European Medicines Agency
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# PRESS RELEASE
# European Medicines Agency:
# Committee for Medicinal Products for Human Use
# 13-15 December 2004

The Committee adopted two positive opinions on initial marketing authorisation applications for:

- **Aloxi** (palonosetron), from Helsinn Birex Pharmaceuticals Ltd, for the prevention of nausea and vomiting associated with cancer chemotherapy. EMEA review began on 18 August 2003 with an active review time of 206 days.
- **Zonegran** (zonisamide), from Eisai Ltd, for the adjunctive therapy of partial seizures in epilepsy. EMEA review began on 24 November 2003 with an active review time of 202 days.

Summaries of these opinions, including the full indications for each product, are available on the EMEA web site: http://www.emea.eu.int

The Committee also gave positive opinions on the extension of indication for medicinal products that are already authorised in the EU:

- **Arixtra** (fondaparinux), Sanofi Synthelabo, and **Quixidar** (fondaparinux), N.V. Organon, to extend its use to the prevention of Venous Thromboembolic Events (VTE) in medical patients who are judged to be at high risk of thromboembolic complications due to acute illness such as cardiac insufficiency, and/or acute respiratory disorders, and/or acute infectious or inflammatory disease. Arixtra and Quixidar were both first authorised in the European Union on 21 March 2002.
- **Pegasys** (peginterferon alfa-2a), Roche Registration Ltd, to extend its use in combination therapy with Ribavirin for the treatment of chronic hepatitis C in patients co-infected with HIV. Pegasys was first authorised in the European Union on 20 June 2002.

The Committee finalised an EU-wide referral for arbitration for **Artirem** (Gadoteric acid) from Guerbet. Artirem is a contrast agent for arthrography using magnetic resonance imaging (MRI) for certain joints and diseases. The referral was initiated by Germany under Article 29 of the Community code on human medicines in March 2004 based on unsolved safety and efficacy objections. After reviewing all available data the Committee concluded that the safety and efficacy for Artirem are sufficiently proven and that a marketing authorisation can be granted in the context of the mutual recognition procedure.

The CHMP began a Community referral under Article 29(2) of Directive 2001/83/EC as amended, for the medicinal product **Adartrel** (ropinirole) from Laboratoires GlaxoSmithKline, following a notification from Spain and The Netherlands. The referral was initiated because of concerns regarding the efficacy and long-term safety of the medicinal product for the symptomatic treatment of moderate to severe idiopatic restless legs syndrome.

A more detailed CHMP meeting report will be published shortly.

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