

To: General Practitioners
NHS Trusts – Medical Director
NHS Foundation Trusts – Medical Director
PCT Medical Directors
PCT Immunisation Co-ordinators
SHA Immunisation Leads
SHA Flu Leads
Chief Pharmacists/Pharmaceutical Advisers of PCTs
Practice Nurses
All Pharmacists

cc: SHA Directors of Public Health
Consultants in Communicable Disease Control
Accident and Emergency Departments
Regional Directors of Public Health
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of General Practitioners

Gateway reference number: 16688

26th September 2011

Dear Colleague

SEASONAL FLU IMMUNISATION PROGRAMME 2011/12 – VIROFLU® VACCINE AND RISK OF FEVER IN CHILDREN UNDER 5 YEARS

I am writing to inform you of advice to avoid use of Viroflu vaccine in children aged under five years because of an increased risk of fever.

In my letter of 13 September 2011, I informed you about the Enzira and CSL Biotherapies generic influenza vaccines marketed by Pfizer that are restricted to use in adults and children from five years of age only. This is because of an increased risk of febrile convulsions in children under five years of age. In addition, a caution has been placed on these vaccines because of an increased risk of fever in children aged five to less than nine years.

A further but related issue with a separate vaccine has arisen. The seasonal influenza vaccine, Viroflu produced by Crucell uses the same starting antigen as the Enzira and CSL Biotherapies generic influenza vaccines marketed by Pfizer. Whilst Viroflu is produced using a different manufacturing process, evidence suggests a higher rate of fever may be associated with use of this vaccine in children under five years of age than is expected with other influenza vaccines. Following discussions by European regulatory authorities, it is anticipated that the market authorisation for Viroflu will carry the following precautionary warning:

"Due to the risk of high fever, consideration should be given to the use of alternative seasonal influenza vaccines in children under the age of 5 years. In case it is used in children, parents should be advised to monitor for fever for 2 - 3 days following vaccination."

In light of this development, I advise clinicians to use alternative seasonal influenza vaccines authorised for use in children under five years of age. This is because, whilst there is no evidence that Viroflu is associated with an increased risk of febrile convulsions in children under five years of age, an increased risk cannot be ruled out. If no suitable alternative vaccines are available, clinicians should make parents aware of the risk and give clear advice about the management of post-vaccination fever in children. Advice will also be given in a revision to the influenza chapter of the Green Book:

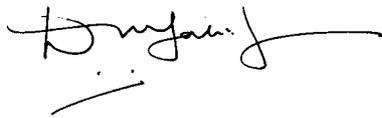
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917

I understand that Crucell will also be communicating with its customers about the warning and has supplies of an alternative vaccine authorised for use in children under five years of age to supply to its customers. I also understand that supplies of Viroflu will only begin to be issued by Crucell from 26 September 2011.

I would be grateful if you could inform those in your organisations who are administering seasonal influenza vaccines of the above information and advice.

Please report any suspected adverse reactions via the Yellow Card Scheme (www.yellowcard.gov.uk).

Yours sincerely



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Director of Immunisation