EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Valtropin

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
A20/0008	Article 20 Review On 10 December 2010, the European Commission initiated a procedure under Article 20 of Regulation (EC) No 726/2004 for somatropin-containing medicinal products authorised in the centralised procedure and requested the CHMP to assess all the available data and its impact on the risk benefit balance for somatropin-containing medicinal products and to give its opinion on measures necessary to ensure the safe and effective use of these medicinal products and whether the marketing authorisations for these products should be maintained, varied, suspended or revoked. The scope of the review was to assess the long-term safety of growth hormone treatments in light of the emerging safety data from the French SAGHE study in particular with regards the potential increased risk of mortality due to diseases of the circulatory system, bone tumours and	15/12/2011	02/03/2012	SPC, Annex II, PL	Please refer to the Assessment Report: Valtropin-H-602-A20-08-Assessment Report-Article 20

[1] Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.
[2] No Commission Decision is issued for type IA and type IB variations or for type II variations and annual re-assessments that do not affect the annexes.
[3] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	subarachnoid or intracerebral haemorrhage in children and when high doses are used. Article 20 Review				
R/0007	Renewal of the marketing authorisation	17/02/2011	18/04/2011	SPC, Annex II, Labelling, PL	Based on the CHMP review of the currently available information and on the basis of a re-evaluation of the benefit/risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit/risk profile of Valtropin continues to be favourable. Valtropin was approved in the EU on 24 April 2006, and was placed on the market in Germany on 6 January 2009. The placing on the market was temporarily ceased as of 1 June 2009 for economical reasons. No post-authorisation adverse events have been reported thus far. Due to the very limited post-marketing safety data available for Valtropin, the CHMP is of the opinion that one additional five-year renewal on the basis of pharmacovigilance grounds is required. The MAH will continue to submit PSURs in line with the PSUR cycle of the reference product. During the renewal procedure, changes were made to the Product Information to bring it in line with that of the reference product, the current EMEA/QRD template, SPC guideline and other relevant guideline(s), which were reviewed by QRD and accepted by the CHMP.
IA/0006	01_Change in the name and/or address of the marketing authorisation holder, 09_Deletion of manufacturing site	09/06/2009	n/a	SPC, Annex II, Labelling, PL	
II/0004	Update of Section 4.4 of the SPC with a warning on Prader-Willi syndrome in line with the reference medicinal product. The PL has been updated accordingly. Update of Summary of Product Characteristics and Package Leaflet	25/09/2008	28/10/2008	SPC, PL	The product information has been updated in line with the reference product with the following warning related to Prader-Willi syndrome: "Valtropin is not indicated for the treatment of patients with growth failure due to Prader-Willi syndrome unless they also have a diagnosis of growth hormone deficiency. There have been reports of sleep apnoea and sudden death after initiating growth hormone therapy in patients with Prader-Willi syndrome, who had one or more of the following risk factors: severe obesity, history of upper airway obstruction or sleep apnoea, or

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					unidentified respiratory infection." The PL has been amended accordingly.
IB/0005	42_a_01_Change in shelf-life of finished product - as packaged for sale	21/10/2008	n/a		
IB/0003	42_a_01_Change in shelf-life of finished product - as packaged for sale	20/12/2007	n/a	SPC, Labelling, PL	
IA/0001	07_a_Replacement/add. of manufacturing site: Secondary packaging site	19/07/2006	n/a		