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# EMA reviews cancer medicine Zydelig

## Review follows concerns over serious adverse events in ongoing clinical trials

The European Medicines Agency (EMA) has, at the request of the European Commission, started a review of the cancer medicine Zydelig (idelalisib), which is authorised in the EU to treat two types of rare blood cancers called chronic lymphocytic leukaemia and follicular lymphoma (one of a group of cancers called non-Hodgkin lymphoma).

The review has been started because an increased rate of serious adverse events including deaths, mostly due to infections, was seen in three clinical trials[1] investigating the medicine in combination with other cancer medicines. The clinical trials involved patients with chronic lymphocytic leukaemia and indolent non-Hodgkin lymphoma. However, the study in chronic lymphocytic leukaemia investigated combinations of medicines that are currently not approved and the studies in non-Hodgkin lymphoma included patients with disease characteristics different from those covered by the currently approved indications.

Investigators of all clinical trials involving Zydelig are currently being informed of the actions to be taken in relation to the conduct of ongoing studies.

EMA will now review the data from these studies to assess whether the findings have any consequences for the authorised uses of Zydelig. In the meantime, patients starting or on treatment with Zydelig should be carefully monitored for signs of infections. If Zydelig is well tolerated, treatment should not be stopped.

EMA is considering whether any other immediate measures are necessary while the review is ongoing. The Agency will communicate further and keep doctors and patients informed as appropriate.

Patients who have any questions about their treatment should contact their doctor.

[1] Study GS-US-312-0123; GS-US-313-0124; GS-US-313-0125.

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## More about the medicines

In the EU, Zydelig is authorised for the treatment of:

- chronic lymphocytic leukaemia in patients who have received previous treatment as well as in previously untreated patients who have certain genetic mutations in their cancer cells. It is used in combination with rituximab.
- a type of non-Hodgkin lymphoma called follicular lymphoma where it is used on its own.

More information on the approved uses of Zydelig can be found here.

## More about the procedure

The review of Zydelig has been initiated at the request of the European Commission, under Article 20 of Regulation (EC) No 726/2004.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use, which will adopt a final opinion.

The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.