EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 April 2012
EMA/CHMP/259852/2012
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Forxiga

dapagliflozin

On 19 April 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 Forxiga, 5 mg, 10 mg, film-coated tablet intended for the treatment of type 2 diabetes mellitus in adults.

The applicant for this medicinal product is Bristol-Myers Squibb/AstraZeneca EEIG. 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 Forxiga is dapagliflozin, drugs used in diabetes, other blood glucose lowering drugs, excl. insulins (A10BX09). Forxiga is a competitive, reversible, selective and orally active inhibitor of the human sodium-glucose co-transporter 2 (SGLT2) which reduces renal glucose re-absorption leading to urinary glucose excretion.

The benefits with Forxiga are its ability to lower blood glucose by increasing urinary glucose excretion. The most common side effects are hypoglycaemia (when used with a sulphonylurea or insulin), urinary tract infection, genital tract infection, dyslipidaemia, dysuria and polyuria. Specific safety issues regarding a tumour imbalance in dapagliflozin treated patients, the limited data available in patients > 75 years old, the use in patients at risk of volume depletion, hypotension and electrolytes imbalances have been evaluated and addressed in the Summary of Product Characteristics (SmPC) and in the Risk Management Plan.

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

The approved indication is: “Forxiga is indicated in adults aged 18 years and older with type 2 diabetes mellitus to improve glycaemic control 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.

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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 will be 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 Forxiga and therefore recommends the granting of the marketing authorisation.