



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 October 2011
EMA/CHMP/838671/2011
Press Office

Press release

European Medicines Agency concludes that benefit-risk balance of angiotensin II receptor antagonists remains positive

Review of evidence does not suggest any link with cancer

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has reviewed the possible link between the use of angiotensin II receptor antagonists (ARBs) and the occurrence of new cancers and concluded that the evidence does not support any increased risk of cancer in patients using these medicines.

Angiotensin II receptor antagonists have been authorised in the European Union since the mid-1990s for the treatment of hypertension (high blood pressure). They are also used in the treatment of conditions such as heart failure and kidney disease in type 2 diabetes and for the prevention of strokes and heart disease.

The review was formally requested by the Italian Medicines Agency following the publication of a meta-analysis which showed a small increased risk of new cancers (particularly lung cancer) with ARBs compared with placebo and other heart medicines (7.2% versus 6%).

The CHMP reviewed all available data on the risk of cancer in patients taking ARBs, including the meta-analysis. It found that the evidence from the meta-analysis was weak, noting several problems with the quality of the data, specifically that patients in the trials were not followed up for long enough to clearly establish a link between ARBs and cancer, information on the risk of cancer before start of treatment was lacking, and there was a possibility of publication bias, whereby studies that showed a link with cancer were more likely to have been included in the analysis.

The CHMP also reviewed data from large population-based studies and more complete meta-analyses that did not have the same methodological problems as the original meta-analysis, and the results did not show an increased risk of cancer with ARBs.

As with all medicines, the safety of ARBs will be continuously monitored by EU regulatory authorities.



Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. All other opinions and documents adopted by the CHMP at its October 2011 plenary meeting will be published on Friday, 21 October 2011 at 12.00 noon UK time on a dedicated webpage.
3. Meta-analysis by: Sipahi I, Debanne SM, Rowland DY, Simon DI, Fang JC. Angiotensin-receptor blockade and risk of cancer: meta-analysis of randomised controlled trials. *Lancet Oncol.* 2010 Jul;11(7):627-36.
4. Several angiotensin II receptor antagonists are authorised in the European Union: candesartan, eprosartan, irbesartan, losartan, olmesartan, valsartan and telmisartan. Of these, irbesartan, telmisartan and valsartan are authorised through the centralised authorisation procedure managed by the European Medicines Agency.
5. The review of angiotensin II receptor antagonists was conducted in the context of a formal review, initiated at the request of the Italian Medicines Agency under Article 5(3) of Regulation (EC) No 726/2004.
6. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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