MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
MEDICAMENTOS
VETERINARIOS

FLUVEX 50 mg/ml solution for injection for cattle, pigs and horses

Company:

SP VETERINARIA S.A

VARIATION ASSESSMENT REPORT

Variation procedure application N° ES/V/0133/001/IB/002

CORREO ELECTRÓNICO

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VARIATION ASSESSMENT REPORT

PRODUCT DETAILS

Name of product	FLUVEX 50 mg/ml solution for injection for cattle, pigs and horses
Active ingredient(s)	Flunixin meglumine
Target Species	Cattle, horses and pigs
Route of administration	Solution for injection Cattle and horses: intravenous use Pigs: Intramuscular use

APPLICATION DETAILS

Type of Application	Type IB
Name and Address of Applicant	SP VETERINARIA SA Ctra Reus Vinyols km 4.1 Riudoms (43330) Spain
Phone and Fax Numbers	Telephone number: +34977768867 Fax number (optional): +34977850405
Email address	M Victòria Gironès E-mail: vgirones@spveterinaria.com
Reference Number for Application	ES/V/0133/001/IB/002
Reference Number in RMS	1755 ESP
Date of the first marketing authorisation in RMS	29-June- 2007

REFERENCE MEMBER STATE DETAILS

Assessment Report prepared by	ES
Date of preparation	14/05/2015
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MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD
Agencia Española de Medicamentos y Productos Sanitarios

NATURE OF VARIATION

C.I.2.a) Change (s) in the Summary of product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medical products following assessment of the same change for the reference product. Implementation of change(s) for which no new additional data is required to be submitted by the MAH (Type IB variation).

Current situation	Proposed changes
SPC authorized after MRP	SPC updated according to SPC of the reference product in Spain.

SUMMARY OF THE DOSSIER

For commercial reasons the applicant has considered that it is necessary to update part IB (SPC and PIL texts) according to reference product in Spain. Subsequently of this change a type IB variation is submitted:

- **C.I.2.a) Change (s) in the Summary of product Characteristics, Labelling or Package Leaflet of a generic/hybrid/biosimilar medical products following assessment of the same change for the reference product. Implementation of change(s) for which no new additional data is required to be submitted by the MAH**

For this purpose the applicant has submitted the following documents to support the update of the SPC and PIL texts

- Track changes and clean versions of the proposed SPC and PIL texts which have been updated according to SPC and PIL texts of the reference product in Spain.

RMS comments

The above variation is considered acceptable on the basis that the application has been submitted simultaneously to all Concerned Member States, the relevant fees have been paid as required by national competent authorities and correct supporting information and documents have also been presented according to the conditions specified for the proposed changes as listed in the Commission Guideline. Failure to comply with this provision may subsequently deem the variations invalid. Consequently, the Spanish Agency (AEMPS) can accept the variation detailed in the application.