Steps taken after granting the Marketing Authorisation

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

- On 21 January 2000 the Marketing Authorisation Holder submitted to the EMEA an application for a Type I variation relating to the increase of batch size of the active substance. On 15 March 2000 the EMEA has notified the European Commission that the change was accepted. The European Commission amended the Decision on 27 April 2000.
- On 12 June 2000 the Marketing Authorisation Holder notified the EMEA of its intention to introduce changes in the Labelling and the Package Leaflet not connected to the Summary of Product Characteristics. On 7 August 2000 the EMEA has notified the European Commission that the changes were accepted. The European Commission amended the Decision on 29 September 2000.
- On 25 August 2000 the Marketing Authorisation Holder submitted to the EMEA an application for a Type I variation relating to a minor change in the manufacturing process. On 19 October 2000 the EMEA has notified the European Commission that the change was accepted.

Subsequent post Marketing Authorisation applications agreed upon are summarised in the table below:

Scope	Application number	Type of modification[1]	Notification/ Opinion issued on[2]	Commission Decision Issued/amended on
Change in the sterility test methodology for the active substance	I-0004	I	26.01.01	-
Changes in Summary of Product Characteristics (SPC), Labelling and Package leaflet (PL). Following 1st PSUR (14 August 1999 - 13 February 2000), as well as the discussion held at the PVWP in July 2000: - In section 4.4 (Special warnings and special precautions for use) of the SPC, to amend an existing warning on the risk of allergic and anaphylactic reactions and the necessity to have medications for the treatment of severe hypersensitivity reactions available for immediate use following administration of palivizumab. - In section 4.8 (Undesirable effects), to add "Apnoea" in the list of rare ADRs reported during post-marketing experience, and "Anaphylaxis", as very rare ADRs (<1/10.000). - To amend the PL, in accordance with the information added in the SPC. Moreover, the MAH took the opportunity of this variation to implement the newly assigned ATC code in section 5.1 of the SPC and to bring the documents in line with the QRD templates.	II-0005	II	25.01.01	01.06.01
Changes to comply with note for guidance on minimising the risk of transmitting Animal spongiform Encephalopathy	II-0006	II	18.10.01	-
Extension of shelf-life from 2 years to 30 months as foreseen at time of authorisation	I-0007	I	21.06.01	24.08.01
Extension of Shelf-life from 30 months to 3 years as foreseen at time of authorisation	I-0008	I	21.12.01	05.03.02
Change in the SPC following 4th PSUR (14 February 2001 – 19 June 2000) to add "Urticaria" to the list of very rare ADRs in section 4.8 (Undesirable Effects).	II-0009	II	21.02.02	24.05.02
Change in the specifications of the active substance	I-0010	I	17.07.02	-
This notification relates to address changes affecting the PL, namely to update the address of the local representatives in all languages and to correct spelling mistakes in the labelling.	N-0011	N	15.01.03	03.02.03

[1] In accordance with Commission Regulation (EC) No. 542/95 of 10 March 1995, as amended for procedures finalised before 1 October 2003. In accordance with Article 6 of Commission Regulation (EC) No 1085/2003 for procedures finalised after 1 October 2003 : **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.

Update of the SPC section 4.4 (Special warnings and special precautions for use) and 5.1 (Pharmacodynamic properties) following the CPMP assessment of clinical studies related to the possible risk of enhanced RSV infection. Additional changes are proposed for section 4.4, to update SPC information on anaphylaxis.	II-0012	II	19.03.03	30.06.03
An amendment to the SPC for Synagis to reflect data now available following the conclusion of clinical study prophylaxis of Respiratory Syncytial Virus in Children with Congential Heart Disease. In line with this, amendments are proposed to the SPC, Sections 4.1 "Therapeutic Indications", 4.4 "Special warnings and special precautions for use", 4.5 "Interaction with other medicinal products and other forms of interaction", 4.8 "Undesirable effects", 5.1 "Pharmacodynamic properties and" 5.2 "Pharmacokinetic properties". Relevant changes are also proposed for the PL.	II-0013	II	24.07.03	20.10.03
This notification relates to address changes affecting the PL, namely to update the address of the local representatives in all languages.	N-0014	N	08.04.03	-
Update of SPC sections 4.2 (Posology and method of administration), 4.4 (Special warnings and special precautions for use), 4.8 (Undesirable effects) and 5.1 (Pharmacodynamic properties) based on new data regarding administration of greater than 5 doses of palivizumab in a single RSV season and on the safety of more than 5 doses of palivizumab in a single RSV season.	II/0015	II	21/01/2004	25/03/2004
Change(s) to the test method(s) and/or specifications for the active substance	II/0016	II	29/07/2004	-
Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	N/0017	N	28/05/2004	-
Renewal of the marketing authorisation	R/0018	R	23/06/2004	09/09/2004