

Environmental and Social Data Sheet

Overview

Project Name: *BIAL INOVACAO RDI II*
Project Number: *20150078*
Country: *Portugal*
Project Description: *Funding BIAL Group's R&D-activities, with a focus on drugs for epilepsy, cardiovascular and Parkinson's diseases, covering the period 2015-2017.*

EIA required: no

Project included in Carbon Footprint Exercise¹: no

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

The project concerns investments in research and development that will be carried out in existing facilities without changing their already authorised scope. An Environmental Impact Assessment (EIA) is therefore not required by EIA Directive 2011/92/EU. The Promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry standards and with EU legislation (2010/63/EU) regarding animal testing.

The research activities undertaken in the project are aimed to result in new and improved treatments for various central nervous system and cardiovascular diseases with a positive impact on healthcare quality. Therefore, the project, if successful, is expected to bring positive social impact.

Considering the above, the project is acceptable for Bank financing.

Environmental and Social Assessment

Environmental Assessment

BIAL has a sound environmental policy including commitments to comply with legal requirements, prevent pollution, continual improvement, regular audits and annual report of its environmental performance. R&D facilities and practices are in compliance with national and EU relevant regulation and the promoter maintains adequate internal procedures and management practices. BIAL adheres to the rules of good laboratory practices (GLP), along with established management systems (based on ISO 9001, ISO 14001 and OHSAS 18001).

BIAL was the first healthcare company in Portugal and one of the first in Europe, to obtain certification of its Quality and Environmental Management Systems under the ISO 9001 and ISO 14001 standards, respectively in 1998 and 2001. The latest ISO 14001 certificate was issued in 2013 and is valid until December 2016.

Additionally BIAL has the following certifications: OHSAS 18001 (Occupational Health and Safety management systems) obtained in 2010 and NP 4457 (Research, Development and

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.

Innovation management) obtained in 2007. BIAL was also the first company in Portugal to obtain this R&D certification.

Social Assessment

The project, if successful, is expected to lead to significant social benefits resulting from new and improved treatments for various central nervous system and cardiovascular diseases such as epilepsy and Parkinson's disease.

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...). 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

BIAL actively participates in associations and initiatives to promote scientific best practices and develop alternative research methods. With regards to animal testing, the promoter follows the guiding principles for more ethical use of animals in testing called Three Rs (3Rs). 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) regarding animal testing.