20 February 2014
EMA/87173/2014
Committee for medicinal products for human use (CHMP)

**Summary of opinion[1] (initial authorisation)**

# Pregabalin Pfizer

pregabalin

On 20 February 2014 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Pregabalin Pfizer 25 mg, 50 mg, 75 mg, 100 mg, 150 mg, 200 mg, 225 mg and 300 mg capsules, intended for the treatment of epilepsy, neuropathic pain and Generalised Anxiety Disorder. The applicant for this medicinal product is Pfizer Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Pregabalin Pfizer is pregabalin, a gamma-aminobutyric acid (GABA) analogue antiepileptic medicinal product (ATC code N03AX16). Pregabalin modulates neuronal excitability in the central nervous system.

The benefits with Pregabalin Pfizer are its ability to reduce pain in central and peripheral neuropathic pain models, reduce seizure frequency as adjunctive therapy in adults with partial seizures and improve symptoms of Generalised Anxiety Disorder. The most common side effects are dizziness and somnolence.

A pharmacovigilance plan for Pregabalin Pfizer will be implemented as part of the marketing authorisation.

The approved indications are:

*Neuropathic pain*

Pregabalin Pfizer is indicated for the treatment of peripheral and central neuropathic pain in adults.

*Epilepsy*

Pregabalin Pfizer is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalisation.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
**Telephone** +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8613
**E-mail** info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

*Generalised Anxiety Disorder*

Pregabalin Pfizer is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Pregabalin Pfizer and therefore recommends the granting of the marketing authorisation.