

## Fablyn

Procedural steps taken and scientific information after the authorisation

No	Scope	Opinion/ Notification <sup>1</sup> issued on	Commission Decision Issued <sup>2</sup> / amended on	Product Information affected <sup>3</sup>	Summary
T/0003	Transfer of Marketing Authorisation	22/12/2011	17/02/2012	SPC, Labelling, PL	Transfer of the Marketing Authorisation from Pfizer Ltd. to Dr. Friedrich Eberth Arzneimittel GmbH.
IG/0044/G	This was an application for a group of variations. C.I.9.e - Changes to an existing pharmacovigilance system as described in the DDPS - Changes in the major contractual arrangements with other persons or organisations involved in the fulfilment of pharmacovigilance obligations and described in the DD, C.I.9.g - Changes to an existing pharmacovigilance system as described in the DDPS - Change of the site undertaking pharmacovigilance activities, C.I.9.h - Changes to an existing pharmacovigilance system as described in the DDPS - Other change(s) to the DDPS that does not impact on the operation of the	02/03/2011	n/a		

<sup>1</sup> Notifications are issued for type I variations (unless part of a group or a worksharing application). Opinions are issued for all other procedures.

<sup>2</sup> 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.

<sup>3</sup> SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	pharmacovigilance system				
II/0001	Update of DDPS (Pharmacovigilance) Update of DDPS (Pharmacovigilance)	25/06/2009	24/07/2009	Annex II	The Detailed Description of the Pharmacovigilance System (DDPS) has been updated (version 2.0) in order to reflect various organisational changes as well as the change of the global safety database. Consequently, Annex II has been updated using the standard text including the new version number of the agreed DDPS.

Medicinal product no longer authorised