Annex IV

Conditions to the marketing authorisation

Conditions to the marketing authorisations

The marketing authorisation holder Astellas shall complete the below conditions, within the stated timeframe, and competent authorities shall ensure that the following is fulfilled:

The MAH Astellas should replace the current Eligard drug device combination product with a new one (e.g. containing two pre-connected syringes) with the objective of reducing the risk of medication errors. Relevant supportive documentation including adequate usability data should also be provided.	The corresponding regulatory procedure should be submitted to the relevant National Competent Authorities for assessment by 31 October 2021.