NSW HEALTH

Safety Alert 005/09

21 October 2009

Distributed to:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

Action required by:

- Chief Executives
- Directors of Clinical Governance
- Directors of Clinical Operations

For response by:

- Directors of Clinical Governance

We recommend you also inform:

- Directors of Pharmacy
- Directors of Intensive Care
- Directors of Neonatal Intensive Care
- Directors of Paediatric intensive Care
- Directors of Neonate Emergency Transfer Services
- Directors of Anaesthesia & Surgery
- Directors of Emergency Medicine
- Directors of Medical Services
- Directors of Nursing and Midwifery
- Medical staff
- Nurses and Midwives

Deadline for completion of action

28th October 2009

Expert Reference Group

- TGA
- Pharmaceutical Services
- ICCMU

Clinical Safety, Quality and Governance Branch

NSW Department of Health
Tel. 02 9391 9200
Fax. 02 9391 9556
Email:
quality@doh.health.nsw.gov.au

Internet Website:
http://www.health.nsw.gov.au/quality/sabs

Intranet Website
http://internal.health.nsw.gov.au/quality/sabs/

Relenza (zanamivir) Inhalation Powder Safety Advisory

Background

The Therapeutic Goods Administration (TGA) has been advised by the US Food and Drug Administration (FDA) of a reported death of a patient who had received Relenza (zanamivir) Inhalation Powder that had been solubilised and administered by mechanical ventilation.

The sponsor is aware of cases in which the Relenza (zanamivir) Inhalation Powder is being removed from its approved packaging and dissolved in various solutions for use via nebuliser in patients unable to take oral medications or inhale Relenza (zanamivir) using the Diskhaler.

The safety, effectiveness, and stability of Relenza (zanamivir) use by nebulisation **have not been established** and the use of the product via nebuliser **has not been approved by the TGA**.

Specific Incident

In the case reported above, death was attributed to obstruction of the ventilator, thought to be due to stickiness caused by lactose in the nebuliser solution. The formulation of Relenza (zanamivir) is not designed or intended to be administered by nebuliser as there is a risk that the lactose sugar in this formulation may obstruct proper functioning of mechanical ventilator equipment.

Mandatory actions for Area Health Services

- Health care practitioners are advised that Relenza (zanamivir) Inhalation Powder is not intended to be reconstituted in any liquid formulation.
- Health care practitioners are advised that Relenza (zanamivir) Inhalation Powder is not recommended for use in a nebuliser or mechanical ventilator.
- Ensure staff are aware the formulation of Relenza (zanamivir) is not designed or intended to be administered by nebuliser as there is a risk that the lactose sugar in this formulation may obstruct proper functioning of mechanical ventilator equipment.
- Remind staff Relenza (zanamivir) Inhalation Powder should only be used as directed in the approved Product Information, and administered by insertion of the Relenza Rotadisk in which the product is supplied, into the Diskhaler device that accompanies the product.

References

- Further information is available at this link (US Site) http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm186081.htm
- Further information is available at this link http://www.tga.gov.au/

Action required by Area Health Services

1. Ensure that this safety alert is distributed to all relevant clinical staff involved with medication administration.
2. Develop processes to ensure that Relenza (zanamivir) Inhalation Powder is used in accordance with the manufacturer's instructions.
3. Formal advice emailed by AHS to quality@doh.health.nsw.gov.au of action taken by the 28th October 2009.