Quadrisol

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
T/0037	Transfer of Marketing Authorisation	31/03/2017	25/04/2017	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from 'Zoetis Belgium SA' to 'VETCOOL B.V.'
T/0036	Transfer of Marketing Authorisation	30/04/2013	22/05/2013	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'.
IB/0035/G	This was an application for a group of variations. B.II.b.1.e - Replacement or addition of a manufacturing site for the FP - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site B.II.b.2.b.2 - Change to batch release arrangements	13/04/2010	14/10/2010	Annex II and PL	The Agency accepted the group of variations to change manufacturers of the finished product, responsible for batch release, secondary packaging, batch control testing and deletion of a supplier of active substance.

[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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	and quality control testing of the FP - Including batch control/testing A.7 - Administrative change - Deletion of manufacturing sites B.II.b.1.b - Replacement or addition of a manufacturing site for the FP - Primary packaging site				
T/0034	Transfer of Marketing Authorisation	14/01/2010	29/01/2010	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to transfer the marketing authorisation from "Intervet International BV, Wim de Körverstraat 35, NL-5831 AN Boxmeer, The Netherlands" to "Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, United Kingdom".
IA/0033	1A-30-a Change (replacement, addition or deletion) in supplier of packaging components or devices	10/12/2009	10/12/2009		The Agency accepted the variation to change a supplier for Quadrisol.
IA/0032	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	10/12/2009	10/12/2009		The Agency accepted the variation to introduce a minor change to an approved test procedure.
IA/0031	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	10/12/2009	10/12/2009		The Agency accepted the variation to introduce a minor change to an approved test procedure.
IA/0030	1A-38-a Change in test procedure of finished product-Minor change to approved test procedure	10/12/2009	10/12/2009		The Agency accepted the variation to introduce a minor change to an approved test procedure.
IB/0029	1B-33 Minor change in the manufacture of the finished product	06/11/2009	06/11/2009		The Agency accepted the variation to introduce a minor change in the manufacture of the finished product.
IA/0027	1A-47-b Deletion of a strength	27/08/2008	25/03/2009	SPC, Annex II, Labelling and PL	The Agency accepted the variation to delete all pack sizes for the pharmaceutical form Quadrisol 50 mg/ml solution for injection for horses (EU/2/97/005/004).
IA/0026	1A-47-b Deletion of a strength	27/08/2008	25/03/2009	SPC, Annex II, Labelling and PL	The Agency accepted the variation to delete all pack sizes for the pharmaceutical form Quadrisol 5 mg/ml oral paste for dogs, 1x and 5x 15 ml and 30 ml (EU/2/97/005/002, 003, 006, 007).
IA/0025	1A-47-b Deletion of a strength	27/08/2008	25/03/2009	SPC, Annex II, Labelling and PL	The Agency accepted the variation to delete all pack sizes for the pharmaceutical form Quadrisol 1 mg/ml oral paste for dogs, 1x and 5x 15 ml (EU/2/97/005/008-009).
IB/0028	1B-25-a-1 Change to comply with Eu. Ph. or with the national pharmacopoeia of a Member State	20/03/2009	20/03/2009		The Agency accepted the variation to comply with a new Ph. Eur. Monograph for vedaprofen.
R/0024	Renewal of the marketing authorisation.	12/09/2007	13/11/2007	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Quadrisol.
IB/0022	1A-08-a Change to batch release arrangements and quality control testing of the finished product 1B-07-c Replacement or addition of a manufacturing site for part or all of manufacturing process	13/01/2005	18/08/2005	Annex II	The Agency accepted the variation together with a consequential type IA variation concerning the addition of a new manufacturing site for the oral gel presentations.

IB/0023	1B-18 Replacement of an excipient with a comparable excipient 1B-33 Minor change in the manufacture of the finished product 1A-37-a Change in specification of the finished product-tightening of specification limits 1B-14-a Change in manufacturer of active substance or starting material-change in site of manuf (replacement or addition)	15/04/2005	15/04/2005		The Agency accepted the variation (replacement of an excipient with a comparable excipient) and consequential variations type IB (minor change in the manufacture of the finished product) and type IB (change in the specification of the finished product).
N/0019	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	12/02/2004	15/03/2004	PL	The EMEA notified the European Commission about changes (i.e. the deletion) of the list of local representatives for all Quadrisol presentations. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of the EPAR.
IB/0018	1B-14-a Change in manufacturer of active substance or starting material-change in site of manuf (replacement or addition)	12/03/2004	12/03/2004		The Agency accepted the variation to add a new manufacturer of the active substance.
IB/0017	1B-10 Minor change in the manufacturing process of the active substance	11/12/2003	11/12/2003		The Agency accepted the variation for a minor change of manufacturing process of the active substance.
I/0016	23_Change in storage conditions	25/07/2003	28/08/2003	SPC, Labelling and PL	The EMEA approved a type I variation of Quadrisol 100 mg/ml oral gel for horses and Quadrisol 5 mg/ml oral gel for dogs submitted by the company harmonising the storage conditions for all Quadrisol oral gel presentations. No special storage conditions are required for the oral gel presentations. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
R/0014	Renewal of the marketing authorisation.	02/10/2002	15/01/2003	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for Quadrisol.
I/0015	20_Extension of shelf-life as foreseen at time of authorisation	04/09/2002	30/09/2002	SPC	The EMEA approved a type I variation of Quadrisol 50 mg/ml solution for injection for horses extending the shelf life of the product from 18 months to 3 years. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
X/0008	X-4-I Addition or change of target species	13/03/2002	10/07/2002	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a new strength for Quadrisol 1 mg/ml oral gel for dogs.
II/0012	II - Other quality changes	13/09/2001	05/12/2001	SPC and PL	The European Commission amended the decision granting the marketing authorisation to allow the use of Quadrisol 100 mg/ml oral gel for horses in pregnant mares.
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	04/07/2001	04/07/2001	Labelling	
I/0010	15_Minor changes in manufacture of the medicinal product	06/04/2001	03/05/2001		The EMEA approved a type I variation for Quadrisol 5 mg/ml oral gel for dogs relating to a minor change in the

					manufacturing. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
I/0009	15_Minor changes in manufacture of the medicinal product	06/04/2001	03/05/2001		The EMEA approved a type I variation for Quadrisol 100 mg/ml oral gel for horses relating to a minor change in the manufacturing. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
N/0007	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	16/11/2000	17/11/2000	PL	The EMEA notified the European Commission about changes in the list of local representatives. Amendments have been incorporated in Annex IIIB of the Commission Decision and the relevant sections of the EPAR.
I/0006	20_Extension of shelf-life as foreseen at time of authorisation	06/03/2000	09/06/2000		The EMEA approved a type I variation for Quadrisol 5 mg/ml oral gel for dogs extending the shelf life of the final product from one to three years. Amendments have been incorporated in Annex I of the Commission Decision and the relevant sections of the EPAR.
I/0005	06_Change in the flavouring system of the product (addition, deletion or replacement of flavour(s))	06/03/2000	06/03/2000		The EMEA approved a type I variation for Quadrisol 5 mg/ml oral gel for dogs, deleting one excipient, chocolate flavour. Amendments have been incorporated in Annex I of the Commission Decision and the relevant sections of the EPAR.
I/0004	30_Change in pack size for a medicinal product	13/10/1999	31/01/2000	SPC and Labelling	The EMEA approved a type I variation for Quadrisol 5 mg/ml oral gel for dogs, introducing an additional pack size of 5 oral syringes per carton box, each syringe containing 15 ml or 30 ml oral gel. Amendments have been incorporated in Annex I of the Commission Decision and the relevant sections of the EPAR.
I/0003	30_Change in pack size for a medicinal product	29/07/1999	28/01/2000	SPC and Labelling	The EMEA approved a type I variation for Quadrisol 100 mg/ml oral gel for horses introducing an additional pack size of 3 syringes per carton box, each syringe containing 30 ml gel. Amendments have been incorporated in the relevant sections of the Commission Decision and of the EPAR.
X/0001	X-3-IV Change or addition of a new pharmaceutical form X-3-III Extension to a new strength	14/07/1999	16/11/1999	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a new pharmaceutical form and target animal species, Quadrisol 50 mg/ml solution for injection for horses.
X/0002	X-4-I Addition or change of target species X-2-II Change of the indication X-3-IV Change or addition of a new pharmaceutical form X-3-III Extension to a new strength	14/10/1998	15/02/1999	SPC, Annex II, Labelling and PL	The European Commission amended the decision granting the marketing authorisation for a new strength and target animal species, Quadrisol 5 mg/ml oral gel for dogs.