Chief Medical Officer Directorate
Pharmacy and Medicines Division

Scottish Government
Riaghaltas na h-Alba
gov.scot

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

IMMEDIATE MESSAGE TO:

1. Directors of Pharmacy
2. Medical Directors NHS Boards

20 September 2023

Dear Healthcare Professional,

DRUG ALERT CLASS 3 DRUG ALERT 36 2023 – CLASS 3 MEDICINES RECALL – ACTION WITHIN 5 DAYS – CHIESI LTD – TRIMBOW 87/5/9MCG PRESSURISED INHALATION SOLUTION

Please see drug alert for onward transmission as below

Could all Directors of Pharmacy please forward this alert to:-

- Community Pharmacists
- Hospital Pharmacists
- Primary Care Pharmacists

Please could Medical Directors arrange to forward this alert on 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
Medicines Policy Team

Medicines & Healthcare products Regulatory Agency

MEDICINES RECALL

CLASS 3 MEDICINES RECALL

Action Within 5 Days
Pharmacy/Wholesaler Level Recall

Date: 20 September 2023 EL (23)A/36 Our Ref: MDR 148-09/23

Dear Healthcare Professional,

Chiesi Ltd.

Trimbow 87/5/9 mcg pressurised inhalation solution **PLGB 08829/0193**

SNOMED Code 34681611000001100

Batch No	Expiry Date	Pack Size	First Distributed
1165031	18/09/2024	1 container with 120 actuations	19/01/2023
1150215	25/12/2023	1 container with 120 actuations	27/04/2022

Active Pharmaceutical Ingredients: 87 micrograms beclometasone dipropionate, 5 micrograms formoterol fumarate dihydrate and 9 micrograms glycopyrronium

Brief description of the problem
Chiesi Ltd has informed the MHRA about a potential issue with the batches listed in this notification. As a precautionary measure, Chiesi Ltd is recalling the above batches at pharmacy and wholesale level, due to intermittent high results for the uniformity of delivered dose of formoterol fumarate observed during stability testing.

Advice for healthcare professionals
Stop supplying the above batch immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process.

Advice for patients
No further action is required by patients, these batches are being recalled at the pharmacy and wholesale level as a precautionary measure. Chiesi Ltd has investigated the issue and its medical assessment has shown that the impacted batches remain beneficial to patients. Patients should continue to take medicines from these batches as prescribed by your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the MHRA Yellow Card scheme.

Further Information
For medical information enquiries please contact medinfo.uk@chiesi.com or telephone 0161 488 5555.

Medicines & Healthcare products
Regulatory Agency

For stock control enquiries please contact customerservices.uk@chiesi.com or telephone 0161 488 5521.

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to 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
DMRC@mhra.gov.uk