

Environmental and Social Data Sheet

Overview

Project Name: AMW (EGFF)
Project Number: 2017-0198
Country: Germany
Project Description: AMW is a pharmaceutical company specialised in the development and manufacturing of innovative drug delivery systems, i.e. technologies aimed at the targeted delivery and controlled release of pharmaceutical compounds in order to improve their efficacy, safety and convenience.

EIA required: no

Project included in Carbon Footprint Exercise¹: no

(details for projects included are provided in section: "EIB Carbon Footprint Exercise")

Environmental and Social Assessment

Environmental Assessment

The project will cover AMW's substantial R&D expenses relating to the development of existing and new products. It will also include an additional R&D facility and purpose-built manufacturing technologies for innovative drug delivery systems together with associated laboratory and manufacturing equipment.

The new facility will be built adjacent to the company's current facility situated in Warngau, Germany. The promoter already has a manufacturing facility on the same site, for the production of transdermal and parenteral dosage forms. The promoter has an integrated environmental management policy and effective operating procedures in place which are in line with best industry standards.

In line with the applicable national laws, the promoter has obtained all the necessary permits and authorisations from the competent authorities that are required to proceed with the construction of the new facility. The afore-mentioned permits and authorisations have been issued in compliance with Directive 2014/52/EU amending the EIA Directive 2011/92/EU. The production process of medicinal products has limited environmental impact and as the promoter is handling known active ingredients, product environmental risk assessments under directive 2001/83/EC are not deemed necessary and their absence will be duly justified by the expert, as is required in the marketing authorisation application. The project will be carried out

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.



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according to state-of-the-art technology and will take into consideration environmentally friendly, low energy-and-resource consuming technologies.

Other Environmental and Social Aspects

The adjacent existing facility of the promoter on the same site is audited, certified and authorised by the relevant German authorities for the manufacturing and release of human medicinal products. Furthermore, its Quality Control laboratory is qualified by the Competent National Authority as well as relevant international bodies. The promoter has a robust quality management system and effective operating procedures which have been duly audited by the Competent Authorities and are in-line with ICH and GMP standards. The new facility will comply with the aforementioned standards.

The promoter has supplied the Bank with copies of all the applicable and relevant authorisation documents during the due-diligence procedure.

Conclusions and Recommendations

The project will not result in significant additional negative environmental and social impacts compared to the current situation without the project. It is therefore considered acceptable for the Bank financing in environmental and social terms.