EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Velactis

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
ART45/0003		15/07/2016	22/08/2016		The European Commission suspended the marketing authorisation for Velactis. The matter was notified to the Committee by the European Commission under Article 45 of Regulation (EC) No. 726/2004 due to concerns for animal health arising from pharmacovigilance data.
IAIN/0002	C.I.9.b - Changes to an existing pharmacovigilance system as described in the DDPS - Change(s) in the safety database and/or major contractual arrangements for the fulfilment of PhV obligations and/or change of the site undergoing PhV activities	27/03/2016	n/a		The Agency approved the variation to update the Detailed Description of the Pharmacovigilance System (DDPS) to replace the database system.
IB/0001	B.II.b.4.a - Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	11/03/2016	n/a		The Agency accepted a variation for a change in the batch size of the finished product.

[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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