous) Extended-Release Tablets

SVC Pharma L.P.

Dronabinol Capsules, USP CIII