EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

ProMeris Duo (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/0011	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/0009	Renewal of the marketing authorisation.	15/09/2011	10/11/2011		The European Commission renewed the marketing authorisation for ProMeris Duo.
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/0008	C.II.6 - Changes to the labelling or the package leaflet which are not connected with the SPC	22/12/2010	07/07/2011	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/0007	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/0006	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 9 days to 2 months was accepted by the European Medicines Agency.
IB/0005	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 No 20(c) for a change in test procedure (to include Near-Infrared spectroscopy for routine identity testing of excipients) was accepted by the European Medicines Agency.
IB/0004	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-Infrared spectroscopy for routine identity testing of active ingredients) was accepted by the European Medicines Agency.
II/0003	II - New safety warning	14/01/2009	17/02/2009	SPC, Labelling and PL	Type II variation to add new new indications for the treatment of demodicosis (caused by Demodex mites) and lice (Trichodectes canis), to change the application site from "between the shoulder blades" to "at the base of the skull" and to add local signs of possible adverse reactions. At the same time the SPC and the product literature were amended with the inclusion of additional precautionary measures concerning respiratory reactions in humans (This amendment was requested by the CVMP following the 3rd PSUR). Amendments have been included in the relevant sections of the Commission Decision and this EPAR.
IB/0002	1B-42-a-1 Change in shelf life of finished product as packaged for sale	23/05/2007	24/07/2007	SPC, Labelling and PL	A Type IB variation to extend the shelf life of the product from 18 months to 24 months was accepted by the European Medicines Agency.
II/0001	II - Other quality changes	13/06/2007	24/07/2007	SPC, Labelling and PL	A Type II variation, changing the SPC section 4.7 to allow use during pregnancy and lactation and deletion of the corresponding contraindication in the labelling and package leaflet. Amendments have been incorporated into the relevant sections of the Commission Decision and of this EPAR.