16 February 2012
EMA/CHMP/101946/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sabervel

irbesartan

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sabervel 75mg, 150 mg and 300mg film-coated tablets intended for the treatment of essential hypertension, and the treatment of renal disease in patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive drug regimen. The applicant for this medicinal product is Pharmathen S.A. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Sabervel is irbesartan, an angiotensin II antagonist, plain (C09CA04). Irbesartan is a selective angiotensin-II receptor (type AT_1) antagonist and it is expected to block all actions of angiotensin-II mediated by the AT_1 receptor, regardless of the source or route of synthesis of angiotensin-II.

Sabervel is a generic of Aprovel, which has been authorised in the EU since 27 August 1997. Studies have demonstrated the satisfactory quality of Sabervel, and its bioequivalence with the reference product Aprovel. A question-and-answer document on generic medicines can be found here.

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

The approved indication is: “Treatment of essential hypertension. It is also indicated for the treatment of renal disease in adult patients with hypertension and type 2 diabetes mellitus as part of an antihypertensive medicinal product regimen.”

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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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