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 the 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:

Prior to launch of Fintepla, the Member States should agree with the marketing authorisation holder (MAH) the content and format of the educational materials (EM) and the controlled access programme (CAP) including communication media, distribution modalities and any other aspects of the programme, with the National Competent Authorities (NCA).

The Member State where Fintepla is marketed should ensure that the MAH has implemented a **CAP** to prevent off-label use for weight management in obese patients, since the benefit-risk ratio in this population is known to be negative.

In addition, the CAP shall be implemented to confirm that prescribing physicians have been informed of the need for periodic cardiac monitoring in patients taking Fintepla due to the potential risk of valvular heart disease and pulmonary arterial hypertension.