

**EUROPEAN COMMUNITY/EEA OFFICIAL BATCH PROTOCOL REVIEW
CERTIFICATE OF APPROVAL
FOR IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCTS**

Name and address of the control authority performing the document review: Veterinary Medicines Directorate,
Woodham Lane, New Haw, Surrey. KT15 3LS


Examined under Article 81 of Directive 2001/82/EC as amended by Directive 2004/28/EC in accordance with the current Procedure for harmonised application of Article 81 for Official Batch Protocol Review of immunological veterinary medicinal products in the European Community.

Trade name:	Covexin 10 Suspension for Injection for Sheep and Cattle
International non-proprietary Name / Ph. Eur. name / common name	Covexin 10
Name and address of marketing authorisation holder	Zoetis UK Limited, 5th Floor, 6 St Andrew Street, London, EC4A 3AE, United Kingdom
Name and address of manufacturer, if different:	Zoetis Belgium, (formerly Pfizer Animal Health SA) 1 Rue Laid Burniat, Louvain-la-Neuve, B-1348, BELGIUM
Marketing authorisation number (Member State / EC) issued by	42058/4022
Manufacturer's batch number(s) appearing on package and other identification numbers associated with this batch (final bulk no, final lot no, packaging lot no)	SFP Lot No: T30284 Packaging Lot No: T33123
Batch number of diluent (where appropriate) ¹	
Type of container:	Flexible bottles of low density polyethylene bottles
Total number of containers in this batch ² :	995
Number of doses/volume per container:	100ml
Date of start of period of validity; Shelf life; Expiry date:	14 February 2013 30 Months 13 August 2015

The signed manufacturer's release protocol for this batch has been examined in conformity with the current procedure for harmonised application of Article 81 for OBPR in the European Community.

This batch IS in compliance with all of the approved specification laid down in the above noted marketing authorisation.

Certificate Number: 13/B1066

Signed:	
Name and function of signatory:	Tom Nash Manager of UK Batch Release Arrangements
Date of issue:	04 September 2013

¹ Provision of different batch numbers of authorised diluent to different Member States should not impair mutual recognition of OPBR for the batch of active component covered by the certificate, however if a diluent batch different from that on the certificate is provided, protocol documentation on the new diluent batch may be requested in addition to the certificate.

² If different fillings exist, please indicate.

