EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ProMeris (WD)

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
IB/0012	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	06/01/2012	20/07/2012	SPC and PL	The European Medicines Agency accepted a variation to update section 4.5 of the SPC regarding special precautions for use, following assessment of a PSUR.
R/0010	Renewal of the marketing authorisation.	15/09/2011	10/11/2011	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for ProMeris.
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 ODPS - Change of the site undertaking pharmacovigilance activities	05/08/2011	05/08/2011		The Agency accepted a grouped IG variation to change the location of the Qualified Person for Pharmacovigilance.
IB/0009	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	22/12/2010	27/07/2011	Labelling	The European Medicines Agency accepted a type IB variation to introduce a single universal foil blister for all countries. The abbreviations "S" and "L", which represent "small" and "large", respectively, are consistent with those already approved for use on the applicator pipettes.

[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).

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T/0008	Transfer of Marketing Authorisation	25/10/2010	26/11/2010	SPC, Annex II, Labelling and PL	Transfer of Marketing Authorisation Holder from "Fort Dodge Animal Health" to "Pfizer Limited".
IB/0007	B.II.b.3.z - Change in the manufacturing process of the finished product - Other variation	15/10/2010	15/10/2010		A Type IB variation to increase flexibility in the manufacturing process by extending the holding time of the bulk product prior to filling from 6 days to 6 months was accepted by the European Medicines Agency.
IB/0006	1B-20-c Change in test procedure for an excipient-other changes to a test procedure	04/12/2009	04/12/2009		A Type IB variation for a change in test procedure (to include near-IR spectroscopy for routine identity testing of excipients) was accepted by the European Medicines Agency.
IB/0005	1B-13-b Change in test procedure for active substance or starting material-other changes test procedure	04/12/2009	04/12/2009		A Type IB variation No 13(b) for a change in test procedure (to include near-IR spectroscopy for routine identity testing of active ingredients) was accepted by the European Medicines Agency.
II/0004	II - New safety warning	13/05/2009	22/06/2009	SPC, Labelling and PL	A Type II variation to remove the warning in Section 4.7 of the Summary of Product Characteristics (SPC) concerning the use in pregnant and lactating cats and to include a statement in section 4.6 of the SPC on local signs of possible adverse reactions was accepted by the European Commission.
IB/0003	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	08/04/2009	08/04/2009	SPC	A Type IB variation to extend the shelf life of the finished product from 30 to 36 months was accepted by the European Medicines Agency.
IB/0002	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	10/12/2007	11/07/2008	SPC	A Type IB Variation to extend the shelf life of the finished product from 24 to 30 months was accepted by the European Medicines Agency.
IB/0001	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	30/04/2007	03/01/2008	SPC, Labelling and PL	A Type IB variation to extend the shelf life of the finished product from 18 to 24 months was accepted by the European Medicines Agency.