Quixidar

Procedural steps taken and scientific information after the authorisation
Changes made after 01/11/2004

For procedures finalised before 01/11/2004, please refer to module 8A

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0033	Update of or change(s) to the pharmaceutical documentation	20/09/2007	09/10/2007	SPC	
II/0032	Update of Summary of Product Characteristics and Package Leaflet	19/07/2007	03/09/2007	SPC, PL	Amendment of the posology (Section 4.2) for the prevention of venous thromboembolism (VTE) in patients with moderate renal impairment. Related changes are also proposed to Section 4.4 of the SPC and Sections 2 and 3 of the Package Leaflet. In addition, the MAH applied for minor changes to Section 4.2, 5.1 and 9 of the SPC and to Section 6 of the Package Leaflet. The Package Leaflet has been updated accordingly.
X/0025	02_v_Change or addition of a new route of administration New intravenous use of the 2.5 mg strength to be administered as the first dose of fondaparinux in patients with STEMI eligible for treatment with fondaparinux (subsequent doses are administered by subcutaneous injection).	21/06/2007	29/08/2007	SPC, Labelling, PL	Please refer to the Scientific discussion: Quixidar-H-404-X-25 and II-24.
II/0024	Extension of Indication of the 2.5 mg strength to include a new indication in the treatment of Acute Coronary Syndromes as follows: Treatment of unstable angina or non-ST segment elevation myocardial infarction	21/06/2007	29/08/2007	SPC, Annex II, Labelling, PL	Please refer to the Scientific discussion: Quixidar-H-404-II-24.

[1] Major changes e.g. Type II variations, Annex II applications, Renewals and Annual Reassessments
[2] SPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet)

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
	(UA/NSTEMI) in patients for whom urgent (<120mins) invasive management (PCI) is not indicated (see sections 4.4 and 5.1). Treatment of ST segment elevation myocardial infarction (STEMI) in patients who are managed with thrombolytics or who initially are to receive no other form of reperfusion therapy The new indication is based on the results of the OASIS-5 (UA/NSTEMI) and OASIS-6 (STEMI) trials.				
R/0027	Renewal of the marketing authorisation	22/02/2007	20/04/2007	SPC, Annex II, Labelling, PL	The CHMP reviewed the extensive data made available during the first 5 years after Marketing Authorisation and concluded that the efficacy of fondaparinux is well established in a number of life-threatening clinical settings and that the safety of fondaparinux is well known and documented in the SPC. The CHMP is of the opinion that the renewal can be granted with unlimited validity.
II/0012	Extension of Indication. The MAH applied for the addition of a new indication, namely "Prevention of Venous Thromboembolic Events (VTE) in patients undergoing abdominal surgery who are judged to be at high risk of thromboembolic complications, such as patients undergoing abdominal cancer surgery (see section 5.1)".	26/05/2005	07/07/2005	SPC, PL	Please refer to the Scientific discussion: Quixidar-H-404-II-12.
II/0010	Extension of Indication. The MAH applied for the addition of a new indication regarding `Prevention of VTE in medical patients who are at risk for thromboembolic complications due to restricted mobility during acute illness'.	15/12/2004	25/01/2005	SPC, PL	Please refer to the Scientific discussion: Quixidar-H-404-II-10.
T/0014	Transfer of Marketing Authorisation Holder	03/12/2004	12/01/2005	SPC, Annex II, Labelling, PL	Transfer of MAH from NV Organon to GlaxoSmithKline.

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
N/0034	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	24/10/2007
IA/0031	04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)		25/04/2007
IB/0030	42_a_01_Change in shelf-life of finished product - as packaged for sale	SPC	07/12/2006
IA/0028	13_a_Change in test proc. for active substance - minor change		25/09/2006
IA/0026	07_a_Replacement/add. of manufacturing site: Secondary packaging site		31/08/2006
IA/0023	04_Change in name and/or address of a manuf. of the active substance (no Ph. Eur. cert. avail.)		21/07/2006
IB/0022	41_a_02_Change in pack size - change in no. of units outside range of appr. pack size	SPC, Labelling, PL	07/02/2006
IA/0020	09_Deletion of manufacturing site		13/05/2005
IB/0019	38_c_Change in test procedure of finished product - other changes		17/01/2005
IB/0018	37_a_Change in the specification of the finished product - tightening of specification limits		17/01/2005
IB/0017	10_Minor change in the manufacturing process of the active substance 12_a_Change in spec. of active subst./agent used in manuf. of active subst. - tightening		17/01/2005
IA/0015	05_Change in the name and/or address of a manufacturer of the finished product	SPC, Annex II, PL	01/12/2004

[3] Minor changes e.g. Type I variations and Notifications
[4] Date of entry into force of the change