

## Efient

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
II/0008	<p>To update Sections: 4.4 and 5.1 of the SmPC with results from the pharmacodynamic/pharmacogenomic study as requested in the CHMP AR for FU2 007.1.</p> <p>Section 2 of the PL was updated accordingly.</p> <p>In addition some minor linguistic changes were introduced in French annexes.</p>	22/09/2011	24/10/2011	SPC, PL	<p>Results of a pharmacodynamic/pharmacogenomic study in 720 Asian ACS PCI patients demonstrated that higher levels of platelet inhibition are achieved with prasugrel compared to clopidogrel, and that prasugrel 60-mg loading dose/10-mg maintenance dose is an appropriate dose regimen in Asian subjects who weigh at least 60 kg and are less than 75 years of age.</p> <p>The conducted study does not suggest the subjects of Asian origin be at an increased risk of adverse reactions to prasugrel. The study did not identify any pharmacogenetic biomarkers associated with efficacy or adverse events. Therefore a warning that therapeutic experience is limited in Asian patients and</p>

<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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					the product should be used with caution in this population of patients was deleted.
II/0006	C.I.4 - Variations related to significant modifications of the SPC due in particular to new quality, pre-clinical, clinical or pharmacovigilance data	17/03/2011	20/04/2011	SPC, PL	<p>Sections 4.4 and 4.8 of the SmPC were updated in line with the recommendations in the assessment reports for PSUR 2 and PSUR 3. The three adverse drug reactions (ADRs), namely: hypersensitivity including angioedema, thrombotic thrombocytopenic purpura and thrombocytopenia were included in section 4.8 and hypersensitivity including angioedema and modification of wording of thrombotic thrombocytopenic purpura were included in section 4.4 of the SmPC.</p> <p>In parallel, a new signal associated with prasugrel was detected in EudraVigilance database. This signal concerned reports of serious hypersensitivity reactions including angioedema in patients receiving prasugrel, including in patients with a history of hypersensitivity reaction to clopidogrel. Therefore, based on these reports it was agreed to strengthen the wording so that angioedema is listed in sections 4.4 and 4.8 with a specific mention of the possibility of this reaction in patients who experienced an angioedema with clopidogrel and that the initiation of treatment with prasugrel in patients who previously experienced angioedema or</p>

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					other hypersensitivity reactions with clopidogrel should be performed with extreme caution and under medical supervision. PL was updated to reflect the changes to the SmPC. In addition a DHCP letter to draw the attention of physicians on the possible occurrence of this serious reaction should be disseminated in line with the agreed communication plan.
IA/0007/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.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 pharmacovigilance system	28/03/2011	n/a		
N/0005	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	26/10/2009	n/a	PL	
IA/0004	41_a_01_Change in pack size - change in no. of units within range of	21/09/2009	21/09/2009	SPC, Labelling	

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	appr. pack size				
IA/0003	41_a_01_Change in pack size - change in no. of units within range of appr. pack size	21/09/2009	21/09/2009	SPC, Labelling	
N/0002	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	19/06/2009	n/a	PL	
IA/0001	06_a_Change in ATC code: Medicinal products for human use	18/05/2009	n/a	SPC, Labelling, PL	