Bovilis BTV8

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
R/0007	Renewal of the marketing authorisation.	10/04/2015	05/06/2015	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for Bovilis BTV8.
IG/0465	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	20/08/2014	n/a		The Agency accepted the variation to change the qualified person for pharmacovigilance (QPPV).
S/0005	3rd annual re-assessment (re-assessment of the benefit-risk balance)	16/01/2014	14/03/2014	SPC, Annex II, Labelling and PL	The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit-risk profile for Bovilis BTV8. Since all specific obligations have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.
S/0004	2nd annual reassessment (re-assessment of the benefit-risk balance)	08/11/2012	14/01/2013		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Bovilis BTV8. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outline in Annex II E of the opinion.

[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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IB/0001	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Extension of storage period of a biological/immunological medicinal product in accordance with an approved stability protocol	09/12/2011	27/06/2012	SPC	The European Medicines Agency accepted a type IB variation to extend the shelf life of the finished product from 12 months to 2 years.
S/0002	Annual reassessment	12/01/2012	12/01/2012		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for Bovilis BTV8. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outline in Annex II E of the opinion.
IG/0128	A.5.b - Administrative change - Change in the name and/or address of a manufacturer of the finished product, including quality control sites (excluding manufacturer for batch release)	06/01/2012	n/a		The Agency accepted a grouping of type IA variations to change the name and address of a manufacturer of the finished product.