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 LEQEMBI 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 lecanemab and prevent off-label use is in place. Initiation of treatment in all patients should be through an imposed central registration system implemented as part of a controlled access programme. The central registration system will collect appropriate and relevant information on the specified data fields prior to the first infusion of lecanemab, for all patients.

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