Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation

National competent authorities of Member State(s) or reference Member State(s), if applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

Conditions	Date
The Marketing Authorisation Holders of valproate and related substances shall perform a drug utilisation study to assess the effectiveness of the risk minimisation measures and to further characterise the prescribing patterns for valproate. The study design should aim to evaluate and quantify the effectiveness of the risk minimisation measures, and should include a pre- and post-implementation analysis and assessment. The study should be conducted in more than one Member State.	
The protocol shall be submitted in accordance with Article 107n (1) of Directive 2001/83/EC:	Within 6 months of the Coordination group agreement.
The first interim report shall be submitted to the PRAC :	Within 12 months after endorsement of the study protocol.
Further interim reports should be submitted to the PRAC 6-monthly thereafter for the first 2 years.	
The final study report shall be submitted to the PRAC:	Within 48 months after endorsement of the study protocol.
The Marketing Authorisation Holders of valproate and related substances shall develop and submit educational materials according to agreed core elements. These materials should ensure that prescriber are informed and the patients understand and acknowledge the risks associated with valproate in utero exposure.	
These should be submitted to the National Competent Authorities:	By 12 January 2015