EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Slentrol

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion / Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IAIN/0007/G	This was an application for a group of variations. A.5.b - Administrative change - Change in the name and/or address of a manufacturer/importer of the finished product, including quality control sites (excluding manufacturer for batch release) B.II.b.2.c.1 - Change to importer, batch release arrangements and quality control testing of the FP - Not including batch control/testing	05/09/2013	n/a	SPC, Annex II, Labelling and PL	The European Medicines Agency accepted a grouped type IA and type IAIN variation concerning changing the name and address of the finished product manufacturer from 'Pharmacia and Upjohn Co' to 'Zoetis P&U LLC' and adding 'Zoetis Belgium SA' as an additional site for batch release.
IG/0328	C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV and/or QPPV contact details and/or back-up procedure	05/09/2013	n/a		The European Medicines Agency accepted a worksharing of a type IAIN variation to update the contact details of the QPPV following the transfer from 'Pfizer Ltd' to 'Zoetis Belgium SA'.
T/0006	Transfer of Marketing Authorisation	30/04/2013	27/05/2013	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Pfizer Ltd' to 'Zoetis Belgium SA'.

[1] Notifications are issued for type I variations (unless part of a group including a type II variation or higher procedure or a worksharing application). Opinions are issued for all other procedures.
[2] A CD is issued for procedures that affect the terms of the marketing authorisation (e.g. SPC, Annex II, Labelling, PL). The CD is issued within 2 months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within 1 year for other procedures.
[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

An agency of the European Union

IB/0005	B.II.f.1.b.1 - Stability of FP - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	11/01/2013	27/05/2013	SPC and Annex II	The European Medicines Agency accepted a variation to increase the shelf life to 5 years of the veterinary product as packaged for sale.
R/0003	Renewal of the marketing authorisation.	09/02/2012	10/04/2012		The European Commission renewed the marketing authorisation for Slentrol.
IG/0005/G	This was an application for a group of variations. C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the contact details of the QPPV C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities	05/08/2011	05/08/2011		The European Medicines Agency accepted a group of type IA variations to change the location of the Qualified Person for Pharmacovigilance.
IB/0002	C.I.3.a - Implementation of change(s) requested following the assessment of an USR, class labelling, a PSUR, RMP, FUM/SO, data submitted under A 45/46, or amendments to reflect a Core SPC - Changes with NO new additional data are submitted by the MAH	10/12/2010	27/07/2011	SPC, Labelling and PL	The European Medicines Agency accepted a variation to add wording under 'Adverse Reactions' in the SPC and package leaflet following the assessment of a PSUR.
IB/0001	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	11/01/2010	09/04/2010	SPC	The European Medicines Agency accepted a variation regarding a change in the shelf-life of the finished product from 2 to 3 years.