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# Questions and answers on Valebo and associated names (tablets containing 70 mg alendronic acid and capsules containing 1 microgram alfacalcidol)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 19 December 2013, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Valebo. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Valebo outweigh its risks, and the marketing authorisation can be granted in Germany and in the following Member States of the EU: Austria, Belgium, Bulgaria, Denmark, France, Hungary, Ireland, the Netherlands, Portugal, Slovakia, Slovenia, Spain and the United Kingdom.

## What is Valebo?

Valebo is a combination of tablets containing 70 mg alendronic acid and capsules containing 1 microgram alfacalcidol. It is to be used for the treatment of osteoporosis (a disease that makes bones fragile) in women who have been through the menopause.

Alendronic acid is a bisphosphonate that has been used for osteoporosis since the mid-1990s. It slows the action of the osteoclasts, the cells that are involved in breaking down the bone tissue. Blocking the action of these cells leads to less bone loss.

Alfacalcidol is a type of vitamin D (a 'vitamin D analogue'), which is required for calcium absorption and normal bone formation. Alfacalcidol has been used for many years in women who have been through the menopause.

## Why was Valebo reviewed?

TEVA Pharma B.V. submitted Valebo to the German medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Austria, Belgium, Bulgaria, Denmark, France, Hungary, Ireland, the Netherlands, Portugal, Slovakia, Slovenia, Spain and the United Kingdom).

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However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 28 February.

The grounds for the referral was a concern raised by Spain that appropriate data had not been submitted to support a statement which was to be included in the indication for Valebo (in section 4.1 of the summary of product characteristics) that alfacalcidol reduces the rate of falls in older people.

## What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that Valebo should be granted marketing authorisation in all concerned Member States for the treatment of postmenopausal women with osteoporosis. However, although alfacalcidol has been shown in some clinical studies to reduce the risk of falls in older people, the Committee considered that this information should be included under section 5.1 of the summary of product characteristics (and not in section 4.1).

The European Commission issued a decision on 10 March 2014.