

Neuraminidase inhibitors for influenza: a systematic review and meta-analysis of regulatory and mortality data

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Pharmacy for its funding support (\$10,000) for a study to analyse written medical information regarding the possible harms of statins. Peter Doshi is also an unpaid member of the IMEDS steering committee at the Reagan–Udall Foundation for the FDA, which focuses on drug safety research. CDelM is the Co-ordinating Editor of the Acute Respiratory Infections Group of the Cochrane Collaboration. CDelM reports personal fees from Key Pharmaceuticals during the conduct of the study; grants from the National Health and Medical Research Council (Australia), grants from NIHR (UK), personal fees from Elsevier and BMJ Books, from conference organisers for International Viral Infections Conference, personal fees from GlaxoSmithKline Pharmaceuticals, personal fees from Key Pharmaceutical, outside the submitted work. Rokuro Hama provided scientific opinions and expert testimony on 11 adverse reaction cases related to oseltamivir for the applications by their families for adverse reaction relief by the Pharmaceuticals and Medical Devices Agency (PMDA) and in the lawsuits for revocation of the PMDA's decision concerning with these reactions. Most of the cases were reported in the *International Journal of Research Studies in Management* (2008:20:5–36). Rokuro Hama was an expert witness in the lawsuit on the adverse reaction of (death from) gefitinib against AstraZeneca and Japanese Minister of Health Labour and Welfare, and provided scientific opinions and expert testimony. He argued that gefitinib's fatal toxicity was known before approval in Japan, as shown in 'Gefitinib story' (<http://npojip.org/english/The-gefitinib-story.pdf>) and in other articles (<http://npojip.org/>). Plaintiffs finally lost the case on 12 April 2013 at the Supreme Court of Japan. Rokuro Hama has received royalties from a published book.

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Plain English summary

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Plain English summary

Regulatory information on trials of oseltamivir (Tamiflu) and zanamivir (Relenza) for influenza in adults and children

Oseltamivir and zanamivir have been stockpiled in many countries to treat and prevent seasonal and pandemic influenza, before an influenza vaccine matched to the circulating virus becomes available.

How this review has been approached

We have updated and combined our reviews on the antiviral drugs zanamivir and oseltamivir for influenza in adults and children on the basis of the manufacturers' reports to regulators (clinical study reports) and the regulators' comments. We have called these comments and reports 'regulatory information'.

What we have found

We have used data from 46 trials (20 oseltamivir and 26 zanamivir studies) in this review. We found that both drugs shorten the duration of symptoms of influenza-like illness (unconfirmed influenza or 'the flu') by less than a day (there was no effect in asthmatic children, but in otherwise healthy children there was). Oseltamivir did not affect the number of hospitalisations. In children with asthma there was no clear effect on the time to first alleviation of symptoms.

Prophylaxis trials showed that oseltamivir and zanamivir reduced the risk of symptomatic influenza.

Oseltamivir use was associated with nausea, vomiting, headaches and psychiatric events; these last two were when it was used to prevent influenza (prophylaxis).

Low-quality data, adjusted for some likely biases, failed to show a reduction in mortality in very ill patients with H1N1 2009 and treated with oseltamivir compared with those who did not receive influenza antiviral drugs.

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This report

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