Annex IV

Condition to the marketing authorisations

Condition to the marketing authorisations

National Competent Authorities (NCAs) of Member State(s) or Reference Member State(s) (RMS) where applicable, shall ensure that the following conditions are fulfilled by the MAH(s):

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.