EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BTVPUR AlSap 8

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/0010	Renewal of the marketing authorisation.	16/01/2014	12/03/2014		The European Commission approved the renewal of marketing authorisation.
IA/0009	B.III.1.b.3 - Submission of a new or updated Ph. Eur. TSE Certificate of suitability - Updated certificate from an already approved manufacturer	15/08/2013	n/a		The Agency accepted the variation to update the CEP of the adult bovine serum following change of name of supplier.
S/0008	Annual reassessment	14/06/2012	03/09/2012	SPC, Annex II and PL	The European Commission approved the updates to the Annex II and agreed that there are no remaining grounds for the Marketing Authorisation to remain under exceptional circumstances.
IG/0142	B.III.2.a.2 - Change of specification(s) of a former non Pharmacopoeial substance to comply with the Ph. Eur. or with a national pharmacopoeia of a Member State - Excipient/AS starting material	18/01/2012	n/a		The Agency accepted the variation on the compliance of an excipient with the current European Pharmacopoeia monograph
IB/0006	B.II.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	19/08/2011	19/08/2011	SPC	The Agency accepted the variation on the extension of the shelf-life to 2 years for the 50 ml and 100 ml presentations.

[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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S/0005	Annual reassessment	04/05/2011	04/05/2011		The European Commission agreed, following CVMP revision of the specific obligations that, overall, the evidence continues to support a favourable benefit/risk profile for BTVPUR AlSap 8. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.
IB/0004	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	10/09/2010	28/03/2011	SPC and PL	The Agency accepted the variation on the change in the section 4.7 of the SPC, following the first annual reassessment.
S/0003	Annual reassessment	14/04/2010	14/04/2010		Following the first annual re-assessment the CVMP concluded that, in relation to the specific obligations, the evidence continued to support a favourable risk/benefit profile for BTVPUR AlSap 8. The CVMP requested additional data regarding the use of BTVPUR AlSap 8 in pregnant cows.
II/0001	II - Other quality changes	09/12/2009	12/01/2010	Annex II	The European Commission amended the decision granting the marketing authorisation on the addition of a new manufacturing site for the active substance.
II/0002	II - Other quality changes	16/09/2009	28/09/2009		The European Commission amended the decision granting the marketing authorisation on the qualified person responsible for pharmacovigilance.