

Annex III

Conditions for lifting the suspension of the marketing authorisations

For the suspension of the marketing authorisation(s) of hydroxyprogesterone caproate-containing medicinal product(s) to be lifted, the competent authorities shall ensure that the condition below has been completed by the marketing authorisation holder(s) (MAH(s)):

The MAH(s) shall provide data demonstrating a positive benefit-risk balance in a defined patient population.