Steps taken after granting the Marketing Authorisation

For procedures finalised after 01 May 2004 please refer to module 8b.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
On 25 July 2002, the Marketing Authorisation Holder submitted a Type I Variation in accordance with Commission Regulation (EC) No. 542/95 as amended. The variation related to a change in the container shape.	I-0001	I	29.07.02	
Urgent Safety Restriction on possible risk of serious hypersensitivity reactions including anaphylaxis and angioedema and serious skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme and exfoliative dermatitis in patients treated with parecoxib.	-	-	16.10.02	-
Change in or addition of manufacturing site(s) for part or all of the manufacturing process.	I-0002	I	20.11.02	
The Urgent Safety Restriction dated 16 October 2002 concerning serious hypersensitivity reactions and serious skin reactions. Sections 4.3 (Contra-indications), 4.4 (Special warnings and special precautions for use) and 4.8 (undesirable effects) of the SPC have been amended. The Patient Leaflet was revised accordingly.	II-0003	II	18.12.02	19.04.03
Minor changes in manufacture of the medicinal product.	I-0004	I	03.04.03	-
Change in the batch size of finished product.	I-0005	I	03.04.03	-
Change in supplier of an intermediate compound used in manufacture of the active substance.	I-0006	I	08.05.03	-
Change in test procedure of active substance.	I-0007	I	03.04.03	-
Change in batch size of active substance.	I-0008	I	08.05.03	-
The MAH applied for changes to the PL not connected to the SPC.	N-0009	N	14.01.04	
Update of sections 4.3 “Contraindications”, 4.4 “Special warnings and special precautions for use”, 4.5 “Pharmacodynamic Interactions”, 4.8 “Undesirable effects” and 5.1 “Pharmacodynamic properties” of the SPC of the medicinal product Dynastat following the request from the CPMP after the adoption of the opinion on the referral procedure under article 31 of Directive 2001/83/EEC, for all medicinal products containing celecoxib, etoricoxib, parecoxib, rofecoxib and valdecoxib. The package leaflet has been updated accordingly.	II-0011	II	26.02.04	22.04.04
The MAH applies for a change in his address to Sandwich, Kent, CT13 9NJ, UK.	I-0012	IA	19.04.04	

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended: **I** refers to a minor variation (Type I variation); **II** refers to a major variation (Type II variation); **I/II** refers to a minor variation following the procedure set out in Article 6, 7 and 8 of the Regulation; **X** refers to an Annex II application.
T refers to a transfer of a Marketing Authorisation in accordance with Commission Regulation (EC) No 2141/96 of 7 November 1996.
N refers to a notification in accordance with Article 10(3) of Council Directive 92/27/EEC of 31 March 1992.
S refers to an annual reassessment.

[2] For Notifications and Type I variations, the date of entry into force of the change is the EMEA Notification date. The Commission Decision will be amended accordingly.