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):

1. A study shall be conducted to generate robust data on the efficacy of domperidone in the relief of symptoms of nausea and vomiting in children at the recommended doses. The Marketing Authorisations Holders of products for which a paediatric indication is approved shall submit the protocols of new or ongoing studies to the National Competent Authorities within 4 months of the commission decision for this procedure. The final study report shall be submitted to the National Competent Authorities within 36 months of endorsement of the protocol, and updates on progress with recruitment to the study shall be submitted to the National Competent Authorities on a yearly basis.
2. The Marketing Authorisation Holders for the rectal formulations that remain authorised shall conduct a pharmacokinetic study to generate data to allow for a comparison between the rectal and oral formulations. The final study report shall be submitted to the National Competent Authorities within 1 year of the commission decision for this procedure.
3. The Marketing Authorisation Holders shall perform a drug utilisation study to assess the effectiveness of the risk minimisation measures and to monitor off-label use. The study shall be conducted in more than one Member State and the protocol shall be submitted to the PRAC within 3 months of the commission decision for this procedure.
4. Within 3 months of the commission decision for this procedure, the MAHs shall submit to the National Competent Authorities a Risk Management Plan containing the key elements described in the PRAC assessment report.