



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Concept paper on the need for revision of Note for Guidance on Clinical Medicinal Products for Treatment of Nociceptive Pain and Guideline on clinical investigation of products intended for the treatment of neuropathic pain

Agreed by CNS Working Party	July 2011
Adoption by CHMP for release for consultation	22 September 2011
End of consultation (deadline for comments)	31 December 2011

The proposed guideline will replace guideline CPMP/EWP/612/00-Note for Guidance on Clinical Investigation of Medicinal Products for Treatment of Nociceptive Pain and the CHMP/EWP/252/03-Guideline on clinical investigation of medicinal products intended for the treatment of neuropathic pain

Comments should be provided using this [template](#). The completed comments form should be sent to cnswpsecretariat@ema.europa.eu

Keywords	Pain, nociceptive, neuropathic, paediatric
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1. Introduction

Pain is the most common symptom for which patients seek medical attention. Although there is no exact definition it has been defined as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage (International Association for the Study of Pain (IASP)). Due to the subjective component of pain and the problems associated with a correct diagnosis patients are frequently undertreated for acute and chronic situations.

Nociceptive and neuropathic pain has been internationally defined. Nociceptive pain can be defined as the process by which intense thermal, mechanical, or chemical stimuli are detected by a subpopulation of peripheral nerve fibers, called nociceptors whereas neuropathic pain can be defined as pain arising as a direct consequence of a lesion or disease affecting the somatosensory system. In addition, pain can be of mixed origin (e.g. cancer pain), thus justifying that the 2 current guidelines are merged in a unique document. When current guidelines on nociceptive and neuropathic pain were written, the experience on clinical development was not large.

The different types of pain which may have different pathophysiological mechanisms and pathways should be considered in the clinical development of new analgesic agents, and the proposed models to evaluate treatment efficacy should be updated in line of the experience gained during the past years.

Fibromyalgia is a complex disease with clinical features other than pain and should be dealt with in a separate document.

2. Problem statement

The current guidelines were adopted by CPMP on November 2002 (nociceptive pain) and on June 2005 (neuropathic pain). Since then, our knowledge on pain has evolved and the individualisation of mixed pain should be emphasised. Moreover, the pain evaluation in children should be updated.

3. Discussion (on the problem statement)

In the proposed update of the guidance document, the following issues will be discussed:

- Proposed models of nociceptive and neuropathic pain in human.
- Patient population
- Primary and secondary endpoints.
- Data needed in children.
- Psychological aspects.
- Clinical safety evaluation

4. Recommendation

Our knowledge on pain definition and evaluation has evolved and to ensure uniformity of clinical studies and to set standards, the CNS Working Party (CNSWP) recommends revising the Note for Guidance on Clinical Investigation of Medicinal Products for Treatment of Nociceptive Pain and the Guideline on Clinical Investigation of Medicinal Products intended for the Treatment of Neuropathic Pain and to elaborate an unique guideline on Clinical Investigation of Medicinal Products intended for the Treatment of Pain.

5. Proposed timetable

It is planned to publish a draft revised guideline no later than Q3 2012. The draft revised guideline will be available for 6-month consultation before its finalisation.

6. Resource requirements for preparation

The preparation of the revised guideline will involve the CNS-WP, PDCO and SAG-CNS if relevant.

7. Impact assessment (anticipated)

It is expected that the revised "Guideline on Clinical Investigation of Medicinal Products for Treatment of Pain" provides guidance for pharmaceutical companies with respect to methodology, assessment tools, measurements, clinically relevant outcomes, etc. for clinical investigation in pain. Furthermore, the revised guidance should ensure uniformity and comparability of the performed clinical studies in nociceptive and neuropathic pain in the European Community.

8. Interested parties

CNSWP/BSWP/RIWP/OncWP/SWP/PDCO