20 November 2014
EMA/CHMP/702486/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

SENSHIO

ospemifene

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Senshio, 60 mg, Film-coated tablet, intended for the treatment of moderate to severe symptomatic vulvar and vaginal atrophy (VVA) in post-menopausal women who are not candidates for local vaginal oestrogen therapy.

The applicant for this medicinal product is Shionogi Limited.
The active substance of Senshio is ospemifene, a Selective Oestrogen Receptor Modulator (ATC code G03XC05) that, alongside with its major metabolite, binds to oestrogen receptors and results in activation of oestrogenic pathways in some tissues (agonism) and blockade of oestrogenic pathways in others (antagonism).

The benefits with Senshio include its ability to improve vaginal pH levels, maturation of the vaginal epithelium and having beneficial effects in terms of Most Bothersome Symptoms (including vaginal dryness and dyspareunia) - for the approved indication. The most common side effect reported were hot flushes.

A pharmacovigilance plan for Senshio will be implemented as part of the marketing authorisation.

The approved indication is: "*treatment* of *moderate to severe symptomatic vulvar and vaginal atrophy (VVA) in post-menopausal women who are not candidates for local vaginal oestrogen therapy (see section 5.1)".*

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2014. Reproduction is authorised provided the source is acknowledged.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Senshio and therefore recommends the granting of the marketing authorisation.