BTVPUR AlSap 1

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/0005	Renewal of the marketing authorisation.	09/07/2015	08/09/2015	SPC, Labelling and PL	The European Commission renewed the marketing authorisation for BTVPUR AlSap 1.
IG/0592	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	04/09/2015	n/a		The Agency accepted a variation to change the QPPV.
WS/0669	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.II.b.3.z - Change in the manufacturing process of the finished or intermediate product - Other variation	04/06/2015	n/a		The Agency accepted the variation relating to a change in the manufacturing process.
IB/0003	B.II.f.1.b.5 Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	14/02/2014	17/02/2015	SPC, Labelling and PL	The Agency accepted the variation to extend the shelf life of the finished product for the 50 ml presentations in polypropylene vials and the 10 ml presentation, and to update the product information in accordance with the current QRD template.

[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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5545
Send a question via our website www.ema.europa.eu/contact

S/0002		07/02/2013	06/05/2013		The CVMP reviewed the specific obligations and concluded that overall, the evidence continues to support a favourable benefit/risk profile for BTVPUR AlSap 1. As all remaining specific obligations were fulfilled the CVMP agreed that exceptional circumstances should be lifted.
S/0001		09/02/2012	20/04/2012	SPC, Annex II and PL	The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit/risk profile for BTVPUR AlSap 1. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II E of the opinion.