



Agence française de sécurité sanitaire
des produits de santé

21 SEP. 2006

Dr Daniel Brasseur
Chairman
Committee for Medicinal Products for Human Use
European Medicines Agency

Dear Dr Brasseur

Request for opinion on non-selective NSAIDs under Article 5(3) of Regulation (EC) No 726/2004

In accordance with Article 5(3) of Regulation (EC) No 726/2004 and further to discussions at the Pharmacovigilance Working Party meeting on 18-20 September 2006 and at the Committee's plenary meeting 19-21 September 2006 on newly available data on the cardiovascular safety of non-selective non-steroidal anti-inflammatory drugs (NSAIDs) stemming from clinical and epidemiological studies, I am writing to request the Committee to draw up an opinion on the cardiovascular risks of non-selective NSAIDs in the context of their overall benefit-risk profile. This opinion should not preclude any further assessment of the respective benefit-risk profile of Cox2 inhibitors which are still under investigation.

This request follows the Committee's review in October 2005 on a number of non-selective NSAIDs. The European Medicines Agency's public statement of 17 October 2005 stated that, "As for all medicinal products marketed in the European Union, NSAIDs are being continuously monitored and if there are any concerns impacting on the benefit-risk balance, appropriate actions will be taken."

I am also asking the Committee to indicate whether there are public health concerns and, if these concerns are considered to be of Community interest, for the Committee to recommend whether the concerns need to be investigated further at Community level using appropriate legal procedures provided in Community legislation.

Yours sincerely

Jean Marimbert