20 March 2014
EMA/CHMP/157961/2014 – Corr(*)
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Jardiance

empagliflozin

On 20 March 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 Jardiance, 10 mg and 25 mg film-coated tablets, intended for the treatment of type 2 diabetes mellitus.

The applicant for this medicinal product is Boehringer Ingelheim International GmbH. 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 Jardiance is empagliflozin, a blood glucose lowering agent, ATC code: A10BX12. Empagliflozin works by blocking a protein in the kidney called the human sodium-glucose co-transporter-2 (SGLT2). This reduces glucose re-absorption in the kidney leading to glucose excretion in the urine, thereby lowering levels of glucose in the blood of patients with type 2 diabetes.

The benefits with Jardiance are its ability to improve glycaemic control. The most common side effects are hypoglycaemia (when used with sulphonylurea or insulin), genital and urinary tract infections, pruritus and increased urination.

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

The approved indication is:

“Treatment of type 2 diabetes mellitus to improve glycaemic control in adults as:

Monotherapy

When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.

[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 7418 8613
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

Add-on combination therapy

In combination with other glucose–lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations)."

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.

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

(*) The correction concerns the deletion of the following sentence “It is proposed that Jardiance be prescribed by physicians experienced in the treatment of type 2 diabetes”.