

### IPSEN BIOPHARMECEUTICALS, INC. COMPREHENSIVE COMPLIANCE PROGRAM

June 2016

#### A. Introduction

Ipsen Biopharmaceuticals, Inc. (Ipsen US) is committed to establishing and maintaining an effective compliance program in accordance with the "Compliance Program Guidance for Pharmaceutical Manufacturers" issued by the Office of Inspector General, U.S. Department of Health and Human Services on May 5, 2003 (the "OIG Guidance") and with the Pharmaceutical Research and Manufacturers of America voluntary guideline entitled "Code of Interactions with Health Care Professionals," effective January 2009 (the "PhRMA Code").

Our Compliance Program is one of the key components of our commitment to the highest standards of corporate conduct. The purpose of our Compliance Program is (a) to provide appropriate training to management, employees and agents; and (b) to prevent and detect violations of law and Company policy. As acknowledged by the OIG Guidance, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. It is Ipsen US's expectation that our employees will comply with our Code of Ethical Conduct in Business (the "Code") and other relevant policies. In the event that Ipsen US becomes aware of violations of law, regulations or Company policy, we will investigate the matter and, as appropriate, take disciplinary action and implement corrective measures to prevent future violations.

The fundamental elements of our Compliance Program are described below. Consistent with the OIG's recommendation, Ipsen US's Compliance Program has been established consistent with the unique environment that exists at Ipsen US. Further, our Compliance Program is dynamic; we periodically engage in a review of our Compliance Program to meet our evolving compliance needs on an ongoing basis.

California Residents: A copy of the description of the Compliance Program, Ipsen US's Declaration of Compliance and related materials may be obtained by calling Ipsen US at 1-866-384-4277.

## B. Summary of Compliance Program

### (1) Leadership and Structure.

## (a) Compliance Officer:

The Company's Compliance Program is led by its Compliance Officer.

We are committed to ensuring that the Compliance Officer has the ability to effectuate change within the Company as necessary and to exercise independent judgment. The Compliance Officer, among other responsibilities, is charged with developing, operating and monitoring the Compliance Program. The Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate, and has access to, and is authorized to, report concerns or issues of any kind directly to Ipsen US officers and directors.

### (b) Compliance Committee:

Ipsen US has established a Compliance Committee, composed of senior management within the organization, to advise the Compliance Officer and assist with the implementation of the Compliance Program.

## (2) Written Standards.

## (a) Code of Conduct:

Ipsen US's Code of Ethical Conduct in Business is our statement of ethical and compliance principles that guide our daily operations. The Code establishes that we expect management, employees and agents of the Company to act in accordance with all relevant laws, regulations and Company policies. The Code articulates our fundamental principles, values and framework for action within our organization.

## (b) Policies and Procedures:

- The OIG Guidance identified several key risk areas for pharmaceutical manufacturers and called on companies to develop compliance policies in these risk areas. These risk areas include:
  - (1) data integrity pertaining to government reimbursement practices;
  - (2) kickbacks and other illegal remuneration;
  - (3) sales, marketing and promotional practices; and
  - (4) compliance with laws regulating prescription drug sampling activities.



Ipsen US has established policies that address interactions with health care professionals (including promotional practices and kickbacks), data integrity, and sampling activity.

ii. We have also established an annual spending limit of \$2,000 per health care professional for certain promotional activities. This amount is an upper limit and addresses spending on health care professionals for occasional meals and snacks, meals provided in connection with a Company speaker program, and any gifts, such as medically related textbooks or journals. This amount does not include the value of pharmaceutical drug samples, grants for medical education, medical scholarships, professional service or consulting fees, patient education materials, and approved scientific reprints. An exception to this \$2,000 amount may be made only upon the prior written approval by Ipsen US's Chief Executive Officer and Ipsen US's Compliance Committee. This limit may also be subject to other state or federal laws addressing interactions with government employees and health care professionals.

### (3) Education and Training.

Education of our employees and agents on their legal and ethical obligations is a key component of Ipsen US's Compliance Program. Ipsen US is committed to taking the steps necessary to effectively communicate our standards and procedures to all of our personnel. In addition, Ipsen US will regularly review and update its training programs and identify additional areas of training on an as needed basis.

## (4) Open Lines of Communication.

Ipsen US has a longstanding policy of fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions or reporting potential instances of improper conduct, ethical violations or fraud and abuse, should know who to turn to for a meaningful response and should be able to do so without fear of retaliation. To that end, Ipsen US has adopted policies regarding confidentiality and non-retaliation policies. Our compliance hotline can be reached by dialing 1-866-384-4277 or at <a href="https://www.ethicspoint.com">www.ethicspoint.com</a>.

# (5) Auditing and Monitoring.

Ipsen US's Compliance Program includes efforts to monitor, audit, and evaluate compliance with the Company's compliance policies and procedures through internal and external resources.

#### (6) Discipline.

Ipsen US has established compliance standards and policies for which employees are accountable. Consequences of violating the law or Company policy include discipline up to and including termination.

## (7) Corrective Actions.

Ipsen US's Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, consistent with the OIG's comments, Ipsen US recognizes that even an effective Compliance Program may not prevent all violations. That being said, Ipsen US's Compliance Program requires that the Company respond promptly to all potential violations of law or Company policy, take appropriate disciplinary action, perform an assessment of the violation to ascertain if the violation reveals a gap in our policies, practices, or internal controls and take appropriate action to prevent future violations.