EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

BTVPUR AlSap 2-4

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/0006	Renewal of the marketing authorisation.	04/06/2015	31/07/2015	SPC, Annex II, Labelling and PL	The European Commission renewed the marketing authorisation for BTVPUR AlSap 2-4.
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.
S/0004	3rd annual re-assessment (re-assessment of the benefit-risk balance of the product)	13/02/2014	11/04/2014	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 BTVPUR AlSap 2-4. Since all specific obligations have been fulfilled, there are no remaining grounds for the marketing authorisation to remain under exceptional circumstances.

[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/0003	2nd annual re-assessment (re-assessment of the benefit-risk balance of the product)	13/12/2012	25/02/2013		The CVMP reviewed the specific obligations and concluded that, overall, the evidence continues to support a favourable benefit-risk profile for BTVPUR AlSap 2-4. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outlined in Annex II of the opinion.
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
S/0001	1st annual re-assessment ((re-assessment of the benefit-risk balance of the product)	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 BTVPUR AlSap 2-4. Full approval will, however, remain conditional on the fulfilment of the outstanding specific obligations as outline in Annex II of the opinion.