Annex IV

Conditions to the marketing authorisations

The marketing authorisation holders shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

<u>All methotrexate-containing products</u> Each MAH should implement the agreed targeted follow-up questionnaires for all medication errors resulting in overdose.	From the date of notification of the Commission Decision
<u>Methotrexate-containing products for oral use with at least one indication requiring once weekly dosing</u> Each MAH should operate a risk management system to be described in a risk management plan (RMP) which shall be submitted to the relevant Competent Authorities. The RMP should reflect the following additional risk minimisation measures to address the important identified risk of medication errors resulting in overdose: - educational material(s) for healthcare professionals developed in accordance with the key elements agreed; - the agreed patient card. For tablet formulations, the following measure should also be implemented: MAHs should replace any bottle or tube used as immediate packaging by blisters.	Within 3 months after Commission decision Within 4 years after Commission decision