European Medicines Agency
Press office

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Press release

EMEA to review COX-2 inhibitors

Following the worldwide withdrawal of Vioxx (rofecoxib), the European Medicines Agency (EMEA) has been asked by the European Commission, as a precautionary measure, to conduct a review of COX-2 inhibitor medicines.

The CHMP, the Agency's scientific committee responsible for human medicines, will look at all aspects of cardiovascular safety of the COX-2 inhibitors celecoxib, etoricoxib, lumiracoxib, parecoxib and valdecoxib, including thrombotic events (e.g. heart attack and stroke) and cardio-renal events (e.g. hypertension, oedema and cardiac failure).

The CHMP had previously reviewed the COX-2 inhibitor class in 2003, but will now be reviewing newly available data.

The objective of this review is to assess whether there is a need to make changes to existing marketing authorisations including labelling throughout the whole of the European Union and whether additional studies are needed.

The outcome of the review will be posted on the Agency's web site once the Committee has reached its conclusion. Meantime, the information to prescribers and patients issued by the EMEA on 6 October 2004 remains valid:

Information to prescribers:

- *Patients prescribed Vioxx (rofecoxib):*
  This product has been withdrawn due to serious thrombotic events. Patients on Vioxx should be reviewed and alternative treatment considered.
  When considering switching patients to other COX-2 inhibitors, prescribers are advised to follow carefully the latest version of the summary of product characteristics (SPC), especially regarding the warnings and precautions in patients with a history of cardiovascular disease.

- *When prescribing other COX-2 inhibitors:*
  Prescribers are advised to carefully follow the latest version of the summary of product characteristics, especially regarding the warnings and precautions in patients with a history of cardiovascular disease.

Information for patients:

- *Patients currently taking Vioxx (rofecoxib):*
  Please be aware that Merck Sharp & Dohme has withdrawn this medicine due to serious cardiovascular events. You are advised to consult your doctor at the next available opportunity to discuss your treatment.

- *Patients currently taking other COX-2 inhibitors:*
  The new data relate to Vioxx. It is unclear if these new data are also relevant for other COX-2

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inhibitors. These medicines already contain warnings regarding heart problems. If you have any concerns about your treatment you are advised to consult your prescriber.

--ENDS--

NOTES FOR EDITORS

1. The 6 October 2004 EMEA statement following the withdrawal of Vioxx (rofecoxib) is available [here].

2. COX-2 inhibitors (cyclo-oxygenase-2 inhibitors) are non-steroidal anti-inflammatory medicines (NSAID). They are approved in the European Union for use in a number of indications – see notes 3 and 4 for information on the different products.

3. Information on the outcome of the previous EMEA review of nationally approved COX-2 medicinal products (containing celecoxib, etoricoxib and rofecoxib) was published in June 2004 and can be found [here].

4. More information on centrally authorised COX-2 inhibitors can be found in the European public assessment reports [here] for Bextra/Valdyn (valdecoxib), [here] for Dynastat/Rayzon (parecoxib) and [here] for Onsenal (celecoxib).

5. This press release, together with other information about the work of the EMEA, may be found on the EMEA web site at the following location: http://www.emea.eu.int

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