EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Trifexis

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
II/0008	C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one	10/11/2016	17/02/2017	SPC, Labelling and PL	The European Commission amended the decision granting the marketing authorisation to amend the indication for prevention of angiostrongylosis.
WS/0906/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.d.1.c - Stability of AS - Change in the re-test period/storage period or storage conditions - Change to an approved stability protocol	14/07/2016	n/a		The Agency accepted the variation to change a testing facility for spinosad, to change the approved stability protocol and other minor changes to both open and closed parts of the ASMF.

[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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IA/0007	B.II.d.2.a - Change in test procedure for the finished product - Minor changes to an approved test procedure	01/04/2015	n/a		The Agency accepted a variation to add an additional acceptance criterion within finished product test methods
IB/0006	C.II.6.b - Changes to the labelling or the PL which are not connected with the SPC - Other changes	13/02/2015	26/02/2016	Labelling	The Agency accepted a variation to include indications on the carton.
IB/0005/G	This was an application for a group of variations. B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.b - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Tightening of specification limits B.I.b.1.c - Change in the specification parameters and/or limits of an AS, starting material/intermediate/reagent - Addition of a new specification parameter to the specification with its corresponding test method	05/08/2014	n/a		The Agency accepted a group of variations to make changes to the active substance manufacturing process and specifications
IAIN/0004	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	14/05/2014	n/a		The Agency accepted a variation to add an alternative secondary packaging site.
IA/0003	B.II.d.1.a - Change in the specification parameters and/or limits of the finished product - Tightening of specification limits	10/01/2014	n/a		The agency accepted the variation to make amendments to the specification.
IG/0386	A.1 - Administrative change - Change in the name and/or address of the MAH	20/12/2013	11/12/2014	SPC, Labelling and PL	The Agency accepted variation to align all products with MAH's full address.
IG/0364/G	This was an application for a group of variations. 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 C.I.9.c - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the PhV system	31/10/2013	n/a		The Agency accepted the variation to change the QPPV and to update the DDPS.