EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 January 2014
EMA/CHMP/25190/2014
Committee for medicinal products for human use (CHMP)

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

# Rivastigmine 3M Health Care Ltd

## Rivastigmine patch



On 23 January the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rivastigmine 3M Health Care Ltd, 4.6 mg/24h & 9.5 mg/24h transdermal patches intended for symptomatic treatment of mild to moderately severe Alzheimer's dementia. The applicant for this medicinal product is 3M Health Care Limited.

The active substance of Rivastigmine 3M Health Care Ltd is is Rivastigmine, an anticholinesterases medicinal product (N06DA03). Rivastigmine is an acetyl- and butyrylcholinesterase inhibitor of the carbamate type, thought to facilitate cholinergic neurotransmission by slowing the degradation of acetylcholine released by functionally intact cholinergic neurones. Thus, Rivastigmine may have an ameliorative effect on cholinergic-mediated cognitive deficits in dementia associated with Alzheimer's disease.

Rivastigmine 3M Health Care Ltd is a generic of Exelon, which has been authorised in the EU since 12 May 1998. Studies have demonstrated the satisfactory quality of Rivastigmine 3M Health Care Ltd, and its bioequivalence with Exelon. A question and answer document on generic medicines can be found here. The approved indication is: Symptomatic treatment of mild to moderately severe Alzheimer's dementia.

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 will be 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 Rivastigmine 3M Health Care Ltd and therefore recommends the granting of the marketing authorisation.

[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.

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