

**Annex related to the Art. 127a**

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

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

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:

- **Additional risk minimisation measures**

Prior to the launch of Tibsovo in each Member State the Marketing Authorisation Holder (MAH) must agree about the content and format of the educational programme, including communication media, distribution modalities, and any other aspects of the programme, with the National Competent Authority.

The educational programme is aimed at patients with AML prescribed Tibsovo, to further provide information regarding the important identified risk of differentiation syndrome.

The MAH shall ensure that in each Member State where Tibsovo is marketed, all patients who are expected to use Tibsovo are provided with the following educational package:

The patient information pack

- Patient information leaflet
- Patient alert card

The patient alert card will be integrated in the packaging and the content will be agreed as part of the labelling (Annex III).