Commission Regulation (EC) No 507/2006 of 29 March 2006 on the conditional marketing authorisation for medicinal products for human use falling within the scope of Regulation (EC) No 726/2004 of the European Parliament and of the Council (Text with EEA relevance)

Article 5

Specific obligations

1 By way of specific obligations, the holder of a conditional marketing authorisation shall be required to complete ongoing studies, or to conduct new studies, with a view to confirming that the risk-benefit balance is positive and providing the additional data referred to in Article 4(1).

In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

2 The specific obligations referred to in paragraph 1 and the timeframe for their completion shall be clearly specified in the conditional marketing authorisation.

3 The Agency shall make the specific obligations and the timeframe for their completion publicly available.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 507/2006. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked in part by S.I. 2019/775 Sch. 9 para. 1(k)