STEPS TAKEN AFTER GRANTING THE MARKETING AUTHORISATION

For procedures finalised after 1 May 2004 please refer to module 8B.

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Update of sections 4.3 "Contraindications", 4.4 "Special warnings and special precautions for use", 4.5 "Pharmacodynamic Interactions", 4.8 "Undesirable effects", 5.1 "Pharmacodynamic properties" and 5.3 "Preclinical safety data" of the Summary of Product Characteristics (SPC) of the medicinal product Onsenal following the request from the CPMP following 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 (PL) has been updated accordingly. Modification of section 4.8 of the SPC by ranking ADRs for frequency within each system organ class, for alignment with celecoxib SPC as adopted through the referral procedure. A few sentences have been moved within the specific section, for alignment purposes. The Marketing Authorisation Holder (MAH) has taken this opportunity to correct a mistake in the section 4.2 of the French SPC for the 400mg capsule. On the basis of the information provided by the MAH and as set out in the appended variation assessment report, the CPMP considers this variation to be a Type II variation.	II-0001	II	26.02.04	22.04.04

[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.

[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.