EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 August 2012
EMA/532364/2012

Public statement

MabCampath (alemtuzumab)

Withdrawal of the marketing authorisation in the European Union

On 6 July 2001 the European Commission issued a marketing authorisation valid throughout the European Union for the medicinal product MabCampath (alemtuzumab) for the treatment of patients with B-cell chronic lymphocytic leukaemia (B-CLL) for whom fludarabine combination chemotherapy is not appropriate.

The marketing authorisation holder (MAH) responsible for MabCampath was Genzyme Europe B.V. The European Commission was notified by letter of the MAH's decision to voluntarily withdraw the marketing authorisation as of the Commission Decision date for MabCampath for commercial reasons.

On 8 August 2012 the European Commission issued a decision to withdraw the marketing authorisation for MabCampath.

The MAH has committed to ensure that patients who need treatment with MabCampath for B-CLL and some other transplant/oncology indications will continue to receive it through patient access programmes. Details of these programmes are being discussed at national level and will be governed by national competent authorities.

Pursuant to this decision the European Public Assessment Report for MabCampath will be updated to reflect that the marketing authorisation is no longer valid.

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