Healthcare Quality and Strategy Directorate
Pharmacy and Medicines Division

T: 0131-244 2528
E: irene.fazakerley@scotland.gov.scot

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Chief Pharmacists NHS Boards
3. Hospital Pharmacy Managers
4. Medical Directors NHS Boards
5. Chief Executives NHS Boards

10 November 2015

Dear Healthcare Professional,

DRUG ALERT CLASS 4 no 11 2015 – Caution in use

Please see the attached drug alert for onward transmission as below.
Could all Directors of Pharmacy please forward this alert to:-

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

Please could Medical Directors forward this alert to:-

- General Practitioners
- Accident & Emergency Departments
- Directors of Public Health
- Relevant Clinics
- Chief Executives of NHS Board

Thank you for your co-operation.

Yours sincerely

IRENE FAZAKERLEY
Healthcare Quality and Strategy Directorate

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use
Distribute to Pharmacy and Hospital Ward Level

Date: 10 November 2015 EL(15)A/11 Our Ref: MDR 43-06/14

Dear Healthcare Professional,

Wockhardt UK Ltd

Amoxicillin Sodium 250mg Powder for Solution for Injection	**PL 29831/0010**
Amoxicillin Sodium 500mg Powder for Solution for Injection	**PL 29831/0012**
Amoxicillin Sodium 1g Powder for Solution for Injection	**PL 29831/0011**

Drug Alert number EL (14)A/09 in connection with the above products was issued on 09 July 2014. In this Alert, healthcare professionals treating neonates and infants (below 1 year old) were asked not to use Wockhardt Amoxicillin Powder for Solution for Injection (all strengths and all batches) in such patients. This was a precautionary measure following receipt of a number of reports of extravasation and injections site reactions.

Since a broader investigation of factors which may have caused this issue is now ongoing within the MHRA, the recommendations in EL (14)A/09 are still applicable. An update will be provided should the situation change. At this time, there is still no evidence to suggest that these products are defective.

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

Yours faithfully

Alison Bunce

Pharmaceutical Assessor
Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZ
Telephone +44 (0)20 3080 6574