European Medicines Agency
Press Office

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Press release
European Medicines Agency consulting on a draft guideline on pharmacovigilance for medicines used in children

The European Medicines Agency (EMEA) has launched a six-month consultation period on a draft guideline on the conduct of pharmacovigilance for medicines used by the paediatric population, children from birth to 18 years of age. This is the first guideline to focus exclusively on the issues of safety of medicines in children. The EMEA is consulting not only on reporting of adverse drug reactions in children, but also on the possible need for studies designed to follow the long-term safety of medicines in children.

According to the European Commission, more than 50 percent of medicines used to treat children are prescribed on an unlicensed or 'off-label' basis because they have not been adequately tested and/or formulated and authorised for use in children.

Differences in age and the stage of growth and development during childhood mean that children may experience adverse drug reactions that vary in nature, type and severity from those seen in adults. The systems for detecting adverse drug reactions in children may not be as effective as for adults. Children may be unable to communicate adverse events or may not be aware that they experience an adverse event. In addition to under-reporting of reactions, off-label use may increase the occurrence of adverse drug reactions. The guideline aims at strengthening the pharmacovigilance system for all medicines used in children, whether specifically authorised for such use or not.

The European Commission proposed new legislation in September 2004 that aims to stimulate the research, development and authorisation of medicines to treat children. The proposed regulation also contains a number of provisions for pharmacovigilance and the EMEA draft guideline is preparatory work with a view to implementing the regulation once it comes into force.

The European Medicines Agency in particular welcomes comments on this guideline from healthcare professionals looking after paediatric patients.

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NOTES:

1. The draft guideline on conduct of pharmacovigilance for medicines used by the paediatric population (EMEA/CHMP/235910/2005) can be found [here].
2. The draft guideline is open for a six-month consultation period until 31 January 2006. The EMEA routinely seeks comments from all interested parties on guidelines and other regulatory initiatives as part of its commitment to openness and dialogue.
3. The draft guideline applies to 'off-label' and unlicensed as well as approved use of medicines. It does not address the paediatric use of vaccines, for which a separate guideline is being developed.
4. More information on the work of the European Medicines Agency on medicines for children can be found here http://www.emea.eu.int/htms/human/peg/pegfaq.htm
5. Details on the European Commission proposed regulation on medicinal products for paediatric use can be found here http://pharmacos.eudra.org/F2/Paediatrics/index.htm
6. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at http://www.emea.eu.int

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