

For Attention and Action by:
Chief Executive of each HSS Trust
General Manager/Chief Executive of each HSS Board
Chief Executive of each Agency



HEALTH ESTATES
ESTATE POLICY

**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

TITLE:

ELI LILLY HUMAPEN ERGO INSULIN PENS

MANUFACTURER/SUPPLIER

Eli Lilly and Company Limited

PROBLEM

Eli Lilly and Company Limited have been replacing original blue insulin cartridge holders in HumaPen Ergo insulin pens with new clear cartridge holders. The breakage of both engagement tabs on the original insulin cartridge holder can result in the delivery of insufficient insulin.

Whilst the majority of HumaPen Ergo users have had the insulin cartridge holder of their pens replaced with the new design a significant number of users have not yet done so. This Advice Notice is intended to remind healthcare professionals of the insulin cartridge holder replacement programme and to advise them of the national advertising campaign aimed at the **remaining users** being run by Eli Lilly and Company Limited in the week commencing 17th June 2002.

DISTRIBUTION

This notice should be brought to the attention of all who need to know or be aware of it, including those listed below, in accordance with local procedures. This will include:

- Liaison Officers
- Risk Managers
- Health & Safety Officers/Advisors
- Device Managers
- Medical Directors
- Nurse Directors
- Trust Pharmacy Managers
- Diabetes Special Nurses
- Diabetes Clinics
- Medical, Nursing and Care Staff
- Endocrinologists
- General Medical Practitioners
- Community Pharmacists
- Social Care and Community Care Staff
- District Nurses
- Residential and Nursing Homes
- Private Clinics
- Hospices

Boards/Trusts should ensure that if appropriate, this information is passed to all persons having the responsibility for the premises registered under "THE REGISTERED HOMES (NI) ORDER 1992.

IMMEDIATE ACTION

1. Healthcare professionals should ensure that all known HumaPen Ergo insulin pen users under their care have checked the insulin cartridge holder.
 - If the insulin cartridge holder is **clear**, then **no further action is required**.
 - If the insulin cartridge holder is **blue**, it should be **replaced** with a new **clear** insulin cartridge holder.
2. Users can obtain new clear insulin cartridge holders from the manufacturer via the Customer Response Centre (Freephone 0800-085-3847). New insulin cartridge holders have already been made available to Community Pharmacists, Diabetes Clinics and dispensing GPs by Eli Lilly and Company Limited.
3. HumaPen Ergo pens fitted with the blue insulin cartridge holders were not distributed by Lilly after October 2000.

ADVICE

NOTICE

BACKGROUND

NIAIC has been informed that the Medical Devices Agency (MDA) and Eli Lilly and Company Limited have received reports of the breakage of both engagement tabs on the blue insulin cartridge holders for the HumaPen Ergo insulin injection pen. Some of these reports of engagement tab breakages have been associated with the delivery of insufficient insulin. Some users have experienced loss of blood sugar control.

The breakage can usually be identified by the user, prior to injection, when the pen is primed in accordance with the manufacturer's instructions and normal Diabetes Clinic training practice. Users are normally aware that if they use a pen that did not prime they may receive an insufficient amount of insulin.

As a result of the reports, Eli Lilly and Company Limited have made design changes to the HumaPen Ergo insulin cartridge holder. The original blue insulin cartridge holder has been replaced with a new clear insulin cartridge holder. The design change appears to have resolved the issue as we have not received any reports of this type of problem with the new design.

The blue insulin cartridge holder was only fitted to HumaPen Ergo pens distributed between October 1998 and October 2000.

Eli Lilly and Company Limited estimate that approximately 250,000 HumaPen Ergo pens are in use in the UK and a replacement programme was initiated in October 2000. The new insulin cartridge holders or pens were made available to Community Pharmacists, Diabetes Clinics, dispensing GPs and direct from the manufacturer. Awareness of the programme was raised by direct mailing to healthcare professionals, distribution of leaflets and posters and the inclusion of information in professional journals and 'Balance' (the magazine of Diabetes UK).

The replacement programme has relied on reaching users directly when they read 'Balance' or via healthcare professionals when they collect their supply of insulin or visit Diabetes Clinics. However it is estimated that 13% of current HumaPen Ergo users (approximately 15,000 people) are still using HumaPen Ergos with the original design insulin cartridge holder.

This Advice Notice is intended to support the actions taken by Eli Lilly and Company Limited by:

- reminding healthcare professionals of the need to replace the HumaPen Ergo blue insulin cartridge holders and the replacement programme; and
- advising healthcare professionals of the national advertising campaign for this replacement programme planned by Eli Lilly for the week commencing 17th June 2002.

ENQUIRIES

Enquiries to the manufacturer should be addressed to:

Eli Lilly and Company Limited – Customer Response Centre, Freephone 0800-085-3847

Enquires to the NIAIC should quote the reference number AN (NI) 2002/06

and be addressed to: Northern Ireland Adverse Incident Centre (NIAIC), Health Estates, Estate Policy Directorate, Stoney Road, Dundonald, Belfast BT16 1US, Tel:02890523714 Fax: 02890523900, Email: NIAIC@dhsspsni.gov.uk

Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in Safety Notice SN (NI) 2002/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety
Áisíneacht Feidhmeannach don Roinn Sláinte, Serbhíslí Sóisialta agus Sábháilteacht Phoiblí*



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