EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Yarvitan (withdrawn)

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
IG/0004/G	This was an application for a group of variations. C.I.9.a - Changes to an existing pharmacovigilance system as described in the DDPS - Change in the QPPV	03/05/2011	03/05/2011		The European Medicines Agency accepted a Type IA variation to change the Qualified Person for Pharmacovigilance
II/0003	Change to detailed description of pharmacovigilance system	15/10/2008	20/10/2008		The European Commission approved a type II variation concerning a change in the qualified person responsible for pharmacovigilance.
T/0002	Transfer of Marketing Authorisation	23/07/2007	27/08/2007	SPC, Labelling, PL	The European Commission approved the transfer of the marketing authorisation holder from "Janssen Animal Health B.V.B.A." to "Janssen Pharmaceutica N.V." Their address is unchanged.
IB/0001	1B-42-a-1 Change in shelf life of finished product-as packaged for sale	18/04/2007	27/08/2007	SPC	The EMEA approved a type IB variation to extend the shelf-life of the finished product from 2 to 3 years.

[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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