EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 April 2013
EMA/177063/2013
Press Office

**Press release**

# European Medicines Agency recommends approval of first treatment for pseudobulbar affect

## Medicine to help curb bouts of uncontrolled emotional expression in patients with certain neurological disorders

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended the granting of a marketing authorisation for Nuedexta, a medicine for the treatment of pseudobulbar affect in adults.

Pseudobulbar affect is a medical condition in which patients experience sudden and uncontrollable bouts of laughing or crying unrelated or disproportionate to their emotional state. It occurs when certain neurological disorders, such as multiple sclerosis (MS) and amyotrophic lateral sclerosis (ALS) or a stroke, damage areas of the brain that are involved in the control of normal expression of emotion. This damage can disrupt brain signalling, resulting in the alteration or loss of control of emotional expression.

Although pseudobulbar affect is a non-life-threatening condition, it can have a significant impact on an individual's ability to interact normally in society and on their relationships with others. There is currently no treatment approved for pseudobulbar affect in the European Union.

Nuedexta is a combination of two known active substances, dextromethorphan hydrobromide and quinidine sulphate. In studies, treatment with these medicines significantly decreased episodes of involuntary, uncontrollable laughing or crying.

Pseudobulbar affect is observed in a number of neurological conditions. Nuedexta has currently only been studied in patients with MS and ALS. Nuedexta is not suitable for treating episodes of laughing or crying brought on by mood swings and not due to pseudobulbar affect.

The CHMP's opinion on Nuedexta will now be sent to the European Commission for the adoption of a marketing authorisation.

**Notes**

1. This press release, together with all related documents, is available on the Agency's website.

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2. The marketing authorisation holder for Nuedexta is Jenson Pharmaceutical Services Ltd.

3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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