Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Primary Care
Date:	19 June 2018
Reference:	CEM/CPhA/2018/9
Category:	Class 4: For Information
Title:	Drug Alert Class 4 (For Information): Kyowa Kirin, Bleo-Kyowa Powder For Solution For Injection (Bleomycin Sulfate), PI 16508/0046
What is this about: Full details are set out below.	
Why has it been sent:	For your information and to pass on to Colleagues

Issue:
Full details of the drug alert are included in the attached PDF file. Please forward to listed recipients. This information is also published on the MHRA website https://www.gov.uk/drug-device-alerts

Appendix 1

To: NHS Wales Shared Services Partnership to forward to:

All General practitioners - please ensure this message is seen by all practice nurses and non-principals working in your practice and retain a copy in your 'locum information pack'.
All Community Pharmacists
Deputising services
HB Chief Pharmacists
HB Prescribing Advisers
Independent/Private clinics and Hospitals and Hospices throughout Wales

To: Chief Executives of Health Boards

To: Medical Directors of Health Boards

To: Nurse Directors Health Boards

To: Directors of Public Health

To: Hospital Principals and Chief Pharmacists to action as per alert

cc: Public Health Wales
Consultants in Pharmaceutical Public Health
Chief Executives, NHS Trusts
Principal Pharmacist Welsh Quality Control
Principal Pharmacist Continuing Care Services
Principal Pharmacist Welsh Medicines Information Centre
CSSIW
NHS Direct

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Background

In April 2017, reports of glass particles in a batch of Bleo-Medac Powder for Solution for Injection, 15,000 IU, resulted in recall in some European countries. No recall action was necessary in the UK as the affected batch had not been distributed in the UK.

The marketing authorisation holder continues to investigate the root cause of this quality defect. To maintain continuity of supply in the UK, the marketing authorisation holder will distribute new batches of Bleo-Kyowa that meet current specifications. However, while investigations continue, the MHRA recommends that healthcare professionals adopt the following precautionary measures during product reconstitution:

- Follow all the recommended steps for the preparation of Bleo-Kyowa in accordance with the Summary of Product Characteristics.
- Carefully inspect the reconstituted product under a bright light.
- If particulate or glass matter is visible after reconstitution, do not administer the product to patients. Please retain the vial, quarantined safely away from other stock and notify the marketing authorisation holder.
- If there is no visible particulate matter after reconstitution, **the use of a standard 5-micron (5 µm) filter needle to withdraw the reconstituted product from the vial prior to administration is recommended** as glass particles may be difficult to see.

Company contact details

If you have any questions about this letter or any other enquiry, please contact Kyowa Kirin Medical Information:

- Tel: +44 (0)1896 664000
- Email: medinfo@kyowakirin.com

Recipients of this Drug Alert should bring it to the attention of all relevant contacts involved with the supply and administration of chemotherapy, including: hospital pharmacists; hospital clinicians; ward staff; chemotherapy unit staff; nursing staff and clinic staff by copy of this letter. In addition, the relevant Healthcare Professionals should be informed where the product is being used in a domiciliary setting. Local area teams are asked to forward this to relevant clinics and hospital pharmacy departments.

Yours faithfully

Defective Medicines Report Centre
151 Buckingham Palace Road
London
SW1W 9SZTelephone +44 (0)20 3080 6574

Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

DRUG ALERT

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Hospital Pharmacy, Ward, Chemotherapy Unit and Clinic Level

Date: 19th June 2018 EL (18) A/09 Our Ref: MDR 147-09/17

Dear Healthcare Professional,

Kyowa Kirin

Bleo-Kyowa®, Powder for Solution for Injection, 15,000 IU (Bleomycin sulfate)	PL 16508/0046

Batch Number	Expiry Date	Pack Size	First Distributed
Y7B290	Oct 2020	10	Jun 2018

Brief description of the problem

- In April 2017, glass particles were detected in a batch of Bleo-Medac (bleomycin sulfate) from the same manufacturer.

Actions for healthcare professionals

- While investigations are ongoing, additional measures should be adopted, as follows:
  - Follow all the recommended steps for the preparation of Bleo-Kyowa in accordance with the Summary of Product Characteristics.
  - Carefully inspect the reconstituted product under a bright light.
  - If particulate or glass matter is visible after reconstitution, do not administer the product to patients. Please retain the vial, quarantined safely away from other stock and notify the marketing authorisation holder (details overleaf).
  - If there is no visible particulate matter after reconstitution, **the use of a standard 5-micron (5 µm) filter needle to withdraw the reconstituted product from the vial prior to administration is recommended** as glass particles may be difficult to see.