
CMDh/247/2011, Rev0
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The Commission Implementing Decision of 13 July 2011 concerning, in the framework of Article 31 of Directive 2001/83/EC of the European Parliament and of the Council, the marketing authorisations of medicinal products for human use which contain the active substances “alendronic acid, clodronic acid, etidronic acid, ibandronic acid, neridronic acid, pamidronic acid, risedronic acid and tiludronic acid” included the following condition of marketing authorisation:

- The MAHs should submit/update the Risk Management Plans (RMPs) to reflect "atypical femoral fractures" as a 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.

In order to implement this condition, the PhVWP has agreed an abbreviated core RMP for bisphosphonates and atypical femoral fractures (Annex 1) and MAHs are now requested to take the following action:

- **For bisphosphonate-containing products without an existing RMP:**
  MAHs are requested to inform National Competent Authorities of 1) their agreement to adopt the abbreviated core RMP for bisphosphonates and atypical femoral fractures and 2) their commitment to adhere to the planned pharmacovigilance actions outlined in the abbreviated core RMP.

- **For bisphosphonate-containing products with an existing RMP:**
  MAHs are requested to inform National Competent Authorities of 1) their agreement to update the existing RMP to incorporate the contents of the abbreviated core RMP for bisphosphonates and atypical femoral fractures and 2) their commitment to adhere to the planned pharmacovigilance actions outlined in the abbreviated core RMP.

All MAHs that have not taken action yet can implement the Commission Decision including changes in product information via a single type IA\textsubscript{IN} variation under classification C.I.1.a (change in the product information following a referral procedure). MAHs must not submit any additional data.
For MAHs that have implemented the product information changes but have not yet submitted a new or updated RMP a further variation may be required. The next steps should be discussed with the Reference Member State.

It is important to note that the abbreviated core RMP for bisphosphonates and atypical femoral fractures has been agreed to specifically address the condition of the Article 31 Referral regarding this issue and is not intended to set a precedent for future issues. With the exception of updating information about atypical femoral fractures, the abbreviated core RMP does not change the contents of existing RMPs and does not preclude the addition of further known and/or potential risks to the RMP in the future.