EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Porcilis Pesti

Procedural steps taken and scientific information after the authorisation

Medicinal product no longer authorised

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2]/ amended on	Product Information affected[3]	Summary
R/0011	Renewal of the marketing authorisation	09/06/2011	16/09/2011	SPC, Annex II, Labelling, PL	The European Commission renewed the marketing authorisation for Porcilis Pesti.
Z/0010	Suspension or lift of suspension	16/06/2010	01/09/2010		The European Commission adopted a decision approving a type II variation submitted by Intervet International BV concerning an amendment of the shelf-life of the product from 3 years to 12 months and change of base for pH adjustment. Consequently the suspension of the marketing authorisation was lifted by the same Commission Decision.
II/0009	B.I.a.2.b - Changes in the manufacturing process of the active substance - Substantial change to the manufacturing process of the active substance which may have a significant impact on the quality, safety or efficacy of the medicinal product	16/06/2010	01/09/2010	SPC	The European Commission adopted a decision approving a type II variation submitted by Intervet International BV concerning an amendment of the shelf-life of the product from 3 years to 12 months and change of base for pH adjustment. Consequently the suspension of the marketing authorisation was lifted by the same Commission Decision.

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0) 20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
ART45/0008	Article 45 Referral	10/12/2008	20/02/2009		The European Commission issued a decision to suspend the marketing authorisation for Porcilis Pesti following a referral under Article 45 of Regulation (EC) 726/2004.
II/0006	II - Other quality changes	15/02/2006	21/03/2006	Annex II	The European Commission adopted a decision amending the marketing authorisation and approving a type II variation to add a production site for the antigen.
IB/0005	1B-38-c Change in test procedure of the finished product	15/09/2005	15/09/2005		The EMEA accepted a type IB variation regarding a change in test procedure of the finished product. The change concerns the method of sterility testing for the final product.
R/0004	Renewal of the marketing authorisation	13/04/2005	24/06/2005	SPC, Annex II, Labelling, PL	The European Commission renewed the marketing authorisation for Porcilis Pesti.
N/0003	Notification	27/02/2004	19/03/2004	PL	The EMEA accepted a notification for the deletion of the local representatives from the Package Insert.
I/0002	20 - Extension of shelf-life (finished product)	26/05/2003	30/06/2003	SPC, Labelling, PL	The European Commission adopted a decision amending the marketing authorisation and approving a type I variation to increase the shelf life of the finished product.
II/0001	II - Other quality changes	02/10/2002	14/10/2002		The European Commission approved a type II variation to comply with Commission Directive 1999/104/EC (TSE compliance). This variation does not require any amendment to the Community authorisation.

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