Steps taken after granting the Marketing Authorisation

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

Ovitrelle

MAJOR CHANGES

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Summary
X/007	Line extension : addition of a new pharmaceutical form	24/07/2003	24/10/2003	Additional pharmaceutical form: solution for injection in a pre-filled syringe
II/0012	Change to an analytical method and related specification	25/09/2003	02/10/2003	Alternative method to quantify the carbohydrate content of luteinising hormone

MINOR CHANGES
(Type I variations, Notifications)

No	Scope	Notification issued on[1]
I/0001	Change in the name of the medicinal product (either invented name of common name)	20/07/2001
I/0002	Change in the name and/or address of the marketing authorisation holder	20/07/2001
I/0003	Change in specification of starting material/intermediate used in manufacturer of the active substance	22/03/2002
I/0004	Change in or addition of manufacturing site(s) for part or all of the manufacturing process	13/09/2002
I/0005	Change in the name of a manufacturer of the medicinal product	21/08/2002
I/0006	Change in supplier of an intermediate compound used in manufacture of the active substance	21/08/2002
I/0008	Change in in-process controls applied during the manufacture of the product	16/01/2003
N/0009	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	10/02/2003
I/0010	Change in name of manufacturer or actual site of manufacture	08/09/2003
I/0011	Change in container shape	08/10/2003
I/0013	Change in ATC code	27/11/2003
I/0014	Change in the shelf-life of the finished product	10/03/2004
N/0015	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	27/07/2004

[1] Date of entry into force of the change