



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

Our reference: PHC/2/09

Date: 16 January 2009

DRUG ALERT

CAUTION IN USE

Dear Healthcare Professional

TARIVID 200 AND 400mg Tablets PL04425/0216 & 0217 Ofloxacin

Sanofi-aventis have informed the MHRA that there is an error in the patient information leaflet (PIL) supplied in most packs of Tarivid 200mg and 400mg Tablets distributed since 2 January 2009. The error is in respect of the tablet descriptions which have been transposed.

In all cases the markings on the tablets themselves are correct with the 200mg tablet actually marked with 'MXI' and the 400mg tablet actually marked with 'MXL'.

We understand that most, **but not all** packs contain incorrect PILs stating the following incorrect information:

Tarivid 200mg tablets are oblong yellow tablets. They are marked on each face with 'MXL' on one side of the score-line and the Hoechst logo on the other.

Tarivid 400mg tablets are oblong yellow tablets. They are marked on each face with 'MXI' on one side of the score-line and the Hoechst logo on the other.

To avoid stock disruption distribution of the stock has not ceased and Sanofi-aventis have stated that stock should not be returned for credit.

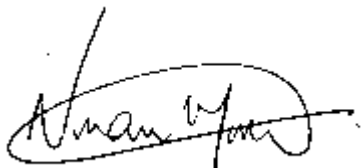
Most future deliveries of packs will continue to display this error until correct leaflets are available. Sanofi-aventis are trying to resolve this issue as rapidly as possible but we have been informed that full resolution of the problem is not expected before May 2009.

For further enquiries, please telephone Sanofi-aventis Medical Information on 01483505515.

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