**Annex related to the 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**

**1. Educational package**

The Member States shall ensure that prior to Kisunla being marketed, all healthcare professionals who are expected to prescribe the medicinal product and patients who will use it, have access to/are provided with the educational package which should include the key elements agreed.

**2. Controlled Access Programme**

The Member States shall ensure that a controlled access programme (CAP) to promote the safe and effective use of Kisunla. The CAP includes the following key principles that will be incorporated within each system in all Member States. These are restricting access of donanemab to preselected centres and implementing a registration system to assist HCPs in assessing patient eligibility, providing quick reference to educational materials, and confirming adherence to the materials.

The MAH shall agree the details of the controlled access programme with each National Competent Authority and must implement such programmes nationally.