Luxembourg, 12 November 2013

Environmental and Social Data Sheet

Overview

Project Name:	CHIESI RESPIRATORY R&D
Project Number:	2013-0282
Country:	ITALY
Project Description:	Financing Chiesi Farmaceutici's clinical R&D programme for the period 2014-2015 for the development of new treatments for respiratory diseases with a particular focus on Asthma and COPD.
EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

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 respiratory system and more specifically COPD and Asthma and neonatology, 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 COPD, Astma and Respiratory Distress Syndrome diseases by developing therapies that offer higher efficacy, tolerability and safety and should therefore clearly benefit the society.

Environmental and Social Assessment

Environmental Assessment

Chiesi Group has been committed to reducing the environmental impact of its operations and of its products. Examples are the new R&D centre in Parma, designed according to modern criteria of eco-sustainability, and the development of manufacturing processes with a reduced environmental impact, e.g. the Modulite technology which involves the replacement of chlorofluorocarbons (CFCs), propellant gases which damage the ozone layer, with hydrofluoroalcanes (HFAs).

The promoter facilities undergo regular audit from Italian Medicines Agency (AIFA) AIFA in order to ensure compliance with EU Good Manufacturing Practice, Good Laboratory Practice and related guidelines as well as from the local public agency of health (ASL, Azienda Sanitaria Locale). The manufacturing sites are ISO 9001 certified and OHSAS 18001.

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.

[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.

Other Environmental

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.