Annex IV

Conditions to the marketing authorisation

Conditions to the marketing authorisation(s)

The marketing authorisation holders (MAHs) shall complete the conditions below, within the stated timeframe, and Competent Authorities shall ensure that the following is fulfilled:

In order to evaluate the effectiveness of the implemented risk minimisation measures with a particular focus on preventing pregnancies and on further characterising the prescribing patterns for topiramate in the target populations for pregnancy prevention, the MAHs of medicinal products containing topiramate as a monocomponent should conduct and submit the results of a drug utilisation study according to an agreed protocol.	Submission of the protocol to the PRAC in accordance with Article 107n(1) of Directive 2001/83/EC within 6 months from the CMDh position.
Interim report(s) should be submitted to the EMA/PRAC:	Every 24 months after endorsement of the study protocol.
The final study report should be submitted to the EMA/PRAC:	Within 48 months after endorsement of the study protocol.
In order to assess the knowledge of healthcare professionals and patients with regard to the risks of topiramate use during pregnancy and the measures to prevent pregnancies together with the receipt/use of the educational materials, the MAHs of medicinal products containing topiramate as a monocomponent should conduct and submit the results of a survey according to an agreed protocol. The survey part among healthcare professionals should also include the behaviour with regard to these risks and the measures to prevent pregnancies should include the receipt/use of the DHPC.	Submission of the protocol to the PRAC in accordance with Article 107n(1) of Directive 2001/83/EC within 6 months from the CMDh position.
The final study report should be submitted to the EMA/PRAC:	Within 12 months after endorsement of the study protocol.
The MAHs should update their RMP or implement a new one and submit it to the relevant national Competent Authorities through an appropriate procedure. The RMP should reflect: – major congenital malformations as an important identified risk and neurodevelopmental disorders as an important potential risk for all topiramate-containing products; – the drug utilisation study and survey mentioned above for topiramate-monocomponent products;	Within 6 months from the CMDh position.

– the additional risk minimisation measures for all topiramate-containing products as: • a healthcare professional guide including a risk awareness form; • a patient guide.	