

Annex IV

Conditions for lifting the suspension of the marketing authorisations

Conditions for lifting the suspension of the marketing authorisation(s)

For the suspension of medicinal products containing nalidixic acid, flumequine, pipemidic acid and cinoxacin to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holders

The MAH should submit appropriate scientific evidence to demonstrate a positive benefit-risk balance of the medicinal product in any indication.