Luxembourg, 3rd October 2014

Environmental and Social Data Sheet

Overview

Project Name:	Ferrer Pharmaceutical RDI II
Project Number:	*20140192*
Country:	*Spain*
Project Description:	The project concerns financing of R&D activities in a number of well-defined therapeutic areas.
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 investments in research and development in the field of pharmacy and biotechnology. The project will be carried out in existing facilities in 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 the national legislation regarding protection of animals used for scientific purposes. Laboratory waste (biohazard) obtains appropriate treatment.

The project per se does not have any residual negative impact on the environment and is, therefore, considered acceptable for the Bank's financing.

Environmental and Social Assessment

Environmental Assessment

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Laboratory waste (biohazard) obtains appropriate treatment.

The project per se does not have any residual negative impact on the environment.

Social Assessment, where applicable

The project, if successful, is expected to lead to significant social benefits resulting from new therapeutic strategies.

[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.

Ferrer is committed to continuously improve the environmental performance of its production processes, to consider, as part of operational management and business initiatives, the environmental needs, to minimize the negative impact that its business activities have on the environment and meet all legislative requirements and regulations. Ferrer implements GMP ICH Q7A and ISO 9001. It also complies with international quality standards, including FDA certification. Ferrer is also certified with HACCP and FAMI QS for food, feed and pharmaceutical ingredients. The company is also certified with ISO 14001 for environment management.

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.

With regards to animal testing the promoter follows the guiding principles for more ethical use of animals in testing called Three Rs (3Rs). Replacement refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim: I) Replacement refers to the preferred use of non-animal methods over animal methods whenever it is possible to achieve the same scientific aim, ii) Reduction refers to methods that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals, and iii) Refinement refers to methods that alleviate or minimize potential pain, suffering or distress, and enhance animal welfare for the animals used. It is fully in line with EU legislation (2010/63/EU).

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