SCOTTISH EXECUTIVE

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Our ref: PLW/3/7
Date: 29 May 2007

IMMEDIATE MESSAGE TO:

1. Specialists in Pharmaceutical Public Health
2. Chief Pharmacists, NHS Boards
3. Hospital Pharmacy Managers
4. Chief Executives NHS Boards

Dear Healthcare Professional**,**

DRUG ALERT NO 7: CLASS 1

Please find attached class 1 drug alert from the Medicines and Healthcare Products Regulatory Agency (MHRA) for onward transmission (see list below).

1. Please could Specialists in Pharmaceutical Public Health/Directors of Pharmacy forward this alert to:-

- Community Pharmacists
- Chief Pharmacists to forward on to Medicines Information Pharmacists

2. Please could Directors of Public Health forward the message on to:-

- General Practitioners
- Dispensing Doctors
- Chief Executives, NHS Boards

Thank you for your co-operation.

Yours sincerely

LESLIE SMITH
Pharmacy Division

* NB: Drug alerts have the following classifications:
1. Action now (including out-of-hours); 2. Action within 48 hours; 3. Action within 5 days;
4. Caution in use

Class 1 Drug Alert (action now - including out of hours): Counterfeit parallel distributed product - Plavix Tablets 75mg Film Coated Tablets (Clopidogrel)

DRUG ALERT

Class 1 medicines recall
Action now - including out of hours
Pharmacy level recall

25 May 2007 EL(07)A/07 Our ref: MDR 36-05/07

Document details:

Type: Drug Alert

Series No: EL(07)A/07

Audience: Healthcare professionals

Published:

Format: Electronic and paper

Size: A4

Pages: 3

Price: Free

ISBN/ISSN:

Author:

sanofi - aventis, Bristol Myers Squibb
Plavix Tablets 75 mg Film Coated Tablets
Clopidogrel
EU/1/98/069/001a - 007b

The MHRA in conjunction with the EMEA, with assistance from sanofi – aventis and Bristol Myers Squibb, are recalling any parallel distributed stock of Lots 3098 and 6Y098 (and lot variants) of Clopidogrel tablets 75 mg branded as Plavix following the discovery of counterfeit tablets in the legitimate supply chain. Please read the comments below about lot number variants used in the parallel distribution trade.

This counterfeit material was supplied in French livery via parallel distributors into the UK supply chain. Counterfeit product may be present in the UK supply chain alongside genuine manufactured product. Stock presenting a patient risk may be present as French livery

cartons with an overlabel applied by a parallel distributor or may have been recartoned into an English carton by the parallel distribution repacking process.
The above lots are genuine sanofi - aventis and Bristol Myers Squibb lot numbers for which the original unchanged lots were supplied to France in French livery.
Please note that sanofi - aventis and Bristol Myers Squibb routinely supply stock to the UK market which is not parallel distributed and is in UK branded livery. This stock is not affected. None of this stock has the above lot numbers or variants.
We have limited information about this problem and understand the EMEA has allowed in excess of 30 UK parallel distributors to supply this product.
Please be aware of the following issues concerning lot numbers:

1. Parallel distribution companies may have added a prefix or suffix to the lot number, such as 6Y098/1 to differentiate different packing runs. These lot number variants are included in the scope of the recall.

2. Parallel distribution companies may occasionally use a completely different lot number on the carton. **If the lot number on the carton is not in the format of one of the quoted batch numbers with or without a suffix or prefix, recipients are advised to contact the parallel distributor listed on the carton for clarification**. We intend to provide updated data if we receive additional information.

Actions Required
Recipients are requested to quarantine the identified lot numbers (3098 and 6Y098 (plus lot variants) and return to sanofi-aventis at Chapeltown Distribution Centre, 51 Cart Road, Chapeltown, Sheffield, South Yorkshire, S35 2PF for examination and suggest you keep full details of any returns.
During normal working hours, please telephone Customer Services (0800 854430), to make arrangements for return, or Medical Information (01483 554919), for medical enquiries. Emergency out of hours number is 01483 505515.
The issue of reimbursement should be discussed with your original supplier (not sanofi-aventis or Bristol Myers Squibb) and we suggest you keep full records.
Please do not return stock to your original supplier but contact sanofi - aventis Customer Services, who will organise collection. Your cooperation is requested in this matter as it will provide useful information about the origins and scope of the problem.
Additional information is available in the Q&As sheet attached.
Primary Care Trusts are asked to bring this information to the attention of Community Pharmacists, GPs and professionals with an interest in cardiovascular medicine by copy of this letter.

Yours faithfully

Ian Holloway
MHRA DMRC Manager

MHRA Distribution (further recipients by cascade): Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

Q&As

Why has a Class 1 Drug Alert been issued in this case?

Initial tests show that samples only contain about 70 - 80% of the labelled active ingredient. In addition, a counterfeit is likely to show a different bioavailability profile and may contain harmful degradants. Work is ongoing to obtain more information but in the interim we consider a recall is needed to minimise patient risk.

Why are both French cartons and some in English livery used?

In some cases the parallel distributor buys the product in small cartons and applies their own label. In other cases the distributor buys the product in large cartons and packs down into smaller amounts in their own carton.

Why can you not be more specific about the lot numbers used?

It is the decision of the parallel distribution company whether they use a prefix, suffix or completely different lot number. We expect that most will use a prefix or suffix but cannot rule out the use of a completely different number on the carton. We believe that waiting for a full answer from over 30 companies would provide an unacceptable delay to the Drug Alert.

Why does the licence number have a suffix e.g. "a"?

This indicates that the product should be packaged in PVC blisters. A "b" suffix indicates Aluminium form packs.

Why have you requested that all stock goes to sanofi – aventis for examination?

We have requested the assistance of sanofi-aventis and Bristol Myers Squibb to effect an efficient recall. Although there are visual differences between genuine and counterfeit parallel distributed stock, some differences are subtle. In addition, we need to obtain as much information as possible about this problem.

What is the difference between parallel distribution and parallel imports?

Parallel traded products are often sold at lower prices in the EU and are allowed to be imported and relabelled for sale in the UK. Parallel distributed products have a marketing authorisation issued by the EMEA and parallel imported products have a marketing authorisation issued by the MHRA.
In both cases the repacking and relabelling are inspected by the MHRA but the importation and/or distribution takes place outside the original manufacturer's supply chain.

Are there any differences between the supply of these lots?

We have no evidence that these lots have differing distribution.