IRISH MEDICINES BOARD

Notice Information: Medical Devices - Warning 05 September 2008

Part 1. Product Information

a)	Title:	Blood Component Bags and Transfusion Giving Sets
b)	Product Name/Type:	Blood Component Bags and Transfusion Giving Sets
c)	Reference:	IMB Safety Notice: SN2008(08)
d)	Manufacturer/Supplier:	Various

Part 2. Target Audience

a)	Target Audience:	CEOs Risk Managers Quality Managers / Officers Chief Medical Scientists – Blood Transfusion Medical Directors Nursing Directors Intensive Care Units Surgical Wards Accident and Emergency Units Haematology / Oncology Units Consultant Haematologists Hospital Transfusion Committee Haemovigilance Officers Nurse Practice Development Coordinators Head of Medical Physics Departments

Part 3. Problem/Issue

a)	Problem/Issue:	The Irish Medicines Board (IMB) has received an increased number of reports relating to the puncturing of blood component bags during insertion of the giving set into the bag port prior to transfusion.

Part 4. Background Information

a) Background Information:

Blood component bags and giving sets are medical devices and as such should be CE marked. In addition to being CE marked, a large number of the blood component bags and giving sets meet the applicable European Committee for Standardisation (CEN) standards that are intended to ensure functional compatibility when these devices are used together. Although each of these individual devices satisfy all the relevant regulatory standards, sometimes compatibility issues can arise when different bags and giving sets are used in combination. These issues include: Difficulty in inserting and removing the giving set; Piercing of the bag (port / face) with the giving set; Inadequate seal forming at the port membrane after insertion. Based on international experience, these issues are particularly prevalent following a change in bag supplier by a blood establishment or a change in the giving set used by a hospital. These issues have generally been related to the historical giving set insertion methods / practices not being compatible with the new bag port / giving set combinations due to variances in insertion force / port length / port thickness / material durability and / or spike design. Late last year, the Irish Blood Transfusion Service implemented a change in bag manufacturer for blood components supplied to hospitals. A number of hospitals have also changed the giving sets they use. Since these changes have been implemented, there has been an increase in the number of incidents surrounding the puncturing of blood component bags reported to the IMB.

Part 5. Action to be taken

a) Action to be taken:

Internal hospital procedures should adequately reflect accepted best practice and the manufacturer's 'instructions for use'. When a new giving set or blood bag is introduced to an institution the suitability of the existing procedures should be reviewed and updated where applicable. The IMB are continuing to monitor the situation to determine if improved awareness of these potential issues and implementation of these actions reduces the incident level. We would ask that you continue to report adverse incidents to the device manufacturer who are then legally obliged to inform the Medical Devices Department of the IMB. In the event of an incident with a blood component bag the quality department of the Irish Blood Transfusion Service (IBTS) should be informed directly. In addition device users are also strongly recommended to report problems encountered with medical devices to the IMB directly.

Part 6. Enquiries

a)	All enquiries should be made to:	All adverse incidents relating to a medical device should be reported to the: Irish Medicines Board Medical Devices Department Kevin O'Malley House Earlsfort Centre Earlsfort Terrace D ublin 2 If you have any enquiries, you may contact the Medical Devices Department at: Telephone: +353-1-6764971 Fax: +353-1-6344033 Email: vigilance@imb.ie Website: www.imb.ie SN2008(08): Blood Component Bags and Transfusion Giving Sets

Part 7. Keywords

a)	Keywords:	Blood Component Bags and Transfusion Giving Sets