Public Health Link Tom the Chief Medical Officer for Wales

Distribution:	As Appendix 2	
From:	Chief Pharmaceutical Officer, Andrew Evans	
Date:	9 April 2019	
Reference:	CEM/CPhA/2019/9	
Category:	Class 4 - For Information	
Title:	DRUG ALERT CLASS 4, FOR INFORMATION, MARTINDALE PHARMACEUTICALS LIMITED - CHLORAMPHENICOL 0.5% W/V ANTIBIOTIC EYE DROPS	
For Action by:		

Dispensing Doctor General Practitioners only – Ensure all dispensary staff see this alert and ensure a copy is placed in the locum file

Community Pharmacists

For Information:	See Annex 2 – Distribution List
What is this about:	Full details are set out below.
Why has it been sent:	For your information, action and to pass on to relevant colleagues.

Issue:

There are two issues with all unexpired batches of Martindale Pharmaceuticals Ltd - Chloramphenicol 0.5% W/V Antibiotic Eye Drops, PL 00156/0109, legal status 'P':

- The Braille is missing from the carton
- Packs contain the Patient Information Leaflet for the product with legal status 'POM'

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

Please do not cascade this alert to GPs other than dispensing GPs

Appendix 1

To: Chief Executives of Health Boards and NHS Trusts

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

To: NHS Wales Shared Services Partnership to forward to:

Dispensing Doctor General Practitioners only – Ensure all dispensary staff see and ensure a copy is placed in locum file

Community Pharmacists

HB Prescribing Advisers

Independent/Private clinics and Hospitals and Hospices throughout Wales





DRUG ALERT CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Distribute to Pharmacy Level

Date: 09 April 2019

EL (19)A/09

Our Ref: MDR 105-03/19

Dear Healthcare Professional.

Martindale Pharmaceuticals Limited

Chloramphenicol 0.5% W/V Antibiotic Eye Drops

PL 00156/0109

Martindale Pharmaceuticals has informed us of two issues with all unexpired batches of the above product, PL 00156/0109, legal status 'P'. The batch numbers are tabulated below:

<u>1810248</u>	<u>1901208</u>
<u>1811060</u>	<u>1901756</u>
<u>1811129</u>	1901757
1811249	<u>1901759</u>
1812309	1901854
<u>1812310</u>	<u>1902375</u>
<u>1812583</u>	1902389
<u>1901163</u>	<u>1902418</u>
1901164	1902601

Brief description of the problem

- The Braille is missing from the carton
- Packs contain the Patient Information Leaflet (PIL) for the product with legal status 'POM'.

Advice for healthcare professionals

In order to maintain supply, the affected batches are not being recalled.

The content of the PIL for the 'P' version is similar to that for the 'POM' version but there are some differences in the way the information is expressed. The correct PIL for the 'P' product can be downloaded via the following link:

https://www.medicines.org.uk/emc/product/9662/pil





Further Information

For any enquiries please contact Martindale / Ethypharm Customer Services, email <u>Licensed@ethypharm.com</u>

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter. NHS Regional Teams are asked to forward this to relevant clinics, community pharmacists and dispensing General Practitioners for information.

Yours faithfully

Defective Medicines Report Centre 10 South Colonnade Canary Wharf London E14 4PU Telephone +44 (0)20 3080 6574