

**Notice Information: - Advisory  
21 December 2010**

**Part 1. Product Information**

- a) Title:
- b) Product Name/Type:
- c) Reference:
- d) Manufacturer/Supplier:

**Part 2. Target Audience**

- a) Target Audience:
- All Hospital staff
  - All Nursing Home staff
  - Risk Managers
  - Nursing Managers
  - Hospital Pharmacists
  - Diabetic Clinics/ outpatients
  - Diabetic nurse specialists
  - Diabetic departments
  - Endocrinology units
  - Endocrinology Consultants
  - Paediatric wards
  - Laboratory Managers
  - Chief Medical Scientists
  - Purchasing / Material Managers

### Part 3. Problem/Issue

a) Problem/Issue:

The risk of bloodborne pathogen transmission when insulin injection pens are used on more than one patient

### Part 4. Background Information

a) Background Information:

Insulin pens are designed to administer accurate doses of insulin. The insulin pen is an injection device with a cartridge or reservoir containing several doses of insulin. Pens are available as pre-filled, disposable units or as re-usable pens, requiring replacement insulin cartridges. A sterile, disposable needle is attached to the pen for each use.

Insulin pens are placed on the market with the “intended purpose” for “single-patient” use and are labelled accordingly.

Using an Insulin pen on more than one patient is contrary to the guidance outlined in the device labelling / Summary of Product Characteristics (SPC). The use of these devices on multiple patients could result, possibly, in the transmission of pathogens (such as Hepatitis B or C or Human Immunodeficiency Virus (HIV) to patients who use the same pen, even when the needles are changed between patients

### Part 5. Action to be taken

a) Action to be taken:

1. Ensure that this notice is communicated to the appropriate personnel within your organisation.
2. Ensure that procedures are in place to ensure that
  - a. single use devices are only used once.
  - b. single patient use devices are not used on multiple patients
3. Examine the guidance produced by Manufacturers in the “instructions for use” or the SPC before use.
4. Ensure that facilities are in place to ensure the safe disposal of these devices.

#### IMB REFERENCES

SN2004(04) The “intended purpose” of a Medical Device

SN2004(06) Instructions for Use provided by the Medical Device Manufacturer

SN2010(14) Single Use & Single Patient Use Medical Devices

## Part 6. Enquiries

a) All enquiries should be made to:

All adverse incidents relating to a medical device or any adverse events or medication errors associated with the use of insulin pens or cartridges should be reported to IMB:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: [vigilance@imb.ie](mailto:vigilance@imb.ie)

Website: [www.imb.ie](http://www.imb.ie)

[Please click here to download a PDF version of the safety notice](#)

## Part 7. Keywords

a) Keywords:

Insulin