

Annex IV

Conditions of the marketing authorisations

National Competent Authorities, coordinated by the Reference Member State as applicable, should ensure the following:

The MAHs should submit/update the Risk Management Plans for all somatropin medicinal products to reflect the following potential risks:

- New neoplasm
- Second neoplasm in childhood cancer survivors
- Intracranial aneurysm and intracranial haemorrhage

The MAHs within 2 months of the Commission Decision should liaise with the National Competent Authorities to agree on the timelines for submission of the Risk Management Plans.