

Luxembourg, 6 May 2019

**Public**

## **Environmental and Social Data Sheet**

### **Overview**

Project Name:	ANIMAL HEALTH R&D SPAIN
Project Number:	2019-0003
Country:	Spain
Project Description:	Investments in R&D related to animal health

EIA required: no

Project included in Carbon Footprint Exercise<sup>1</sup>: no

### **Environmental and Social Assessment**

#### **Environmental Assessment**

The project's R&D activities concern the development of innovative biological products for animal health and are a central part of the promoter's operations. They will be embedded in the existing organisational and management structure. The project activities are not listed in any annexes of the Directive 2014/52/EU amending the EIA Directive 2011/92/EU and will be carried out in existing facilities already authorised that will not change their scope due to the project.

#### **Other Environmental and Social Aspects**

The promoter utilises an environmental management system and safety programmes and is conducting its business in compliance with all applicable environmental laws and regulations.

The promoter complies with the following frameworks:

- EU Guidelines on Good Manufacturing Practices (GMP);
- OCDE Guidelines on Good Laboratory Practices (GLP);
- The International Standards Organisation – ISO 14001:2015 Environmental management systems, ISO 9001:2015 Quality management systems.

The promoter is audited, certified and authorised by the Spanish Agency for Medicines and Health Products (AEMPS) for the manufacturing and commercialisation of veterinary medicinal products. Furthermore the promoter is compliant with applicable regulation, including Regulation (EC) 726/2004 and Directive 2001/82/EC relating to veterinary medicinal products.

<sup>1</sup> Only projects that meet the scope of the Carbon Footprint Exercise, as defined in the EIB draft Carbon Footprint Methodologies, are included, provided estimated emissions exceed the methodology thresholds: 20,000 tonnes CO<sub>2</sub>e/year absolute (gross) or 20,000 tonnes CO<sub>2</sub>e/year relative (net) – both increases and savings.

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The promoter is committed to animal welfare and their responsible use for scientific purposes. Moreover, the promoter complies with the European Directive 2010/63/EU on the protection of animals used for scientific purposes.

## Conclusions and Recommendations

In the light of the above, the proposed investments do not require any additional permits and fall within an already authorised scope. The promoter has an integrated environmental management policy and effective operating procedures in place, which are in line with best industry standards. As such, the project is acceptable for financing in environmental and social terms.

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