Annex IV

Conditions to the marketing authorisations

Conditions to the marketing authorisation

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

Conditions	**Date**
The MAHs should circulate the agreed DHPC in coordination with the NCAs according to the action plan agreed by CHMP.	Within 30 days following EC decision
The MAHs should submit a risk management plan (including outline of DUS and educational materials, see also below) in EU format.	Within 2 months following EC decision
Thiocolchicoside takes part in the PSUR synchronisation project of the Heads of Medicine Agencies. The MAH(s) should submit the next PSUR by:	4 July 2015
The MAH(s) should provide within the risk management plan submission, a protocol for the drug utilisation study to characterise prescribing practices for the medicinal products during typical clinical use in representative groups of prescribers and to assess main reasons for prescription. Final study report by:	November 2017
The MAHs should provide within the risk management plan educational material for prescribers and patients. This will highlight the risks and warnings of genotoxicity reactions.	Within 2 months following EC decision