



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

London, 15 November 2004
Doc. Ref. EMEA/149436/2004

PRESS RELEASE
MEDICINES FOR THE TREATMENT OF PAIN IN CHILDREN –
EMEA WORKSHOP, 28 October 2004

The EMEA took the initiative to organise a workshop on pain treatment in children. This workshop is part of an ongoing work undertaken by the Paediatric Expert Group (PEG) of the Committee for Medicinal Products for Human Use (CHMP) in reviewing paediatric needs, including the treatment of pain at European level. More than 50 attendees from the PEG, Academia, national Medicines Agencies, Patients' Organisations, and Industry participated.

Treatment of pain represents a good paradigm of the unmet needs with respect to children's medicines, all the more so as all children, including the smallest neonates, experience pain.

In the three situations that can be distinguished, chronic pain, acute pain, and pain in neonates, experts shared their experience on pain management, pain assessment, and clinical trials in children. They highlighted the lack of adequate paediatric formulations, which is not specific to pain treatment but common to medicines used in children. The differences in the practices of pain management in Europe were also discussed, as exemplified by differences in palliative care based on preliminary results from a survey conducted by the PEG in Europe including the new Member States. Participants took an active part in the discussion of the presentations.

Although pain treatment is an area where some medical needs are met, all experts agreed that there are still many challenges to overcome in order to improve its management in children.

Finally, the conclusions of the day were positive, insisting on the need for collaboration between the different partners to tackle the challenges at each level:

- Efforts should be made by Industry and Regulators to reduce existing differences between Member States relating to availability of pain medicines in children, in terms of formulations, and/or posology, indications. This should ensure proper access of children of all ages to existing pain treatments.
- Where medical needs are clearly unmet, Industry should develop appropriate formulations and provide further studies and data on long-term use to allow proper use of pain medicines in children including in neonates. This may be best achieved in collaboration with Academia.
- Regulators should develop adequate guidance documents to help the development of medicines for pain in children. For example, there is a need for standardised methodology in measuring pain in the youngest, and for data requirements on long-term treatment.
- There is a need to harmonise pain management in Europe through specialists and academia, and to further educate all concerned physicians in recognising and treating pain.
- Patients' organisations are directly involved and should raise awareness of parents on children's participation in clinical trials to further improve the level of information on proper use of pain treatments.

More information on this Workshop will be made available in proceedings which will be made available on the EMEA website beginning of 2005. The EMEA intends also to pursue the initiative to encourage the clinical development and availability of paediatric medicines in pain as in other therapeutic areas.