

Public Health Link

From the Chief Medical Officer for Wales

Distribution:	As Appendix 1
From:	Andrew Evans, Directorate of Primary Care
Date:	21 June 2018
Reference:	CEM/CPhA/2018/10
Category:	Class 2 Action within 48 Hours)
Title:	Drug Alert Class 2 (Action Within 48 Hours): Children's Glycerine And Blackcurrant Cough Syrups Manufactured By Bell, Sons & Co, PI 03105/0066
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>

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

Community Optometrists

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



DRUG ALERT

CLASS 2 MEDICINES RECALL

Action Within 48 hours
Store, Pharmacy and Patient Level Recall

Date: 20 June 2018

EL (18) A/10

Our Ref: MDR 025-06/18

Dear Healthcare Professional,

Bell, Sons & Co.

PL 03105/0066

**Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour;
Bell's Healthcare Children's Dry Cough Glycerin 0.75g/5ml Syrup;
Morrisons Children's Dry Tickly Cough Glycerin 0.75g/5ml Oral Solution;
Numark Children's Dry Cough 0.75 g/5 ml Oral Solution;
Sainsbury's Children's Dry Cough 0.75g/5ml Syrup;
Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution;
Tesco Children's Dry Cough Syrup;
Wilko Tickly Cough 0.75g/5ml Oral Solution**

Brand & Product Description	Batch Number	D Code	Expiry Date	Pack Size	Date Released
Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour	274V1	D10-5120	01-Aug-2020	200 ml	27/09/2017
Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour	276V1	D10-5120	01-Oct-2020	200 ml	31/10/2017
Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour	278V1	D10-5120	01-Dec-2020	200 ml	02/01/2018
Asda Children's Dry Cough Syrup Glycerol Blackcurrant Flavour	283W1	D10-5120	01-Feb-2021	200 ml	19/02/2018
Bell's Healthcare Children's Dry Cough Glycerin 0.75g/5ml Syrup	280V3	D10-4315	01-Dec-2020	200 ml	04/01/2018
Morrisons Children's Dry Tickly Cough Glycerin 0.75g/5ml Oral Solution	282W1	D10-4325	01-Jan-2021	200 ml	30/01/2018
Numark Children's Dry Cough 0.75 g/5 ml Oral Solution	280V1	D10-4042	01-Dec-2020	200 ml	04/01/2018
Numark Children's Dry Cough 0.75 g/5 ml Oral Solution	288W1	D10-4042	01-Apr-2021	200 ml	27/04/2018
Sainsbury's Children's Dry Cough 0.75g/5ml Syrup	275V1	D10-0112	01-Sep-2020	200 ml	11/10/2017
Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution	280V2	D10-4695	01-Dec-2020	200 ml	04/01/2018



Brand & Product Description	Batch Number	D Code	Expiry Date	Pack Size	Date Released
Superdrug Children's Dry Tickly Cough Glycerin 0.75 g/5 ml Oral Solution	284W1	D10-4695	01-Mar-2021	200 ml	24/03/2018
Tesco Children's Dry Cough Syrup	277V1	D10-4271	01-Oct-2020	200 ml	31/10/2017
Tesco Children's Dry Cough Syrup	278V2	D10-4271	01-Dec-2020	200 ml	02/01/2018
Tesco Children's Dry Cough Syrup	281W1	D10-4271	01-Jan-2021	200 ml	30/01/2018
Wilko Tickly Cough 0.75g/5ml Oral Solution	275V2	D10-0310	01-Sep-2020	200 ml	11/10/2017

Brief description of the problem

Bell, Sons & Co is recalling 15 batches of the cough syrups listed above to patient-level as a precautionary measure due to a small number of reports of mould.

Advice for healthcare professionals

This Drug Alert is provided to healthcare professionals for information in case you receive any queries or ADRs relating to this issue.

This is a GSL product which has been sold from the retail shops Tesco, Asda, Wilkos, Sainsbury, Morrisons, Superdrug in the retailer's livery and one pharmacy chain (Numark, in Numark livery). It has also been supplied in Bell, Sons & Co livery to Poundstretcher and to a number of wholesalers. All retailers and wholesale customers have been notified and stock is already being recalled at store level. Patients are being asked to return bottles from the above batches to the shop they bought it from.

At the time of writing the MHRA has not received any reports of ADRs relating to this issue.

The mould has been identified as *Penicillium decumbens*, *Penicillium corylophilum* and *Penicillium brevicompactum*. Although these moulds may be inactivated in the stomach, there is a low potential risk of systemic infection in younger or immunocompromised children, causing symptoms of infection such as fever.

Penicillium brevicompactum and *Penicillium corylophilum* can produce mycotoxins. Reactions to these mycotoxins are rare in reported literature but there is a low risk they could induce non-specific toxin reactions that could include rashes, breathing difficulties and Gastro-Intestinal (GI) symptoms.

There is also a low risk of allergen-mediated disease either through inhalation or ingestion of *Penicillium* antigens to occur, causing allergic symptoms.

Grocery stores and Numark Pharmacies

Please quarantine and return all stock of this product to your supplier as per the instructions provided by Bell, Sons & Co. If your customers return stock to you, please return it to your supplier.



Wholesalers

Wholesalers are requested to return any remaining stock of this product to their original supplier for credit. Wholesalers who have received affected stock in Bell, Sons & Co livery (Batch 280V3) are listed below:

Wholesalers	
Aprino	Inspira
Awan	Lexon
B&J Supplies	Mister Discount
De Pharma	Rayburn
Durham	Roys Of Wroxham
Eclipse	Sangers Maidstone
Ethigen	Sangers NI
GD Cooper	Sigma
Heath & Pratt	Trago Mills
Homeware	

Patients and parents

It is important for people to check if they have any bottles from the batches of the blackcurrant cough syrups listed above. If they do, they should not take them or give them to others. They should return any bottles of the batches above to the shop or pharmacy they bought it from. The mould is not always visible so they should return any bottles of the cough syrups from the batches above even if they can't see the mould.

Whilst the possibility of a reaction to the mould is low, if parents are concerned their child has had a reaction they should speak to their GP, pharmacist or other healthcare professional.

As with any medicine, we strongly encourage anyone to report any suspected side effects to the MHRA via our Yellow Card Scheme.

Company contacts for further information

Medical information enquiries

Trevor Price
Pharmacovigilance Manager and Qualified Person for Pharmacovigilance (QPPV)
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Stock enquiries

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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 community pharmacists, hospital pharmacists and general practitioners for information.

Yours faithfully

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London, SW1W 9SZ, Telephone +44 (0)20 3080 6574**