RE: Celecoxib (Celebrex®) and cardiovascular safety

Following the release of the Committee for Human Medicinal Products' (CHMP) statement on celecoxib (Celebrex®), the Medicines Authority (MA) is of the opinion that the advice provided on the use of Celebrex® is opportune and appropriate. In relation to this the MA has taken the following measures in order to communicate this new important safety information to its stakeholders. The Medicines Authority has held discussions with the local representatives of Pfizer, who will be circulating a Dear Doctor Letter to all general practitioners, geriatricians, rheumatologists and orthopaedic surgeons by 24/12/04. Moreover, Healthcare Professionals are being informed through The Synapse, a local network for medical professionals (www.thesynapse.net) as well as an e-mail sent via The Synapse.

The Medicines Authority is committed to keeping Healthcare Professionals informed regarding new and emerging safety information. Once the outcome of the review of this new safety information is available, the Medicines Authority will immediately make it available. In the interim, prescribers are advised to follow carefully the latest version of the product information of Celebrex® (which will be circulated by Pfizer together with the Dear Doctor Letter) and the recommendations which the CHMP has made in the press release issued by the European Medicines Agency.

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