



European Medicines Agency
Press office

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PRESS RELEASE

European Medicines Agency advises of risk of fever in young children following vaccination with Pandemrix

The European Medicines Agency is warning that young children may experience fever after their second dose of the pandemic influenza vaccine Pandemrix. Prescribers and parents should monitor the temperature of the vaccinated child and, if necessary, take measures to lower the fever (e.g. giving an antipyretic such as paracetamol). However, the Agency noted that the second dose increases the immune response against pandemic influenza.

The Agency has recommended that this information be included in the prescribing information, and be taken into consideration when deciding whether to give a second dose to children.

This follows the review of new data submitted by the manufacturer GlaxoSmithKline from an ongoing clinical trial in children aged from 6 months to three years. These data showed a higher proportion of children developing fever (temperature above 38°C, when measured under the armpit) after the second dose of Pandemrix, compared with after the first. The data also showed that there was more soreness at the site of injection and more general symptoms such as drowsiness, irritability and loss of appetite after the second dose.

The study also showed that a single dose of vaccine triggered a good immune response in young children, but that the second dose further increased the immune response.

The Agency will continue to evaluate all information that becomes available and make further recommendations as necessary.

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NOTES

1. More information is available in the question-and-answer document: <http://www.emea.europa.eu/pdfs/human/pandemicinfluenza/78039109en.pdf>.
2. For more details on the recommended changes, please refer to the updated product information for Pandemrix: http://www.emea.europa.eu/influenza/vaccines/pandemrix/pandemrix_pi.html
3. More information on adverse reactions reported with centrally authorised pandemic vaccines is provided in the weekly pandemic influenza pharmacovigilance update report: <http://www.emea.europa.eu/influenza/updates.html>
4. More information on the Agency's activities in relation to the influenza pandemic can be found on the Agency's pandemic influenza website: <http://www.emea.europa.eu/influenza/home.htm>
5. This press release, together with other information on the work of the European Medicines Agency, can be found on the Agency's website: www.emea.europa.eu

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