



Department of

**Health, Social Services
and Public Safety**

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AN ROINN

**Sláinte, Seirbhísí Sóisialta
agus Sábháilteachta Poiblí**

MÄNNYSTRIE O

**Poustie, Resydènter Heisin
an Fowk Siccar**

From The Chief Pharmaceutical Officer
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Upper Newtownards Road
Belfast BT4 3SJ

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Facsimile: 028 90 522335

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For Action: Directors of Pharmaceutical Services of the Boards & CSA
Directors of Pharmaceutical Services of HSC Trusts
Regional Quality Improvement Authority

Our reference: PHC/14/08

Date: 29 September 2008

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

**JANSSEN-CILAG LTD
IONSYS IONTOPHORETIC TRANSDERMAL SYSTEM
FENTANYL 40 MCG PER DOSE
EU/1/05/326/001**

Janssen-Cilag Ltd are recalling all Ionsys transdermal system stock, irrespective of batch number, to patient level. Some units of one batch of the transdermal system have been found to self-activate which has the potential to cause overdose.

Medical advice is that the device should be removed from patients immediately, alternative analgesia provided and patients monitored appropriately. Physicians and nursing staff in wards and ITUs should be informed so symptoms of toxicity may be promptly detected.

Medical information can be obtained from Janssen-Cilag Ltd, Medical Information Department on 0800 0323013.

All unused stock of Ionsys should be quarantined and returned for credit via the original supplier. For returns and credit enquiries, please contact Janssen-Cilag Ltd on 01494 567400.

No other Fentanyl products from Janssen-Cilag are affected and these may continue to be used.

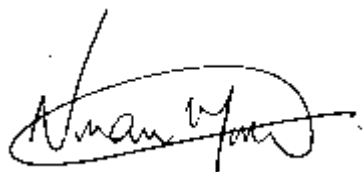
HSC Trust hospitals, hospices and independent clinics contacts were informed of this issue by the emergency telephone cascade on Sunday 28 September. Contacts were informed that further written details would follow.

All recipients are requested to cascade this information immediately even though the majority of this product is expected to be used post-operatively in hospitals.

Area Boards/RQIA should bring this information to the attention of private hospitals/clinics registered with them, Out of Hours Centres and any other relevant care facilities.

The Central Services Agency is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners **directly**.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Norman Morrow', written over a horizontal line.

DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:

CMO
CNO
CDO
CISSI
SMO
Director, Health Estates
Public Health Branch
DHSSPS, Library
Extended nurse prescribers

Regional Medicines and Poisons Information Service
Regional Director of Supplies
RPLS
Pharmaceutical Society of NI
Senior Prison Pharmacist
Prison Service, Dundonald House
Nursing Officer, Health Estates
Medical Officer, Castle Buildings
Regional Procurement Pharmacist
NICPPET