European Medicines Agency
Press office

London, 25 September 2008
Doc. Ref. EMEA/504716/2008

PRESS RELEASE
Takeda withdraws its marketing authorisation application for Ramelteon

The European Medicines Agency (EMEA) has been formally notified by Takeda Global Research & Development Centre (Europe) Ltd of its decision to withdraw its application for a centralised marketing authorisation for the medicine Ramelteon (ramelteon) 4 and 8 mg tablets. Ramelteon was expected to be used for the treatment of primary insomnia in patients aged 18 years or over.

The application for marketing authorisation for Ramelteon was submitted to the EMEA on 21 March 2007. On 30 May 2008, the Committee for Medicinal Products for Human Use (CHMP) adopted a negative opinion, recommending the refusal of the marketing authorisation for the medicine. Following this, the company requested a re-examination of the opinion, which was under review by the CHMP at the time of the withdrawal.

In its official letter, the company stated that the withdrawal of the application was based on its current plan to consider seeking scientific advice with a view to extending the clinical programme, which would address the CHMP's questions regarding the medicine's benefit-risk profile.

More information about Ramelteon and the state of the re-examination procedure at the time of withdrawal will be made available in a question-and-answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website in due course.

-- ENDS --

Notes:

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. More information about the CHMP's negative opinion on Ramelteon is available in a question and answer document: http://www.emea.europa.eu/pdfs/human/opinion/Ramelteon_26821608en.pdf
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu