European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

CONCEPT PAPER ON THE NEED FOR REVISION OF POINTS TO CONSIDER ON CLINICAL INVESTIGATION OF MEDICINAL PRODUCTS FOR THE TREATMENT OF OSTEOARTHRITIS (CPMP/EWP/784/97)

AGREED BY EFFICACY WORKING PARTY	April 2008
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END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 July 2008

Comments should be provided using this template to EWPSecretariat@emea.europa.eu

Fax +44 20 74 18 86 13

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7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20)74 18 86 13
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

1. INTRODUCTION

Since 1998, this guideline has presented guidance for studies addressing pharmacological treatments of osteoarthritis (OA) for a large group of products aiming at symptom- and/or structure-modification (e.g., non steroidal anti-inflammatory drugs [NSAID], coxibs, symptomatic slow-acting drugs in osteoarthritis [SYSADOA], disease-modifying osteoarthritis drugs [DMOAD]). In the last years efforts have been made to determine criteria for diagnosis, management and improvement of study design in this field. Therefore some important additions and changes are needed to express the current status of scientific knowledge in this guideline.

2. PROBLEM STATEMENT

The search for improved and meaningful endpoints and study design has prompted several groups of scientists to develop new assessment instruments to assess symptom control**,** functional status, and structural progression of the disease, and to provide new recommendations for conducting clinical studies. A need is identified to update the regulatory guidance on the clinical development of medicinal products intended for the treatment of OA is identified.

3. DISCUSSION (ON THE PROBLEM STATEMENT)

The main topics that may be discussed when revising the guidance document are:

1. Main efficacy variables according to the possible therapeutic indication (symptom and/or structure modification). There are several new instruments and scales available to measure changes.
2. New composite indices for different joints.
3. Clinical relevance of the observed effects and definition of responders.
4. Appropriateness of study designs to evaluate flares.
5. Measurement time points and duration of the trials for efficacy evaluation, either for the acute and slow symptom modification or for the modification of the radiological progress.
6. Other therapeutic approaches for the treatment of osteoarthritis.

4. RECOMMENDATION

It is proposed to revise the current CHMP Guideline addressing the clinical investigation of medicinal products for the treatment of osteoarthritis in order to achieve a European common position on the above-mentioned issues.

5. PROPOSED TIMETABLE

It is anticipated that a new draft CHMP Guideline may be available 6 months after adoption of the recommendation for revision to be later released for 3 months for external consultation and, therefore finalised within 6 months.

6. RESOURCE REQUIREMENTS FOR PREPARATION

The preparation of this revision of the Guideline will involve the EWP, including one Rapporteur and one Co-Rapporteur. It is anticipated that at least two plenary session discussions at the EWP will be needed.

7. IMPACT ASSESSMENT (ANTICIPATED)

The revision of the points to consider on clinical investigation of new products for the treatment of osteoarthritis will be helpful to achieve more consensus in the evaluation of such products by regulatory authorities. Furthermore, it is expected that such guidance document would improve quality and comparability of submitted studies by pharmaceutical industries.

8. INTERESTED PARTIES

It is envisioned to contact the Outcome Measures in Rheumatology (OMERACT), the European League against Rheumatism (EULAR), the European Society for Clinical and Economic Aspects of Osteoporosis and Osteoarthritis (ESCEO) and the Group for the Respect of Ethics and Excellence in Science (GREES).

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