7 July 2010
EMA/CHMP/735863/2009 Rev. 1
EMEA/H/A-29/1238

Questions and answers on Levact and associated names[1] (bendamustine hydrochloride, 2.5 mg/ml, powder for concentrate for solution for infusion)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Levact and associated names. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Levact outweigh its risks, and that the marketing authorisation can be granted in Germany and in the following Member States: Austria, Belgium, Denmark, Finland, France, Ireland, Italy, Luxembourg, Norway, Poland, Spain and the United Kingdom.

What is Levact?

Levact is an anticancer medicine. It is used to treat the following types of cancer:

- chronic lymphocytic leukaemia (a cancer of a type of white blood cell called lymphocytes) in patients for whom treatment with fludarabine (another anticancer medicine) is not appropriate;
- non-Hodgkin's lymphoma (a cancer of the lymph tissue, part of the immune system) in patients whose cancer got worse during or following treatment containing rituximab (another anticancer medicine);
- multiple myeloma (a cancer of the bone marrow) in combination with prednisone in patients older than 65 years who are not eligible for stem-cell transplantation and cannot be treated with thalidomide or bortezomib (other anticancer medicines).

The active substance in Levact, bendamustine hydrochloride, belongs to a group of anticancer medicines called 'alkylating agents'. It binds to the DNA of cells while they are reproducing, which stops cell division. As a result, the cancer cells cannot divide and the growth of tumours slows down. Bendamustine has been used in anticancer medicines in Germany since the early 1970s.

[1] Levact is also known as Ribomustin.

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Why was Levact reviewed?

Astellas Pharma GmbH submitted Levact to the German medicines regulatory agency for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance Germany) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance Belgium, Denmark, Finland, France, Ireland, Italy, Luxembourg, Norway, Poland, Spain and the United Kingdom).

However, the Member States were not able to reach an agreement and the German medicines regulatory agency referred the matter to the CHMP for arbitration on 2 October 2009.

The grounds for the referral were that one Member State, the United Kingdom, could not approve the indication non-Hodgkin's lymphoma, and two Member States, Belgium and France, could not approve the indication multiple myeloma because not enough data on the effectiveness of this medicine were available to support these indications.

What are the conclusions of the CHMP?

The CHMP assessed the two clinical studies presented by the company to support the multiple myeloma and non-Hodgkin's lymphoma indications. Based on the evaluation of these data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Levact outweigh its risks for the two indications for which objections were raised. The Committee therefore recommended that Levact be granted marketing authorisation in Germany and all concerned Member States for all the indications that were applied for.

The European Commission issued a decision on 7 July 2010.

Rapporteur:	Harald Enzmann (Germany)
Co-Rapporteur:	Jean-François Baurain (Belgium)
Referral start date:	22 October 2009
Company responses provided on:	14 January 2010 and 17 February 2010
Opinion date:	18 March 2010