

# **LUNDBECK'S CODE OF CONDUCT - THIRD PARTY OBLIGATIONS**

Under <u>Lundbeck's Code of Conduct</u> **Third Parties** are professionals and entities performing activities within Lundbeck's core business areas either on behalf of or in the material interest of Lundbeck. The activities performed by Third Parties include, but are not limited to, non-clinical safety research and other research activities, clinical research, interactions with authorities e.g. customs or medicines agencies, manufacturing of Lundbeck medicinal products, market access activities, medical information or promotional activities, sales and marketing activities including distribution and public relations activities.

To the extent relevant for its exercise of rights and performance of obligations under the agreement(s) entered into with Lundbeck (the "Agreement"), a Lundbeck Third Party must undertake to comply with the obligations below:

The version of these obligations in effect at the time of execution of the Agreement or amendment thereof shall apply (see Change Log at the end of this document).

A Lundbeck Third Party shall ensure that all relevant employees are aware of their below obligations and trained as needed. A Lundbeck Third Party shall promptly notify Lundbeck, if it suspects or becomes aware of any acts or omissions by its employees that conflict with its below obligations. In case of inconsistency between the terms and conditions of the Agreement and the below requirements, the terms and conditions which represent the strictest obligations on a Lundbeck Third Party shall apply.

Lundbeck shall have the right to audit relevant books, records, facilities etc. of a Lundbeck Third Party to ensure compliance with the below obligations. A Lundbeck Third Party shall assist in good faith and make all appropriate personnel, procedures, books, records etc. available to Lundbeck auditors during any such audits.

# **Responsible and Transparent Interactions**

A Lundbeck Third Party shall perform its obligations under the Agreement with professional-ism and without bias or conflicts with its own professional or personal interests. Furthermore, a Lundbeck Third Party must only interact with Public Officials when this is necessary, legitimate and mutually beneficial. This signifies that the interaction shall always have a professional purpose, be conducted in a manner that is transparent, free from undue influence or conflicts of interest, and shall benefit both Lundbeck and society. Furthermore, all such interactions including any related expenses must be in accordance with applicable laws and regulations.

# **Fair and Open Competition**

A Lundbeck Third Party shall comply with all applicable laws, regulations, guidelines and industry standards in order to preserve and protect free and open competition and to avoid abusive behaviour that may restrain competition.

### **Anti-corruption**

A Lundbeck Third Party has not and shall not engage directly or indirectly in bribery including small amount bribes or facilitation payments. Furthermore, a Lundbeck Third Party has not and shall not engage directly or indirectly in financial fraud against Lundbeck, its partners or government entities. A Lundbeck Third Party shall maintain accurate books and records re-

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lating to its performance under the Agreement and ensure that there are adequate internal controls in place with respect to prevent such fraud and corruption.

## Interactions with healthcare professionals and patient organisations

A Lundbeck Third Party shall ensure that all interactions with healthcare professionals, healthcare organisations and patient organisations are for legitimate reasons and in accordance with applicable laws, regulations and industry standards. Specifically, when interacting with healthcare professionals, healthcare organisations and patient organisations a Lundbeck Third Party shall

- be able to document the legitimate need for and professional purpose of any interaction:
- ii) ensure that any interaction is free of conflicts of interest;
- iii) ensure that a written agreement is in place before the commencement of any collaboration or fee for service arrangement and the compensation offered reflects the fair market value:
- iv) ensure that only appropriate locations and venues that are conducive to the professional purpose of events are selected or sponsored;
- v) not provide any entertainment leisure or social activities at events and ensure that no spouses, family members and other companions are invited;
- vi) only pay for travel, meals, accommodation and registration fees if inviting participants to events and keep all related costs reasonable;
- vii) not supply, offer or promise any gift or pecuniary advantage (in cash or benefit in kind) to healthcare professionals, healthcare organisations and patient organisations; and
- viii) maintain systems and procedures to ensure all transfers of value to healthcare professionals, healthcare organisations and patient organisations are recorded, reported or disclosed according to applicable regulations and standards

### **Donations and grants**

A Lundbeck Third Party shall ensure that any donations or grants provided by such Lundbeck Third Party under the Agreement are subject to written approval by Lundbeck on a case by case basis. Furthermore, all donations and grants

- i) must be provided for bona-fide purposes;
- ii) shall not be given to obtain business advantages; and
- iii) must adhere to applicable laws, regulations, guidelines and industry standards

### **Animal Research**

A Lundbeck Third Party shall maintain animal research policies and procedures that comply with applicable laws, regulations, guidelines and industry standards and that are consistent with <u>Lundbeck's Animal Ethics Policy</u>. Furthermore, a Lundbeck Third Party shall ensure that all of its employees working with animals have received appropriate and documented education and training.

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#### **Clinical Research**

A Lundbeck Third Party shall ensure that all clinical research activities are performed in accordance with applicable laws, regulations, guidelines and industry standards, including, without limitation, international guidelines, Good Clinical Practice (GCP) and ethical standards that meet international requirements. Furthermore, a Lundbeck Third Party shall ensure that all of its employees have been trained in relevant study procedures prior to being involved in clinical research activities.

### **Promotional Activities**

A Lundbeck Third Party shall ensure that all promotional activities performed by such Lundbeck Third Party fully adhere to applicable laws, regulations, guidelines and industry standards. Specifically, a Lundbeck Third Party shall

- i) never offer any undue or inappropriate benefits in exchange for prescribing, recommending purchasing, supplying or administering medicinal products;
- ii) only use promotional materials that are updated, complete and clearly give references to the source of information;
- iii) only use promotional materials approved following Medical, Legal and Regulatory review:
- iv) only carry out promotion of products that have a valid market authorisation in the country where such Lundbeck Third Party operates;
- v) never engage in off-label promotional activities;
- vi) only provide off-label information in accordance with applicable local laws, regulations and local Lundbeck procedures; and
- vii) ensure that all samples provided to healthcare professionals are only provided upon request, controlled and can be accounted for

A Lundbeck Third Party's relevant employees shall complete appropriate promotional practices/activities compliance training as reasonably required by Lundbeck.

# The Safety of Our Patients

A Lundbeck Third Party shall maintain an effective pharmacovigilance system that meets applicable international and national laws, regulations, guidelines and industry standards. A Lundbeck Third Party shall promptly report to <a href="mailto:safety@lundbeck.com">safety@lundbeck.com</a> any suspected adverse events associated with the use of Lundbeck's products. Furthermore, a Lundbeck Third Party shall promptly report to <a href="mailto:complaint@lundbeck.com">complaint@lundbeck.com</a> any detected incidences of counterfeit or suspected counterfeit Lundbeck products.

### **Human Resources**

A Lundbeck Third Party shall ensure that it complies with applicable national and international laws relating to human rights and labour rights. Specifically, a Lundbeck Third Party shall ensure that it

- i) provides their employees with at least a minimum amount of income to meet their basic needs;
- ii) provides their employees with the right to rest;
- iii) protects employees against discrimination in the workplace;

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- iv) protects employees against coercion and degrading treatment;
- v) respects employees right to freedom of association; and
- vi) upholds the effective abolition of child labour

## Health, Safety and Environment

A Lundbeck Third Party shall ensure that

- i) it maintains health, safety and environment procedures to ensure compliance with applicable laws, regulations, guidelines and industry standards; and
- ii) its employees have the working conditions and required knowledge to carry out their jobs in a healthy and safe manner and to minimise the impacts on the environment

## [END]

## **Change Log**

### **April 2017**

## Clarified applicability of Donations and Grants requirements

#### April 2016 <u>Link to this</u> <u>version</u>

### Revision reflecting updates to Lundbeck's Code of Conduct

Renamed the document. **Responsible and Transparent Interactions** revised to provide strengthened requirements when Third Parties interact with Public Officials. Such interactions must be necessary, legitimate and mutually beneficial. **Interactions with HCPs** restructured and tightened language added to emphasise the prohibition on providing gifts to healthcare professionals. **Donations and Grants** renamed and added requirement that any donation or grant provided by a Third Party must be subject to written approval by Lundbeck on a case by case basis. **Safety of our patients** added specific mail address for reporting any detected incidences of counterfeit or suspected counterfeit Lundbeck products.

### Jan 2014 <u>Link to this</u> version

### Revised due to tightened regulations in Industry Codes of Practice

The **Events**, **Gifts and Hospitality** section renamed as **Interactions with HCPs** with a wider scope. New requirements introduced in this section to record, report or disclose all transfers of value to HCPs; ensure that written agreements are in place for consultancies or other relevant services conducted by HCPs; and avoid the provision of entertainment or social activities at events. The wording **Sponsorships** has also been removed from the **Donations** section title to provide greater clarity.

### May 2012 Link to this version

#### Added Change Log

### Deleted in its entirety the section:

#### Supplier Standards

A Lundbeck Third Party shall ensure that its first tier suppliers are obligated to comply with applicable national and international laws relating to human rights, labour rights, environmental protection and the prevention of corruption. Specifically, a Lundbeck Third Party is obliged to ensure that its first tier suppliers (i) provide their employees with at least a minimum amount of income to meet their basic needs; (ii) provide their employees with the right to rest; (iii) protect employees against discrimination in the workplace; (iv) protect employees against coercion and degrading treatment; (v) respect employees right to freedom of association; (vi) uphold the effective abolition of child labour; (vii) provide employees safe and healthy working conditions; (viii) protect and improve the environment; and (ix) work against corruption in any form.

### Oct 2011

Launched "Principles of the Lundbeck Code of Conduct, Third Party Obligations"

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