Annex V

Conditions for lifting the suspension of the marketing authorisation(s) for Fosfomycin intramuscular and Fosfomycin trometamol (2g) medicinal products

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

Fosfomycin-containing medicinal products intended for intramuscular administration

For the suspensions of intramuscular fosfomycin containing medicinal products to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holders:

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

Fosfomycin trometamol 2g granules for oral solution

For the suspension of fosfomycin 2g granules for oral solution containing medicinal products to be lifted, the competent authorities shall ensure that the below conditions have been completed by the marketing authorisation holders:

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