

ACCEPTANCE OF NOTIFICATION

Product Name: **Enrocill 50 mg/ml solution for injection for calves, pigs and dogs**
Procedure Number: ES/V/0208/001/IA/001
Start Date: 07/10/2014
CMS: PT.

The Spanish Agency (AEMPS) **accepts** the Type IA variation detailed in your application. The following change has been notified:

C.I.1.a) Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet intended to implement the outcome of a Union referral procedure. The medicinal product is covered by the defined scope of the procedure

The notification is considered acceptable on the basis of the Marketing Authorisation Holder undertaking that:

- i. The notification of change complies with all conditions specified in the Commission guideline on the details of the various categories of variations.
- ii. All supporting documentation as listed in the Commission guideline on the details of the various categories of variations has been provided.
- iii. The application has been submitted simultaneously to all Concerned Member States and the relevant fees have been paid as required by each national competent authority.

Failure to comply with any of the above may subsequently deem the notification unacceptable.

Madrid, 06/11/2014

CORREO ELECTRÓNICO

mresvet@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 54 01
FAX: 91 822 5443