



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

Update on ongoing European review of pioglitazone-containing medicines

Suspension of use of these medicines in France while Europe-wide review continues

The European Medicines Agency (EMA) has been informed by the French Medicines Agency (Afssaps) of its decision to suspend the use of pioglitazone-containing medicines in France (Actos, Competact), while awaiting the outcome of the ongoing European review on the benefits and risks of these antidiabetic medicines.

This decision by the French authority follows receipt of results of a retrospective cohort study carried out in France which became available today. These results appear to suggest an increased risk of bladder cancer with pioglitazone.

The EMA's Committee for Medicinal Products for Human Use (CHMP) started a European review of pioglitazone-containing medicines in March 2011 to investigate the signal of a possible increased risk of bladder cancer with pioglitazone.

The CHMP is currently reviewing all relevant data, including data from pharmacoepidemiological studies, non-clinical and clinical data, post-marketing reports of bladder cancer and published data to assess their impact on the balance of benefits and risks of these medicines. The Committee will now also assess the results of the French study and its potential impact on the use of these medicines across the whole EU. The CHMP will discuss this issue at their next meeting on 20-23 June 2011 and recommend appropriate actions as necessary.

The Agency will make further announcements as soon as new information becomes available.



Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The European review of the centrally authorised pioglitazone-containing medicines Actos, Glustin, Competact, Glubrava and Tandemact and the occurrence of bladder cancer is being conducted in the context of a formal review, initiated at the request of the European Commission under Article 20 of Regulation (EC) No 726/2004, on 16 March 2011. CHMP March press release: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2011/03/news_detail_001225.jsp&murl=menus/news_and_events/news_and_events.jsp&mid=WC0b01ac058004d5c1
3. The French targeted epidemiological study is a retrospective cohort study conducted by the French health insurance (Caisse National d'Assurance Maladie) following antidiabetic patients taking antidiabetic medicines between 2006 and 2009. It can be found on the website of the afssaps: http://www.afssaps.fr/var/afssaps_site/storage/original/application/b42a6bf9a1b63c3dbec7388d3914687b.pdf
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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