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Press release

European Medicines Agency confirms positive benefit-risk balance for Champix

Benefits as a smoking-cessation medicine outweigh slight reported increase in cardiovascular events

The European Medicines Agency has confirmed that the benefit-risk balance for Champix (varenicline) remains positive, despite the results of a recent meta-analysis of the medicine's side effects affecting the heart and blood vessels.

The Agency's Committee for Medicinal Products for Human Use (CHMP) and Pharmacovigilance Working Party concluded that the slightly increased risk of cardiovascular events reported by the study's authors does not outweigh the benefits of Champix in helping people to stop smoking.

Champix has been authorised in the European Union for the cessation of smoking in adults since September 2006. Its product information already includes information on cardiovascular side effects.

The meta-analysis, published in the *Canadian Medical Association Journal* on Monday, 4 July 2011, looked at the number of cardiovascular events seen in a total of 8,216 people taking either Champix or placebo in 14 randomised clinical trials lasting up to a year. The events included heart attack, stroke, disruption of the heart rhythm, heart failure and death related to cardiovascular problems.

The largest of the studies included over 700 patients with pre-existing cardiovascular disease.

The meta-analysis found that events were rare in both groups, but that there was a slightly increased number in the people taking Champix: 1.06% of those taking Champix had an event (52 out of 4,908) compared with 0.82% of those taking placebo (27 out of 3,308). This did not result in a difference in death rates between the two groups.

The Committee identified a number of limitations of the meta-analysis, including the low number of events seen, the types of events counted, the higher drop-out rates in people receiving placebo, the lack of information on the timing of events, and the exclusion of studies in which no-one had an event. Because of these limitations, the Committee could not draw robust conclusions from the meta-analysis.

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The Committee has asked Pfizer, the marketing-authorisation holder for Champix, to submit a variation to include more information on cardiovascular events in the medicine's product information. Pfizer has informed the Agency that it will submit this application in early August this year.

The Committee will review this application in an expedited fashion, aiming to conclude with a recommendation to the European Commission at its plenary meeting of 19-22 September 2011.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The meta-analysis is available on the *Canadian Medical Association Journal*'s website: Singh S *et al.* 2011 Risk of serious adverse cardiovascular events associated with varenicline: a systematic review and meta-analysis. CMAJ July 4, 2011. doi: 10.1503/cmaj.110218. Available at: http://www.cmaj.ca/content/early/2011/07/04/cmaj.110218
3. More information on Champix is available in the European public assessment report on the Agency's website.
4. A meta-analysis is a statistical method that combines the results of several independent studies. Meta-analyses aim to give a precise estimate of the effect of a treatment.
5. The CHMP regularly reviews the results of published studies whose results could have an impact on the balance of benefits and risks of any centrally authorised medicine.
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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