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.