EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 June 2014
EMA/CHMP/372924/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Daklinza

daclatasvir

On 26 June 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 Daklinza, 30 and 60 mg, film-coated tablet, intended for the treatment of chronic hepatitis C virus (HCV) infection in adults. The applicant for this medicinal product is Bristol-Myers Squibb Pharma 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 Daklinza is daclatasvir, (ATC code not yet assigned). Daclatasvir (DCV) is a NS5A replication complex inhibitor and is the first in class as regards its mechanism of action. Daclatasvir inhibits both viral RNA replication and virion assembly.

The benefits with Daklinza used in combination with other medicinal products is its ability to inhibit viral replication in infected host cells which can lead to the eradication of the virus, correlating to a cure of chronic hepatitis C virus infection. The most common side effects when used in combination were fatigue, headache, and nausea.

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

The approved indication is: "Daklinza is indicated in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults (see sections 4.2, 4.4 and 5.1).

For HCV genotype specific activity, see sections 4.4 and 5.1."

It is proposed that Daklinza be prescribed by physicians experienced in the treatment of chronic hepatitis C infection.

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.

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