The European Agency for the Evaluation of Medicinal Products
Press office

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Press release
EMEA strengthens handling of safety concerns for human medicines

The EMEA has introduced a revised procedure for the handling of safety concerns for centrally processed applications, leading to a more proactive conduct of pharmacovigilance. The revised procedure comes into effect from April 2004 and applies to all applications under review and approved medicines for human use.

Under the revised procedure there will be a case-by-case decision on whether the handling of safety concerns for a medicine both pre- and post-authorisation requires additional scientific input. The Committee for Proprietary Medicinal Products (CPMP) can request the involvement of the Pharmacovigilance Working Party (PhVWP) and in cases where specialised scientific input is needed, it can draw additional expertise from a pool of almost 100 specialised experts covering areas such as pharmacoepidemiology, risk management, risk communication, etc.

The Agency is recommending such involvement for certain types of products in the pre-authorisation phase, in particular for orphan drugs, emerging therapies, new compounds of a completely new therapeutic class or compounds for which risk management plans have been submitted by the applicants. Issues to be addressed by the experts could include:

- Whether any other safety areas need to be monitored in addition to those already identified
- Whether in addition to spontaneous and periodic reporting other tools are needed to monitor side effects
- What is the appropriate frequency and nature of spontaneous and periodic reporting in cases where standard measures need to be intensified
- Commenting on the appropriateness, feasibility and design of post-authorisation safety studies to be conducted by marketing authorisation holders
- Commenting on risk management plans submitted by pharmaceutical companies or recommending the submission of such plans

In the post-authorisation phase the procedure foresees a more systematic involvement of the PhVWP. Specialised experts would be involved in certain situations such as the follow-up of issues that required specialised expertise in the pre-authorisation phase or in cases where new issues arise during the post-authorisation phase.

The procedure is the first action delivered as part of the EMEA improvement plan for human medicines announced on 14 January 2004 and is an important pillar of the Agency's risk management strategy. It is designed to further strengthen the scientific evaluation of human medicines at Community level and will support rapporteurs and co-rapporteurs in their work while enhancing the collaboration between pre-authorisation and pharmacovigilance experts involved in the assessment process. In addition to improving the availability of specialised expertise at EU level for the handling of safety concerns, the procedure also facilitates the role of the PhVWP in its support to the CPMP.

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NOTES:

1. The paper 'Handling by the CPMP of safety concerns for pre- and post-authorisation applications submitted in accordance with the centralised procedure' (EMEA/CPMP/4285/04/Final) is available at www.emea.eu.int, together with information about the work of the Agency.

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