

Annex IV

Conditions for the lifting of the suspension of the Marketing Authorisations (intranasal formulations)

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In order to lift the suspension of the MA, National Competent Authorities shall ensure that the following conditions are fulfilled by the MAH(s) of intranasal formulations of calcitonin-containing medicines:

The MAH(s) should provide new randomised controlled data that will be able to robustly demonstrate that the benefits of calcitonin-containing medicines outweigh risks in patients with osteoporosis taking into account the increased risk of cancer and cancer mortality associated with long term use of calcitonin.