

Annex IV

Conditions of the marketing authorisation

For all bisphosphonates

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

The MAHs should submit/update the Risk Management Plans to reflect "atypical femoral fractures" as potential risk. 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.

National Competent Authorities should ensure that Health Care Professionals will be informed of the measures agreed by CHMP to minimise the risk of atypical femoral fractures. The communication should be based on the "key communication messages document" agreed by CHMP and annexed to the assessment report.