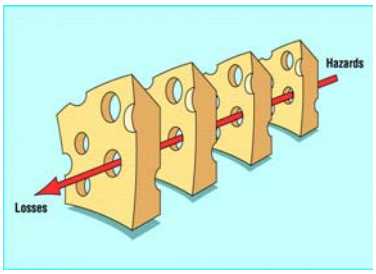

Medicines Governance Project

SAFETY MEMO 2

From: Medicines Governance Pharmacists, 28/10/02
Tracey Boyce Barbara Milliken Brendan Moore
Sharon O'Donnell Jillian Redpath Lisa Smith

To:
Dr N. Morrow, Chief Pharmacist, DHSSPSNI.
Directors of Pharmaceutical Services / Trust Pharmacy Managers
Directors of Pharmacy, HSS Boards

RE: LABELLING OF VANCOMYCIN INJECTION BY GENERIC MANUFACTURERS

Background

As you may be aware, Eli Lilly have warned of supply problems with their IV vancomycin preparation (Vancocin®). When current supplies are exhausted this product will be unavailable in the UK until February 2003 at the earliest. The labelling and availability of technical information provided by generic manufacturers has been highlighted as a potential cause of medication related incidents. Although the generic products now have a Summary of Product Characteristics, the information on the outer packaging does not make reference to the need for further dilution following reconstitution. Without such information there is an increased risk of this product being administered as an IV bolus. Such administration can cause a severe reaction in some patients.

Recommended action to reduce the risk

- DBL/Faulding brand should be used in preference to other generic manufacturers as it has suitable accompanying technical information.
- If necessary, an additional label should be placed on the outer packaging of each individual vial, highlighting the need for further dilution.
- Labels should be attached in a uniform position on the outer packaging of each vial ensuring no other information is obscured.
- A sample label is shown. These can be obtained from Norprint.

Many hospitals will be aware of, and have dealt with, this issue. However it is advised that HPSS Trusts review their arrangements for supply of generic vancomycin injections to clinical areas.

Sharon O'Donnell
On behalf of the Medicines Governance team