Luxembourg, 4 June 2013

Environmental and Social Data Sheet

Overview

Project Name:	**LUNDBECK CNS DISORDER RDI RSFF**
Project Number:	**2012-0434**
Country:	Denmark
Project Description:	Financing Lundbeck's synoptic R&D activities for the 2013-2017 period for the development of new innovative patented drugs for the treatment of Alzheimer's and Parkinson's diseases with high unmet medical need.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

Summary of Environmental and Social Assessment, including key issues and overall conclusion and recommendation

The project concerns R&D activities oriented towards disorders of the central nervous system and more specifically Alzheimer's and Parkinson's diseases covering different stages of development (including pre-clinical and clinical studies) that will be carried out in existing facilities without changing their already authorised scope. This type of activities is not specifically listed in the EIA Directive 2011/92/EU; therefore an Environmental Impact Assessment (EIA) is not required.
This project addresses high unmet medical needs in Alzheimer's and Parkinson's diseases by developing therapies that offer higher efficacy, tolerability and safety and should therefore clearly benefit the society.

Environmental and Social Assessment

Environmental Assessment

The promoter's HSE (Health, Safety and Environment) activities are coordinated via an ISO 14001 certified HSE management system that covers R&D, manufacturing as well as the headquarters' functions.
Lundbeck has a sound environmental policy including regular audits and reporting. R&D facilities and practices are in compliance with national and EU relevant regulation and the promoter maintains adequate internal procedures and management practices.
All promoter's HSE activities are coordinated via an ISO 14001 certified HSE management system that covers R&D, manufacturing as well as the headquarters' functions.

Social Assessment

The clinical trials which are included in the project are performed under regulated and strictly controlled conditions, in existing specialised facilities which are regularly inspected by competent authorities - EMEA in Europe and/or national equivalent bodies in the rest of the World (FDA, PMDA, SFDA, etc.). The recruitment of patients is performed in accordance with the European directive (2001/20/EC) and/or equivalent international regulations in case of clinical trials performed outside Europe.

Other Environmental and Social Aspects

The promoter uses animals for research, safety testing of products where no acceptable alternative methods exist, as animal testing are necessary at pre-clinical stage. Still, the promoter is highly committed to apply the "3R" principle that consists in Replacing animal use by alternative methods when possible, Reducing the number of animals used as much as possible and Refining the testing methods to reduce animals' pain and distress.

[1] Only projects that meet the scope of the Pilot Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: above 100,000 tons CO2e/year absolute (gross) or 20,000 tons CO2e/year relative (net) – both increases and savings.