Teslascan

Procedural steps taken and scientific information after the authorisation
Changes made after 01/07/2002

For procedures finalised before 01/07/2002, please refer to module 8A

MAJOR CHANGES[1]

No	Scope	Opinion issued on	Commission Decision Issued/ amended on	Product Information affected[2]	Summary
II/0016	Update of Summary of Product Characteristics Update of section 4.2 of the Summary of Product Characteristics (SPC) to indicate that the use in children is not recommended, further to the request of the CHMP following the assessment of paediatric data submitted in accordance with Article 45 of Regulation (EC) No1901/2006, as amended (P45-007).	24/09/2009	23/10/2009	SPC	In accordance with Article 45 of the Paediatric Regulation 1901/2006, the Marketing Authorisation Holder (MAH) submitted available paediatric data. Following the assessment of these paediatric data, the CHMP concluded that, due to the insufficiency of the data, assessment of risk/benefit could not be made with justifications, and an empirical basis for proper dosing instructions did not exist. Therefore, section 4.2 of the Summary of Product Characteristics was updated as follows: "Use in children There are limited data available on the use of Teslascan in children. The available data do not support safety and efficacy in the paediatric population and therefore such use is not recommended."
R/0015	Renewal of the Marketing Authorisation	22/03/2007	22/05/2007	SPC, Annex II, Labelling, PL	Based on the CHMP review of the available information and on the basis of a re-evaluation of the benefit/risk balance, the CHMP is of the opinion that the quality, safety and efficacy of this medicinal product continues to be adequately and sufficiently demonstrated and therefore considered that the benefit/risk profile of Teslascan continues to be favourable. In the absence of specific safety problems, given the stability of the population exposed to Teslascan, the MAH can hereby change to a 3-year PSUR cycle. During the renewal procedure, changes were made to the Product

[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
					Information to bring it in line with the current EMEA/QRD template, SPC guideline and other relevant guideline(s), which were reviewed by QRD and accepted by the CHMP.

MINOR CHANGES[3]

No	Scope	Product Information affected[2]	Date[4]
N/0014	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	PL	19/09/2006
IA/0013	05_Change in the name and/or address of a manufacturer of the finished product		19/09/2006
IA/0012	01_Change in the name and/or address of the marketing authorisation holder 05_Change in the name and/or address of a manufacturer of the finished product	SPC, Annex II, Labelling, PL	19/09/2006
N/0011	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	Labelling, PL	17/12/2004

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