European Medicines Agency
Press office

London, 13 October 2006
Doc. Ref. EMEA/410100/2006

PRESS RELEASE
Novo Nordisk withdraws its application to extend the marketing authorisations for NovoNorm and Prandin

The European Medicines Agency has been formally notified by Novo Nordisk A/S of its decision to withdraw its application for a change to the marketing authorisations for NovoNorm (repaglinide) and Prandin (repaglinide) 0.5 mg, 1 mg and 2 mg tablets.

NovoNorm was first authorised in the European Union on 17 August 1998 and Prandin on 29 January 2001. Both products are currently indicated for use in patients who have non-insulin-dependent diabetes (type-2 diabetes). They are used in conjunction with diet and exercise to lower blood glucose (sugar) in patients whose hyperglycaemia (high blood glucose) cannot be controlled by diet, weight reduction and exercise alone. They may also be used with metformin (another anti-diabetes medicine) in type-2 diabetes patients who are not satisfactorily controlled on metformin alone.

On 21 December 2005, Novo Nordisk A/S submitted an application for the extension of the marketing authorisations to include the use of NovoNorm or Prandin in combination with a thiazolidinedione (another type of anti-diabetes medicine) such as rosiglitazone or pioglitazone, for the treatment of type-2 diabetes.

Following review of the data submitted, the Agency's Committee for Medicinal Products for Human Use (CHMP) had some concerns and was of the provisional opinion that NovoNorm or Prandin in combination with a thiazolidinedione could not be approved. In its official letter, the company stated that the reason for withdrawing was the Committee's consideration that the data provided did not allow it to conclude on a positive benefit-risk balance of the concomitant use of repaglinide and thiazolidinediones.

More information about NovoNorm and Prandin and the current state of the scientific assessment 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 after the next meeting of the CHMP on 16-19 October 2006.

--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 NovoNorm and Prandin is available in the European Public Assessment Reports (EPARs): http://www.emea.europa.eu/humandocs/Humans/EPAR/novonorm/novonorm.htm and http://www.emea.europa.eu/humandocs/Humans/EPAR/prandin/prandin.htm.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://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