Luxembourg, 13 March 2014

Environmental and Social Data Sheet

Overview

Project Name:	*SPRINT – RISK SHARING DEVELOPMENT FUNDING (RSFF)*
Project Number:	*20130428*
Country:	*BELGIUM*
Project Description:	Contingent risk sharing financing for the research and development of various medical compounds addressing particular unmet clinical need at various stages of development.

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 will be carried out in existing facilities without changing their already authorised scope. Research and development activities on pharmacy and biotechnology are not listed in any annexes of the directive 2011/92/EU and therefore do not need an Environmental Impact Assessment (EIA). The research activities undertaken in the project aim to create new therapeutic strategies improving health care quality and thus, the project, if successful, is expected to bring positive social impact. The promoter acts in line with locally relevant legislation regarding protection of animals used for scientific purposes.

Overall, the project can therefore be classified as acceptable with positive or no residual impact.

Environmental and Social Assessment

Environmental Assessment

The promoter complies with the strict regulations governing the biopharmaceutical world and is subject to regular audits from the competent authorities. All production sites are GMP (Good manufacturing practices) facilities. The promoter has defined a set of KPIs / benchmarks according to the Global Reporting Initiative (GRI), which are assured by external auditors.

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 - EMA 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.

Operating in a caring and socially responsible manner, especially when it comes to improving the lives of people with severe diseases through innovative therapies and support programmes, has been important for the promoter for many years. The results of these efforts are published in the Corporate and Societal Responsibility (CSR) report on a yearly basis. Furthermore the promoter has an ISO 14001 certificate for its main production sites.

Other Environmental 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.