Medicinal Products Recalls Vendor Guide

Ref. No.	GSLQMPR28
Version:	4.0
Effective Date:	28/09/2023
Last Updated:	25/09/2023
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Purpose

To provide the vendor with the actions needed in the event of a branded medicinal product recall.

Related Policies, Procedures and Documents

- GSLQMPR27 Medicinal Product Recalls Process Guide

Definitions

Recall (Red Alert) Action to remove a product from distribution and stores and customers for legal and quality reasons where the product presents a risk to health and/or safety of customer.
MHRA Medicines & Healthcare products Regulatory Agency
MEDPAN Medicinal Product Action Notification (transparent document that triggers initiation)
CBS Co-op Business Services
POS Point of Sale
GDP Good Distribution Practice

Scope

This applies to medicinal product recalls only. For non-medicinal product recalls and withdrawals (including Medical Devices.) Please refer to the Product Recall and Withdrawals Vendor Process Guide.

Procedure

Please only notify us when you are decided on the action you need to take and have the full details of the product and all expiry dates and batch codes affected. To maximise the effectiveness of the recall and to minimise disruption please ensure that all affected products, batch codes and expiry dates are identified before notifying us. As the brand owner you must provide us with sufficient and accurate information and instruct us of the actions to take. When you complete Section 1 the MEDPAN Form you will be required to confirm the quantity of affected stock supplied to the Co-op.

To comply to Good Distribution Practice (GDP) medicinal product recalls will be categorised according to the MHRA classifications displayed in the table below: -

MHRA Classification	Timescale to notify our customers	In Hours Recall Action	Out of Hours Recall Action
National Patient Safety Alert (=Class 1 Medicines Recall)	Immediate	Yes	Yes
Class 2 Medicines Recall	Action within 48 hours	Yes	No
Class 3 Medicines Recall	Action within 5 days	Yes	No
Class 4 Medicines Notification	As stated in the notification	No	No

The Co-op Medicinal Product Recall Process only applies to National Patient Safety Alerts (Class 1 recalls), or Class 2 or 3 medicines recalls.

* Class 4 Medicines Notifications

Class 4 medicines notifications are issued when there is negligible threat to patients or no serious defect likely to impair product use or efficacy and therefore do not initiate a product recall. Class 4 medicines notifications detail "Caution in Use" requirements and are generally used for minor defects in packaging or other printed materials.

If medicinal products supplied to Co-op are subject to a Class 4 Medicines Notification, the Vendor must notify their Buyer and the Co-op's Responsible Person (RP) RP@coop.co.uk without delay. The Vendor may be contacted by the RP or Deputy RP to clarify whether any action required and to support the Co-op carrying out the actions specified in the medicines notification (for example – providing a POS notice to advise consumers of missing information in a patient information leaflet).

The MHRA have 4 levels of alert. The impact of the actions within the Co-op is detailed below: -

Level of alert	Impact within Co-op
Wholesaler	Prevent stock from entering the supply chain at the Co-op's licensed wholesale warehouse
Store	Remove stock from sale at stores supplied by the Co-op by way of wholesale distribution
Retailer	Remove stock from sale at **all** stores supplied by the Co-op
Patient	Remove stock from consumers who have purchased stock from all stores supplied by the Co-op

Initiate

To be in line with the CBS team's working hours, the terms 'In Hours' and 'Out of Hours' throughout this section relate to the following times:

	Monday to Friday*	Weekends*	Contact Number
In Hours (CBS)	07:30 / 19:00	08:00 / 16:00	03300 606 9490
Out of Hours (Retail Resilience and Response)	19:00 / 07:30	16:00 / 08:00	0843 290 6662

*Closed on Christmas Day

Branded

The Vendor is accountable for initiating a Branded recall. • If the product is being recalled at patient level, then a POS must be supplied.

In hours

• The Vendor should immediately call the CBS team on the appropriate contact number above to notify them that there is an incident.

• For medicinal product recalls the Vendor should download the 'Supplier Medicinal Product Action Notification' form (MEDPAN Form) from the Supplier Information Hub and complete Section 1. This includes product information and actions required.
• The MEDPAN Form should be downloaded from the Supplier Information Hub for each incident to ensure the correct version is being used.
• For National Patient Safety Alerts (Class 1 recalls) and Class 2 and 3 recalls the Vendor should send their completed MEDPAN Form and POS if required within 4 hours to the CBS Team on (GDL_ProductRecallNotifications@coop.co.uk) and mark the communication as 'URGENT'. They should also cc recall@nisaretail.com and their Co-op Buyer to inform them.
• Once received, CBS check Section 1 of the MEDPAN Form to ensure all fields have been completed by the Vendor and that product codes match to our internal records. The Vendor will be contacted if further clarification is required.
• When received, the Vendor should complete and return the Branded Medicinal Product Recall Vendor Mandate Form.

Out of Hours

• If there is a **National Patient Safety Alert (Class 1 Recall)** and it is **"out of hours"** the Vendor should immediately call the Retail Resilience & Response team on the appropriate contact number above to notify them that there is an incident.
• The Vendor should email Retail Resilience & Response Team immediately on Response@coop.co.uk with the following details for each product affected and mark the communication as 'URGENT':
o **NSL Code & Article No.**
o **Consumer Unit Barcode**
o **Product Title**
o **Unit Size/Weight**
• Expiry Date and Batch Code information is not required at this time since the emergency comms will advise stores to remove all stock of the affected product off sale. Further comms will be issued by the Co-op the next day with instructions to re-merchandise any unaffected batch codes and expiry dates.
• The Vendor is **not** required to complete and return a MEDPAN form "out of hours".
• The Vendor should send their completed MEDPAN Form and POS if required as soon as practical after 8am the next day but no later than 11am, to the CBS team (GDL_ProductRecallNotifications@coop.co.uk) and mark the communication as 'URGENT'. They should also cc recall@nisaretail.com and their Co-op Buyer to inform them.

• If there is a **Class 2 or 3 Recall** and it is **"out of hours"** the Vendor should wait until in hours the next day and follow the "in hours" process above.

Co-op Brand

• The Vendor must notify their Co-op Technical Manager (in hours) or their Lead Technical Manager (out of hours) of the issue and provide all of the necessary information to enable the Technical Manager to complete Section 1 of the MEDPAN Form.
• The Vendor is not responsible for completing the MEDPAN Form.

In hours

• The Technical Manager is accountable for initiating a Co-op Brand recall with your support.

Out of hours

• If there is a **National Patient Safety Alert (Class 1 Recall)** and it is **"out of hours"** the Vendor should notify the Lead Technical Manager immediately.
• The Vendor must phone the Retail Resilience & Response team on the appropriate contact number above to notify them that an incident is in flight.
• The Vendor emails Retail Resilience & Response Team Response@coop.co.uk and copies the Lead Technical Manager, Technical Manager and Buyer with the following details for each product affected and mark the communication as 'URGENT':
o NSL Code & Article No.
o Consumer Unit Barcode
o Product Title
o Unit Size/Weight
• Expiry Date and Batch Code information is not required at this time since the emergency comms will advise stores to remove all stock of the affected product off sale. Further comms will be issued by the Co-op the next day with instructions to re-merchandise any unaffected batch codes and expiry dates once a completed MEDPAN form has been received.
• The Lead Technical Manager is required to ensure that a Technical Manager is available to complete the MEDPAN form as a priority "in hours" on the next CBS working day.
• The Technical Manager is required to complete Section1 of the MEDPAN form "in hours" the next CBS working day.
• If there is a Class 2 or 3 Recall and it is "out of hours" the Vendor should wait until "in hours" the next day and notify the Technical Manager.

Uplift of Stock

• If the Vendor is required to uplift the stock from the Co-op, then once all the affected stock has been collated at our National Distribution Centre the Supply Chain Analyst will liaise with you to arrange collection of affected stock.

Invoicing

• The Co-op Finance Team will raise an invoice for costs arising from the recall.
• If there are any disputes relating to the invoice you will have has at least 30 days' notice to raise them with the Buyer.
• The Vendor will receive a separate invoice for costs arising from the recall from Nisa, if Nisa has purchased the affected products from the Co-op.

Version Control			
Version	**Author**	**Date**	**Changes**
1.0	Jane Marshall	21/07/2021	Original version introduced

2.0	Jane Marshall	09/08/2021	RSC team replaced by Retail Resilience & Response team
3.0	Gemma Vinter	31/08/2023	In hours contact number updated
4.0	Tanya Casey	26/09/2023	In hours contact number updated