Rydapt

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
T/0003	Transfer of Marketing Authorisation	20/03/2018	30/04/2018	SmPC, Labelling and PL	
II/0002	Update of sections 4.5 and 5.2 of the SmPC in order to reflect the results from study R1701192 "In vitro assessment of cytochrome P450 3A4 and 3A5 enzyme inhibition by midostaurin, CGP52421 and CGP62221" and update of section 5.2 of the SmPC to	26/04/2018		SmPC	

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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	reflect the results from study R1600721 “Assessment of midostaurin and its metabolites (CGP052421 and CGP062221) as inhibitors of human bile salt export pump (BSEP)", in fulfilment of the post-authorisation measures MEA 011 and REC 014. In addition, the MAH took the opportunity to update section 5.2 to correct figures, to amend a minor typographical error in section 4.2 of the SmPC, as well as to align information regarding women of childbearing potential in section 4.6 of the SmPC with section 4.4. The RMP version 2.2 has also been submitted. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data				
IB/0001	B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	15/11/2017	30/04/2018	SmPC, Labelling and PL	