



European Medicines Agency
Press office

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PRESS RELEASE

EMEA releases guidelines on development of medicines for Alzheimer's disease and Parkinson's disease

The European Medicines Agency (EMA) has released two guidelines for companies developing medicines for the treatment of Alzheimer's disease and other dementias, and for Parkinson's disease, in the light of recent scientific progress in the understanding of these diseases and conditions.

Advances in clinical science, physiopathology and molecular biology have stimulated new interest in the development of more effective symptomatic or disease-modifying treatments, i.e. early treatments that may prevent the emergence or slow down the progression of disease. The guidelines were developed in response to the need of companies developing these new types of medicines for guidance on appropriate clinical-trial designs.

As life expectancy increases, neurodegenerative diseases and dementia will affect more and more people over the coming decades, and these guidelines are expected to help improve the availability of medicines to treat such diseases and conditions. The guidelines will come into effect on 1 February 2009.

Scientific guidelines, which help companies to submit valid marketing-authorisation applications for their medicines, are prepared by the EMA's expert bodies, in this case the Committee for Medicinal Products for Human Use (CHMP) and its relevant working parties, in consultation with the Agency's stakeholders. They reflect an approach to specific scientific issues that is harmonised across the European Union (EU), and are based on the most up-to-date scientific knowledge. However, the recommendations they contain are not binding, and sponsors may deviate from them, provided they can substantiate their approach.

The therapeutic area of neurodegenerative diseases is part of the mandatory scope of the centralised procedure for the authorisation of medicines. This means that, in the EU, all applications for marketing authorisation for new medicines in this area have to be submitted to the EMA. The other therapeutic areas in the mandatory scope are: HIV/Aids, cancer, diabetes, autoimmune diseases and other immune dysfunctions, and viral diseases.

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Notes:

1. The 'Guideline on medicinal products for the treatment of Alzheimer's disease and other dementias' (CPMP/EWP/553/95 Rev.1) can be found [here](#). The 'Guideline on clinical investigation of medicinal products in the treatment of Parkinson's disease' (CHMP/563/95 Rev.1) can be found [here](#).
2. These guidelines are substantially revised versions of earlier EMA guidelines, and have been updated to reflect new scientific understanding of Alzheimer's disease, dementia and Parkinson's disease.
3. The guidelines were released for public consultation in July 2007. Comments received during the consultation phase will be published on the EMA website shortly.
4. This press release, together with other information on the work of the EMA, can be found on the EMA website: www.ema.europa.eu

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