22 July 2016
EMA/CHMP/500725/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Zydelig

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On 25 February 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending an extension of the indication for the medicinal product Zydelig.

The marketing authorisation holder for this medicinal product is Gilead Sciences International Ltd.

On 21 July 2016, the Committee adopted another opinion recommending further changes to the indication in relation to an evaluation under Article 20 of Regulation (EC) No 726/2004.

As a result the existing indication will change as follows[2]:

> "Zydelig is indicated in combination with **an anti-CD20 monoclonal antibody** (rituximab **or ofatumumab**) for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
>
> - who have received at least one prior therapy, or
> - as first line treatment in the presence of 17p deletion or *TP53* mutation in patients ~~unsuitable for chemo-immunotherapy~~**who are not eligible for any other therapies**."

For information, the full indications for Zydelig will be as follows:

> "Zydelig is indicated in combination with an anti-CD20 monoclonal antibody (rituximab or ofatumumab) for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):
>
> - who have received at least one prior therapy, or
> - as first line treatment in the presence of 17p deletion or *TP53* mutation in patients who are not eligible for any other therapies.
>
> Zydelig is indicated as monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment."

Changes were also made to section 4.4 (Special warnings and precautions for use) and 4.8 (Adverse effects).

[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
[2] New text in bold, deleted text in strikethrough

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