

6th July 2009

Dear Colleague

Swine flu - reporting suspected adverse reactions to Tamiflu, Relenza and future Swine flu H1N1 vaccines

As you know, the UK has stockpiled the antiviral medicines Tamiflu (oseltamivir) and Relenza (zanamivir) for management of the Swine flu pandemic. I am writing to clarify arrangements for reporting suspected adverse drug reactions (ADRs) to these medicines and, when available, the H1N1 Swine flu vaccines.

The new Swine Flu ADR Portal

So that we can efficiently monitor the safety of Tamiflu and Relenza as their use increases we have put in place a special web-based system for reporting suspected ADRs to these medicines – **the Swine Flu ADR Portal**.

This is available now (www.mhra.gov.uk/swineflu) and will remain in operation for the duration of the pandemic. The Portal has been designed to make completing a report as quick and easy as possible. We strongly encourage you to make use of the Swine Flu ADR Portal to report suspected ADRs to Tamiflu and Relenza. When H1N1 Swine flu vaccines become available in the Autumn, the Portal should also be used to report suspected ADRs to these vaccines.

How to report a suspected adverse reaction

- Please report suspected ADRs to Swine flu antivirals via the Swine Flu ADR Portal at www.mhra.gov.uk/swineflu
- Please remember to include the following important information in your report:
 - the patient's age
 - the indication (prophylaxis or treatment)
 - information on any underlying risk factors for influenza complications or the ADR; or state if there are no known risk factors
 - any other information about the patient or additional clinical details which will help us in our assessment of the case

As with the Yellow Card Scheme, the Swine Flu ADR Portal will be open to members of the public as well as healthcare professionals. Please remind patients of this. The NHS antiviral leaflets, which will be handed to patients with their antivirals, will also encourage use of the Portal to report suspected ADRs to Swine flu medicines.

What about the existing Yellow Card Scheme?

The existing Yellow Card Scheme will remain in operation for reporting suspected ADRs to all other medicines. Again, we ask that you make use of the on-line reporting system for the Yellow Card Scheme at www.yellowcard.gov.uk. If you require further information on the role of the MHRA or the Yellow Card Scheme, please visit www.mhra.gov.uk.

I recognise that this will be an especially busy time for healthcare professionals and I appreciate your extra effort to report. Remember, every report matters. Thank you for your help in monitoring the safety of these important medicines.



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