

13 September 2010

Dear colleague,

MONITORING THE SAFETY OF SEASONAL INFLUENZA VACCINES IN CHILDREN

As you begin to take stock of seasonal influenza vaccines, I am writing to ask your particular help with monitoring the safety of these vaccines in children.

As you may be aware, the Department of Health¹ has advised that two particular brands of seasonal influenza vaccine, **Enzira** and **CSL Biotherapies** generic influenza vaccine (both manufactured by CSL and marketed by Pfizer) should not be administered this year to children aged under five years.

Recent use of these vaccines in Australia² was associated with an increased risk of febrile convulsions within 72 hours of vaccination in children. This risk appears to be specific to CSL's influenza vaccines and evidence from Australia has not indicated a similar level of risk from vaccination with other products.

It is important that children over six months of age who are in clinical risk groups¹ receive influenza vaccination. The alternative vaccines should continue to be used as recommended. Although there is no evidence that other seasonal influenza vaccines carry this risk in children, it is important that we closely monitor the safety of all influenza vaccines used in the forthcoming immunisation campaign.

We strongly encourage you to promptly report any cases of febrile convulsion occurring within 72 hours of receiving an influenza vaccine. It is very important that the **brand name** of the vaccine given, and **batch number** if available, are reported to us. If you do not have this information at hand, please still report to us and we will follow up with you for further information.

Reports can be submitted to MHRA via the Yellow Card Scheme by post [Freepost Yellow Card] but we encourage you to report on-line via www.yellowcard.gov.uk We will compare the reporting rate for febrile convulsion amongst those vaccinated with the expected background rate during previous influenza vaccination campaigns, to enhance our ability to detect any change quickly.

Every Yellow Card report matters. Thank you for helping us to monitor the safety of influenza vaccines in children, and all vaccines and medicines on the UK market.

Yours faithfully,



Dr June Raine CBE
Director, Vigilance and Risk Management of Medicines (VRMM)

¹ <http://www.dhsspsni.gov.uk/hss-md-31-2010.pdf>

² www.tga.gov.au/alerts/medicines/flu vaccine-report100702.htm