Luxembourg, 16/05/2017

Environmental and Social Data Sheet

Overview

Project Name:	GRIFOLS BIOSCIENCE R&D II SPAIN
Project Number:	2017-0093
Country:	Spain
Project Description:	Financing the promoter's R&D programme for new plasma proteins for various therapeutic areas, including Alzheimer disease, vascular and cardiovascular surgery and arterial thrombolysis.

EIA required:	no
Project included in Carbon Footprint Exercise[1]:	no

Environmental and Social Assessment

Environmental Assessment

Grifols 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. Each stage of development and production of Grifols has passed all the required inspections has and been given all of the necessary authorisations by the Food and Drug Administration (FDA) in the United States and the Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) in Spain. Grifols adheres to the rules of good manufacturing practices (GMP), these being the main safety benchmark, along with established management systems (based on ISO 9001, ISO 13485, ISO 14001, and OHSAS 18001). The Bioscience division also adheres to the quality standards of the QSEAL (Quality Standards of Excellence, Assurance, and Leadership) program and the IQPP (International Quality Plasma Program) of the Plasma Protein Therapeutics Association (PPTA).

The R&D headquarters in Spain are ISO 14001 certified.

Social Assessment

The project, if successful, is expected to lead to significant social benefits resulting from new and improved plasma protein treatments for various diseases.

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

[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.

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

Grifols 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 minimise potential pain, suffering or distress, and enhance animal welfare for the animals used. It is fully in line with EU legislation (2010/63/EU).

Conclusions and Recommendations

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 and quality management system and effective operating procedures in place which are in line with best industry standards. The research activities undertaken in the project are aimed to result in new and improved plasma protein treatments for various 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.