

**LUNDBECK COMPREHENSIVE COMPLIANCE PROGRAM PURSUANT TO  
California Health & Safety Code, §§ 119400-119402**

NOTICE OF COMPLIANCE: the following information is provided pursuant to the requirements of California Health & Safety Code § 119402 (S.B. 1765) *Adoption of Comprehensive Compliance Program by pharmaceutical companies; contents of policy; annual dollar limits on certain items; drug samples; annual declaration of compliance*, which requires pharmaceutical companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promoting of their products.

**Introduction:** Lundbeck and its other U.S. affiliates have complied with the requirements of the California Health & Safety Code §§ 119400-19402 (S.B. 1765) through the establishment of a Corporate Compliance Program in accordance with the April 2003 United States Department of Health and Human Services, Office of Inspector General OIG Compliance Program Guidance for Pharmaceutical Manufacturers publication.

**Compliance Program and Organization:** Lundbeck is committed to full compliance with all applicable international, federal, state and local laws as well as all applicable industry and ethical standards. To ensure full compliance, Lundbeck has established a Corporate Compliance Program governed by the Lundbeck Corporate Ethics and Compliance Manual and the Lundbeck Code of Conduct. The Lundbeck U.S. President has the authority to appoint the Corporate Compliance Officer and has appointed John Borgerding, Vice President, Chief Compliance Officer, and Corporate Counsel, to serve in this capacity. John Borgerding serves as the Chairman of the Corporate Compliance Committee. With the support of the Compliance Committee, the Compliance Officer is responsible for the overall implementation and maintenance of the Compliance Program.

**Written Policies and Procedures:** Lundbeck has written policies and procedures to assure substantial compliance with all applicable laws, rules, regulations and industry standards pertaining to interactions with health care professionals and the marketing and promotion of Lundbeck products. Included in the Lundbeck Comprehensive Compliance Program are policies that incorporate and take into account the Pharmaceutical Research and Manufacturers of America (PhRMA) “Code on Interactions with Health Care Professionals,” January, 2009.

Lundbeck’s Compliance Policies govern all interactions with health care providers, including, but not limited to:

**Meals:**

It is Lundbeck policy to enhance the practice of medicine via exchange of information about Lundbeck products and that occasional meals may be offered to physicians and other health care providers. Meals provided to physicians or other health care providers must be modest in amount and must occur in a venue conducive to an informational discussion regarding the Company’s products and comply with any state, local or

institutional requirements. Any such meals offered in connection with informational presentations made by field sales representatives or their immediate managers should also be limited to in-office or in-hospital settings. If the off-site meal is to be conducted outside of the United States, the Chief Compliance Officer must be consulted in order to determine an appropriate limit per individual. Meals may not be provided to a health care provider's spouse, children, or other guests. However, if the meal is provided at the practitioner's office, it may be provided to the office staff as well as to the health care provider and any relevant support staff. A company representative must be present at every meal. All receipts submitted for reimbursement must list each health care provider that attended the Company-sponsored meal for aggregate spend and transparency purposes.

Gifts of Educational and Practice-Related Items: Providing items for health care professionals' use that do not advance disease or treatment education—even if they are practice-related items of minimal value (such as pens, note pads, mugs and similar “reminder” items with company or product logos) are prohibited. Such non-educational items will not be offered to health care professionals or members of their staff, even if they are accompanied by patient or physician educational materials. It is appropriate to provide product samples for patient use in accordance with state law and the Prescription Drug Marketing Act.

Where permitted by law, it is permissible to offer items designed primarily for the education of patients or health care professionals if the item(s) are not of substantial value (\$100 or less) and do not have value to health care professional(s) outside of their professional responsibilities. Educational items should not be offered on more than an occasional basis, even if each individual item is appropriate. Some states have more stringent laws, which must be followed in those states.

Entertainment: Provision of any type of entertainment (i.e., golf, sporting events, plays, concert tickets, etc.) is prohibited.

Educational Grants: In accordance with U.S. Department of Health and Human Services Guidance for Industry, Industry-Supported Scientific and Educational Activities Policy and ACCME Standards for Commercial Support, Lundbeck may provide unrestricted grants for continuing medical education programs. Lundbeck will fund educational programs through appropriate organizations (e.g., CME providers) and institutions (hospital CME departments).

Research Grants: Research Grants are evaluated for their scientific merit and rigor. They are conducted in accordance with all applicable laws, rules and regulations including, but not limited to, F.D.A., G.C.P. and privacy laws.

Compensation for Services: It is appropriate to pay fees to health care providers who serve as consultants, contractors, or other third party agents on behalf of Lundbeck. Payments are allowed in those instances where the services required are legitimate and necessary and if the payments represent fair market value and reasonable consideration

for the services rendered. Consultants may only be selected based on their qualification and expertise and not with the intent to induce or in exchange for an explicit or implicit agreement or understanding that the Company's products and/or services will be used, purchased, prescribed or recommended.

**Legitimate Travel Expenses of Healthcare Professionals:** Reimbursement for travel, lodging and meal expenses for legitimate consulting services, whether it be for advisory boards, speaker's bureaus or clinical investigator meetings must be modest and reasonable as judged by local standards. Travel, lodging and meal expenses may not be provided to a health care provider's spouse, children, or other guests.

**Training and Education:** Lundbeck is committed to educating and training its employees about the Compliance Program. All employees must be educated and trained on the standard operating policies and procedures related to the Compliance Program. In addition to the Compliance Program, each respective division must be trained on their particular applicable divisional policies and procedures.

**Communication:** Lundbeck encourages open and candid discussion between management and employees regarding compliance matters. It is the duty of every employee to report in a timely manner, in good faith, if he or she believes that a violation of Lundbeck policy has occurred. Employees are to report suspected violations to their supervisor, the Compliance Officer, Human Resources, or any member of the Compliance Committee in writing or in person. Lundbeck has also provided a toll-free hotline that employees can use as well to make an anonymous report.

**Auditing and Monitoring:** Lundbeck is committed to robust and comprehensive monitoring and auditing of Lundbeck activities. The Compliance Officer with the support of the Compliance Committee will periodically audit and/or monitor various departments and activities of Lundbeck to ensure compliance with applicable laws, regulations, and internal operating procedures. The Compliance Officer shall have the authority and financial resources to retain outside auditors as needed. The Compliance Officer shall audit at least one department of Lundbeck per year. The Compliance Officer may conduct additional audits as necessary. Each department may be subject to additional audits per year.

**Response to Internal Monitoring and Auditing:** The Compliance Officer or Compliance Committee will establish a corrective action plan in response to an actual violation. Suspected violations of Lundbeck policy and procedures will be investigated, and violators may be disciplined, all in a fair manner regardless of the suspected violator's position within the organization. Lundbeck may discipline all violators of Lundbeck policies and procedures. If the investigation by the Compliance Officer determines that an actual violation has occurred, then the corrective action plan established by the Compliance Officer or Compliance Committee shall be put into effect, which may include disciplinary action, up to and including termination of employment as necessary for any violators identified.

**Limitations on Gifts or incentives provided to medical or health professionals:**

California law requires the Company to limit the annual dollar amount of gifts, promotional items and activities provided to medical or health care professionals. California requires each pharmaceutical company to establish explicitly in its comprehensive Compliance Program a specific annual dollar limit on gifts, promotional materials, or items or activities that the pharmaceutical company may give or otherwise provide to an individual medical or health care professional in accordance with the Compliance Program Guidance for Pharmaceutical Manufacturers and with the Code on Interactions with Health Care Professionals. Lundbeck has decided that it may not spend more than \$1,700 on gifts, promotional materials, or items or activities on an individual California medical or health care professional in any fiscal year. The following items, however, are excluded from the scope of this policy: (1) drug samples for patients, (2) CME financial support, (3) health education scholarships that conform to the OIG and PhRMA guidelines, and (4) fair market value professional and consulting fees, along with associated reasonable expenses.

**Annual Declaration for Purposes of California Health & Safety Code, §§ 119400-119402**

Based upon a good faith understanding of the applicable statutory requirements of California Health & Safety Code, §§ 119400-119402, Lundbeck established a Comprehensive Compliance Program that encompasses the compliance program requirements stated in California Health & Safety Code, §§ 119400-119402.

As of December 2016, Lundbeck declares that it is, to the best of its knowledge and in all material respects, in compliance with California Health & Safety Code, §§ 119400-119402 and the Lundbeck Comprehensive Compliance Program. The Lundbeck Compliance Manual is available at <http://www.lundbeck.com/us/about-us/lundbeck-in-the-u-s/compliance> and copies of the Manual and this written declaration of compliance may be obtained by calling 1-866-337-6996.