Annex

Conditions or restrictions with regard to the safe and effective use of the medicinal product to be implemented by the member states

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The Member States should ensure that all conditions or restrictions with regard to the safe and effective use of the medicinal product described below are implemented:

Prior to launch of the product in each Member State, the Marketing Authorisation Holder shall agree the content and format of a Safety Information Communication with the national competent authority, including the need and the timing of any follow-up Safety Communication Information, as well as the distribution list of such information.

The Marketing Authorisation Holder (MAH) should ensure that, at launch, all Healthcare Professionals who are expected to use and/or prescribe Topotecan Eagle are provided with a Safety Information Communication.

The Safety Information Communication should contain the following:

- The risk of medication error due to the higher concentration than the dilution concentration of the originator, with potentially life-threatening consequences.
- Reference to the vial collar as visual reminder of this difference and the instruction that it must not be removed at any time.
- The anticipated effects of overdose (e.g. bone marrow suppression).
- An encouragement of reporting of actual medication errors and any safety events that might be a consequence of a medication error.
- A form to report medication errors