



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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For Action: Assistant Director Pharmacy and Medicines Management
HSC Board & BSO
Heads of Pharmacy & Medicines Management of HSC Trusts
Regional Quality Improvement Authority

Our Ref: PHC/9/11

Date: 14 March 2011

DRUG ALERT MEDICINES RECALL

Dear Healthcare Professional

Sanofi-aventis

**Ditropan Elixir 2.5mg/5ml, 150ml
(Oxybutynin)**

PL 04425/0286, PL 11723/0316

Please replace the Drug Alert issued on 10th March 2011 with this revised document.

Sanofi-aventis have informed us that, due to a change of ownership in 2009, there is unexpired product in the supply chain with the PL no. 11723/0316. The company apologises for any additional inconvenience this may cause.

Sanofi-aventis is recalling all unexpired stock of the above product as a precaution due to the detection of low levels of non-pathogenic yeasts in some samples during routine stability testing. No complaints associated with microbial contamination have been received by the company.

We understand that the product is likely to be unavailable for up to 24 months as a result of this recall. Tablet presentations of the product will continue to be available, however.

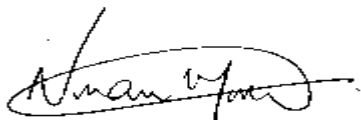
Pharmacists are asked to quarantine all unexpired stocks of the product and return them to the original wholesaler for credit. For further stock enquiries, please contact sanofi-aventis Customer Services on 0800 854 430.

For medical information enquiries, please contact Sanofi-aventis medical Information on 0800 281 973.

HSC Board/RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly.

Yours sincerely



DR NORMAN MORROW
Chief Pharmaceutical Officer

For information:

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

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