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Public

Environmental and Social Data Sheet

Overview

Project Name:	Collagen Technologies (MGF)
Project Number:	2015-0010
Country:	Germany
Project Description:	The project is an allocation under a global authorisation program. The project concerns R&D using the company's proprietary collagen technologies for the development of surgical implants and other pharmaceutical products. The products combine proven therapeutics with its proprietary collagen technology, enabling the creation of biocompatible and biodegradable products with customized drug release profiles, localised drug delivery and easy administration. Major indications addressed are pain, post-surgical adhesion and diabetic foot ulcer infections. Furthermore the project includes the upscaling of the manufacturing capacities.
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 promoter’s investments concern research, development and innovation activities as well as production deployment that will be in large part carried out in existing facilities already authorised for similar activities and volumes and that do not require an Environmental Impact Assessment (EIA) according to the relevant EU Directives.

The investment related to the expansion of production capacity at the current production site in Germany. This location is already part of an existing urban development plan and therefore a new EIA is not required. No impact on protected flora and fauna has been reported (Habitats 92/43/EEC and Birds 79/409/EEC). A **construction permit** for the building expansion **has been already been issued.**

The promoter is an innovative mid-cap company. The results of the promoter’s RDI activities are expected to contribute to the development of novel treatments that address a high unmet medical need. The project is overall considered as environmentally acceptable with minor negative residual impact as the resulting manufacturing activities will still add to the environmental load.

[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.

Environmental and Social Assessment

Environmental Assessment

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

Other Environmental and Social Aspects

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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