EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Zubrin

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IB/0032	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	01/06/2011	01/06/2011	SPC, PL	The European Medicines Agency accepted a type IB variation to update the SPC and package leaflet following assessment of a PSUR.
T/0031	Transfer of Marketing Authorisation	25/02/2011	18/03/2011	SPC, Labelling, PL	The European Commission approved a transfer of the marketing authorisation from "S-P Veterinary Ltd" to "Intervet International BV".
IA/0030	1A-08-b-01 Change to batch release arrangements and quality control testing of the finished product	29/01/2008	25/08/2008	Annex II, PL	The EMEA accepted a type IA variation for a replacement of the manufacturer of the finished product. The new batch release site is S-P Veterinary, Harefield, UK.
IA/0028	1A-05 Change in name and/or address of a manufacturer of the finished product	06/12/2007	06/12/2007		The EMEA accepted a type IA variation for a change in the name of a manufacturer of the finished product.

[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).

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IA/0025	1A-07-a Replacement or addition manufacturing site for part or all of manufacturing process	07/03/2007	07/03/2007		The EMEA accepted a type IA variation for the addition of a new manufacturing site for secondary packaging: Cardinal Health, United Kingdom.
IA/0023	1A-22-a Submission of a new or updated TSE Eu. Ph. certificate of suitability for an excipient	21/12/2006	21/12/2006		The EMEA accepted a type IA variation for the submission of a new TSE Ph. Eur. Certificate of Suitability for an excipient, provided by a new supplier for gelatin.
IA/0024	1A-04 Change in name and/or address of a manufacturer of the active substance	21/12/2006	21/12/2006		The EMEA approved a type IA variation for a change in the name of a manufacturer of the active substance.
R/0022		18/01/2006	15/03/2006	SPC, Annex II, Labelling, PL	
II/0019	II - New Indication (same therapeutic area)	09/11/2005	19/01/2006	SPC, Labelling, PL	The European Commission approved a type II variation extending the indication and the duration of treatment in order to allow the treatment of chronic musculoskeletal disorders. Amendments have been incorporated in the relevant sections of the Commission Decision and the EPAR.
N/0018	Notification	20/04/2004	23/12/2005	PL	A notification of an update in the package insert and changes in the local representatives was sent to the European Commission.
IA/0020	1A-47-b Deletion of a strength	21/04/2005	23/12/2005	SPC, Labelling, PL	The EMEA accepted a type IA variation withdrawing the 30 mg strength presentation of Zubrin oral lyophilisates for dogs. Amendments have been incorporated in the product literature and the relevant sections of the EPAR.
IB/0021	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	23/09/2005	23/12/2005	SPC, Labelling	The EMEA accepted a type IB variation extending the shelf life of the product from 2 to 3 years. Amendments have been incorporated in the product literature and the relevant sections of the EPAR.

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II/0016	II - Update of SPC and PL	15/10/2003	29/01/2004	SPC, Labelling, PL	The European Commission approved a type II variation allowing the administration of Zubrin with food. Furthermore, a warning under "undesirable effects" has been strengthened. Amendments have been incorporated in to the relevant sections of the Commission Decision and the EPAR.
I/0017	01b - Change in name of manufacturer of the finished product	14/10/2003	23/10/2003		The EMEA accepted a type I variation changing the name of the manufacturef of the finished product from "DDS Scherer Limited"to "Cardinal Health UK 416 Limited". No changes were made to the product literature.
I/0014	14 - Change in active substance specification	06/11/2002	12/11/2002		The EMEA accepted a type I variation changing the specification of the active substance. Amendments have been incorporated in the relevant sections of the EPAR, however no changes were made to the product literature.
I/0015	17 - Change in specification of finished product	06/11/2002	12/11/2002		The EMEA accepted a type I variation changing the specification of the medicinal product. Amendments have been incorporated in the relevant sections of the EPAR, however no changes were made to the product literature.
I/0013	16 - Batch size of finished product	13/06/2002	19/06/2002		The EMEA approved a type I variation changing the batch size of the finished product. Amendments have been incorporated in the relevant sections of the EPAR.
N/0012	Notification	09/04/2002	17/04/2002	Labelling, PL	The European Commission issued a corrigendum for the Finnish, German, Greek, Italian, Portuguese and Swedish translations of the product literature. Amendments have been incorporated in the relevant sections of the EPAR.
N/0011	Notification	22/11/2001	17/12/2001	PL	A notification of a change in the local representatives

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					was sent to the European Commission.
II/0001	II - Other quality changes	11/07/2001	17/12/2001	SPC, Labelling, PL	The European Commission approved a type II variation extending the duration of treatment. Furthermore, an updated list of local representatives was provided. Amendments have been incorporated in the relevant sections of the Commission Decision and the EPAR.
I/0006	19 - Change in specification of excipient	01/06/2001	19/07/2001		The EMEA approved a type I variation for the provision of EDQM certificates to confirm TSE compliance.
I/0005	30 - Change in pack size	01/06/2001	19/07/2001	SPC, Labelling	The EMEA approved a type I variation to change the number of blisters per presentation. Amendments have been incorporated in the relevant sections of the Commission Decision and the EPAR.
I/0003	03 - Name and/or address of Marketing Authorisation Holder	01/06/2001	19/07/2001	SPC, Annex II, Labelling, PL	The EMEA accepted a type I variation to change the name of the marketing authorisation holder from "Schering Plough Ltd" to "S-P Veterinary". Amendments have been incorporated in the relevant sections of the Commission Decision and the EPAR.
N/0009	Notification	01/06/2001	19/07/2001	PL	A notification of a change in the local representatives was sent to the European Commission.
I/0007	20 - Extension of shelf-life (finished product)	01/06/2001	19/07/2001	SPC, Labelling, PL	The EMEA accepted a type I variation extending the shelf life from 18 months to 2 years. Amendments have been incorporated in the relevant sections of the Commission Decision and the EPAR.
I/0008	30 - Change in pack size	01/06/2001	19/07/2001	SPC, Labelling	The EMEA accepted a type I variation to Increase the number of lyophilisates per blister pack. Amendments have been incorporated in the relevant sections of the EPAR.
I/0004	11 - New active substance	01/06/2001	19/07/2001		The EMEA accepted a type I variation changing the

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	manufacturer(s)				supplier of the active substance. Amendments have been incorporated in the relevant sections of the EPAR.
I/0002	01a-Modification of manufacturing authorisation	01/06/2001	19/07/2001	SPC, Annex II, Labelling, PL	The EMEA accepted a type I variation changing the batch release site. Amendments have been incorporated in the relevant sections of the EPAR.
I/0010	16 - Batch size of finished product	05/07/2001	09/07/2001		The EMEA accepted a type I variation changing the batch size of the finished product. Amendments have been incorporated in the relevant sections of the EPAR.