

PRODUCT RECALL/WITHDRAWAL
(Suggested Allowance for Distributor Cost Recovery)
Green Paper

Index

Background.....	1
Objective.....	1
Rationale.....	1
Distributor Recall/Withdrawal Activities.....	2
Suggested Elements in Manufacturer Notification.....	2
Suggested Allowance for Distributor Cost Recovery.....	3
Suggested Reimbursement Formulas.....	3
Pharmacy Distributor Activity Check List.....	5
Pharmacy Distributor Activity Sheet.....	6
Suggested Allowance Worksheet.....	7
Product Recall Notice (English Version).....	8
Product Recall Notice (French Version).....	11
Glossary of Terms.....	14
Pharmacy Distributor Recall/Withdrawal Contact List.....	15
Self-distributing Retailer Contact List.....	15
Non-member Contact List.....	15

PRODUCT RECALL/WITHDRAWAL (Suggested Allowance for Distributor Cost Recovery) *Green Paper*

Background

Product recalls/withdrawals while infrequent or rare for an individual manufacturer, in totality occur often within the pharmaceutical industry (approximately 400 per year). The recalls/withdrawals referred to in this paper are health or safety related recalls/withdrawals.

A significant burden is placed on pharmacy distributors to arrange the recall/withdrawal activity. While compensation for the costs of such activities is expected and reasonable from the manufacturer involved, the formula for assessing these costs is often unclear. This results in non-value added costs being incurred by both pharmacy distributors and manufacturers in negotiating an acceptable formula. It also leads to tensions and disputes over what should be considered fair compensation.

Objective

CAPDM's objective in developing a suggested product recall/withdrawal procedure and formula is to offer an efficient and effective method by which manufacturers may recover products from both distributors and their customers.

While trading partners must independently determine their own policies, the adoption of this procedure is suggested in order to avoid the non-value added activities associated with negotiating compensation for recall/withdrawal processing.

A common format for communicating the recall/withdrawal and calculating the suggested allowance for distributor cost recovery should be in place.

Rationale

Costs of recall/withdrawal activities are related to labor and material costs associated with the physical handling of product, notification of customers, accounting and bookkeeping activities related to credits and deductions.

We need to establish a "value of service" for the distributor. The recall/withdrawal is very time consuming and requires immediate attention. This value needs to be determined and compensated for.

There is no relation between the cost of the activities involved in a recall and the total dollars or cost of product involved. The facts point to the need for a formula based on the number of transactions or quantity of product handled rather than the totals dollars or cost of product involved. This results in an activity based cost model as opposed to a percent based calculation.

Distributor Recall/Withdrawal Activities

Distributors act voluntarily and promptly in response to recall/withdrawal instructions from manufacturers or governmental agencies. The need for exact and immediate action is well recognized and should be compensated for. The distributor will perform the functions detailed on the "checklist" provided by the manufacturer.

When reimbursement to retail is requested by the manufacturer, the distributor will reimburse the retailer the actual acquisition cost (i.e. including part bottles and all up-charges or taxes if applicable). This could include performing third party credit processing.

Suggested Elements in Manufacturer Notification

Significant variance exists among manufacturer's notification for recalls/withdrawals, and they may be vague, incomplete and in general, confusing. This results in delay as a result of a need to confirm instructions or worse, inappropriate or incomplete action.

Including the suggested elements in a notice represents an opportunity for decreased costs and increased efficiency in processing product recalls/withdrawals.

Manufacturers should include the following elements in their recall/withdrawal notification to distributors:

1. Class of recall/withdrawal, i.e. Class I, II or III
2. Complete item description, including package size
3. DIN number of item
4. Lot number and expiry date of item
5. Date(s) the items were shipped to the distributor
6. Brief summary of product problem
7. Clear instructions for requests to notify customers and dispose of items, complete check list
8. Contact person, phone number and email address
9. Post on company website if possible
10. Possible end date to recall/withdrawal (if applicable)

In the event, a product that was initially announced as a withdrawal becomes a recall product, the manufacturer should notify the pharmacy distributor.

Suggested allowance for distributor cost recovery

The formula outlined below is suggested for all products and is not restricted to pharmaceuticals. It is intended to cover all recalls/withdrawals that may be:

1. Voluntary on the part of the manufacturer
2. Directed by the TPD
3. Replacement of existing merchandise with an improved product or new package design

The formula represents a suggested approach for calculating the cost of distributor activities in carrying out a manufacturer's notification.

It is:

1. Easy to communicate, understand and calculate
2. Applicable to all three levels of recalls/withdrawals/companies
3. Able to accommodate special requests by manufacturers
4. Applicable to large and small recalls/withdrawals/companies
5. Non-manipulative and verifiable
6. True over time

Suggested Reimbursement Formulas

Part A – Administration Costs

- A \$250.00 recall/withdrawal fee should be charged regardless of the size of recall. This covers the cost of opening the recall file, pulling sales data, and responding to the manufacturer. If more than one distribution centre is involved, an additional fee of \$100.00 per distribution centre is appropriate.

Part B - For Items retrieved from Distributor inventory

- Credit for the merchandise at the manufacturer current selling price to the pharmacy distributor, plus:
 - i. Reimbursement at the Average Invoice Line Handling Cost x 0.5 x the number of purchasing units pulled

Purchasing unit is defined as the multiple in which the distributor purchases the product. Published data indicate the average invoice line handling cost is a close proxy to the actual cost to return a unit of merchandise. Additionally, it is an easy to understand and readily verifiable number. Since the average invoice line handling cost is a measure of cost to deliver product to a customer, and in this case a distributor is only pulling stock from their own, not their customers' inventory, the proxy is cut in half – that is multiplied by $\frac{1}{2}$ (0.5). Distributors still incur cost by checking their stock regardless of whether any recalled product is found inventory.

Part C - For Items Retrieved from Customers' Inventory and handled by the Distributor

- Credit for the merchandise at the manufacturer's current selling price to the wholesaler, plus:
 - i. Upcharge paid by customer
 - ii. Reimbursement at the Average Invoice Line Handling Costs x the number of units pulled

This method follows the rationale outlined above with the full average invoice line handling cost applied because the merchandise is being processed from the customer's inventory. When the number of units per customer is excessive, it may be appropriate to negotiate the fee.

Part D - Communications to Customers

- Distributors notify their customers of a recall/withdrawal regardless of class. Notification is usually made by fax, phone, mail, letter with shipment or invoice message. Distributors should be compensated for the cost incurred in this notification according to the following:
 - i. For a Class 1 recall/withdrawal - Number of customers of distribution center x (4 x cost of letter postage). The rationale for compensating at 4 times the cost of postage is to cover the estimated cost of labor and materials (paper, envelopes, printer ink etc.) used in producing and mailing the notification. This would also cover the cost of the notification reconciliation that the distributors are required by health Canada.
 - ii. For a Class 2 & 3 recall/withdrawal - communication as instructed by the affected manufacturer, usually via tote or invoice. Cost of one letter postage would cover this activity.

Part E - Third Party Credit Notes

- Manufacturer can request the processing of third party credit note. The distributor should charge \$5.00 per credit note processed.

Part F - Shipping and/or Disposal

- Credit for the actual cost of shipping items back to manufacturer or cost of disposal, based on manufacturer's written instructions.

Manufacturers should compensate distributors for the cost of returning recalled product to the indicated location. If the manufacturer requests that the wholesaler dispose of the product, the disposal cost should be added to the transport cost and reimbursed. Additionally, manufacturers should provide "hold harmless in perpetuity" provisions to distributors when requesting that they dispose of recalled product.

Pharmacy Distributor Activity Check list

Manufacturer _____

Product Name _____

Create Recall/withdrawal File

- Notify Health Canada of initiated recall/withdrawal
- Physically check all stock (pick, overstock, returns, put away, and receiving area)
- Segregate affected inventory from all locations
- Create recalled item tags and post at affected locations
- Notify receiving/returned goods department to prevent restocking
- Adjustments to computer file (inventory adjustment, flag item)
- Phone/fax/mail/email communications with manufacturer during recall/withdrawal

Notification of Accounts

- Develop and produce recall/withdrawal notification materials – including a response form for retailers
- Check product sales to identify purchasing retailers and quantities
- Notification: phone, postage, fax, email notices including the response form
- Fill out applicable forms for controlled substance recalls/withdrawals
- Reconcile responses from retailers. Contact those retailers who have not responded.
- Preparation of any special return/pickup forms, stickers/stamps, and instructions
- Any special notification requested by manufacturer

Physical Return of Goods

- Shipping to DC or pickup by distributor delivery vehicles or carriers*
- Count and secure partials (varies by Manufacturer)*
- Issue credits/refunds for retailers*
- Processing of third party credit notes****
- QPIC check-off for controlled substances*
- DC receiving, processing, and recording*
- Segregation and storage of recalls/withdrawals from other returns*
- Restocking and adjusting inventory for affected returns*
- Provide Health Canada with summary of returned product from retail and wholesale respectively*

Disposition of recall/withdrawal returns

- Sort, count and assemble item by SKU and manufacturer*
- QPIC check-off for controlled substances*
- Track return shipping costs (as required)****
- Obtain disposal permits and certificate of destruction (as required)*
- Track disposal costs (as required) ****

Reimbursement and reorder

- Create debit note*
- Reordering, receiving, stock new inventory*

*** Costs over and above the AILHC

items included in the AILHC

“CAPDM assumes no liability for reliance on or use of this Pharmacy Distributor Activity Check List. It is a suggested protocol only.”

Pharmacy Distributor Activity Sheet

(on manufacturer letter head)

Recall/withdrawal _____
Manufacturer _____
Product _____
Lots _____
Recall/withdrawal Class _____

- Pull all stock from inventory
- Segregate and return to manufacturer
- Cease distribution of all lots
 only lots indicated above
- Process pharmacy returns current price (including up-charge)
until _____(date)
 Credits processed after the above date in the
amount of _____% pf current price (excluding up-charge)
- Return recall/withdrawal stock To manufacturer
 To third party
Specify _____

- Reimbursement Distributor to credit pharmacy (AAC)
 Manufacturer to credit Pharmacy

Additional Comments _____

Date: _____ Time: _____AM/PM

Contact Name: _____

Title _____

Signature: _____

"CAPDM assumes no liability for reliance on or use of this Pharmacy Distributor Activity Sheet. It is a suggested protocol only."

Suggested Allowance for Distributor cost recovery for Product Recall/Withdrawals Worksheet

Charge to:		From:			
Address:		Address:			
	Product Description	Size	Lot Number	Lot Number	Lot Number
Product #1					
Product #2					
Product #3					

PART A - Administration					
Administration Fee for opening recall/withdrawal file \$250.00					\$250.00
Distribution Centre (DC) Fee- for each additional DC involved in recall/withdrawal \$100.00 per DC					
Total PART A					\$

PART B - Distributor Inventory					
Item #	Product Description	Units Returned		Unit Cost	Extension
			X	\$	=
			X	\$	=
			X	\$	=
			X	\$	=
	Item #	Purchase Multiple Returned		Fee	Extension
			X	\$1.25	=
			X	\$1.25	=
			X	\$1.25	=
			X	\$1.25	=
Total PART B					\$

PART C - Customer Inventory					
Item #	Product Description	Units Returned		Unit Price**	Extension
			X	\$	=
			X	\$	=
			X	\$	=
			X	\$	=
Units returned x Unit Price including up-charge					
**Unit price includes up-charge	Item #	Units Returned		Fee	Extension
			X	\$2.50	=
			X	\$2.50	=
			X	\$2.50	=
			X	\$2.50	=
Total PART C					\$

PART D - Notification Costs					
	Customers Notified- see attached			Fee	Extension
			X		=
			X		=
Total PART D					\$

PART E - Third Party Credit Notes					
	Number of credit notes processed			Fee	Extension
			X	\$5.00	=
Total PART E					\$

PART F - Shipping and/or Disposal Costs					
Via	Carrier	Date			\$
Disposal by - as per agreement	Company	Date			\$
Total PART F					\$
Sub Total Amount Due (A+B+C+D+E+F)					\$
GST					\$

Debit Note/Invoice # = **TOTAL** = \$

URGENT PRODUCT RECALL NOTICE

ATTENTION: All Pharmacies and Distributors
(Depending on Level of Recall)

Date: _____

Manufacturer: _____

Product Description: _____

Product/ Strength	Size	DIN	UPC/GTIN	Lot#	Expiry Date	Date of 1 st Sale

Reason For Recall:

Class of Recall:

Level I – Public advisory to patient plus;	<input type="checkbox"/>
Level II – Advisory to pharmacies plus;	<input type="checkbox"/>
Level III – Advisory to distributors;	<input type="checkbox"/>
Level IV – Voluntary withdrawal	<input type="checkbox"/>

Special Instructions:

Note to Pharmacist:

Consumers and health care professionals are asked to report any suspected adverse events associated with the use of these products to *<Manufacturer>* or Health Canada using the following contact information:

Canadian Adverse Reaction Monitoring Program (CADRMP)
 Marketed Health Products Directorate
 HEALTH CANADA
 Address Locator:
 Ottawa, Ontario K1A 1B9
 Toll free phone: 1-866-234-2345
 Toll free fax: 1-866-678-6789
cadrmpp@hc-sc.gc.ca

**Return Procedure:
(Cont'd)**

Pharmacies:
All further distribution of the above lot numbers must cease. Please return all affected stock immediately marked as “**Recalled Material – Not for Use**” **via courier collect**. Please contact *<your courier>* and quote *<account #>* and request package pick up. Please send your return to the following address:

**Credit Policy and
Pharmacist
Compensation:**

All recalled stock will receive 100% credit based upon *<Manufacturer's>* current list price.
<Manufacturer> will compensate pharmacists directly involved in this recall with a professional fee of \$ *<X>* for each *<Product Name>* prescription returned and replaced. TO facilitate this process we ask that you complete the attached Recall Return Form and include it with your return. Please be advised that recalled stock and pharmacist claims for professional fees will be accepted by *<Manufacturer>* until *<Date: 30 days after notice sent>* .

Please note: Prior to returning any product to us, we ask that you remove any patient information from each returned prescription.

Should you require additional information concerning the return of affected stock, please contact *<Manufacturer>* Customer Service at *<Phone #>* .

**<PRODUCT NAME & STRENGTH>
RECALL RETURN FORM**

Store Name/Store #: _____ <Manufacturer> Direct Account #: _____

Address: _____ **OR**

_____ Distributor Name: _____

_____ Distributor Account: _____

Recall Claim # or Reference #: _____ Pharmacist's Name: _____

Date: _____ Telephone #: _____

PHARMACY ONLY				DISTRIBUTOR ONLY	
# of <Product> Units Returned by Patients	Professional Fee(s) @ \$ _____ for patient returns only	# of <Product> Units returned from your inventor	Format	# of <Product> Units Returned from your inventory	
			<Product Name & Strength>		
Total:	Total:	Total:		Total:	

**PLEASE INCLUDE THIS FORM WITH YOUR RECALLED PRODUCT RETURN BY
<Date: 30 days after notice sent out>**

Please contact <Manufacturer> Customer Service at <Phone #> , if you have any questions regarding the recall.

Return to: <Address>

URGENT

AVIS DE RETRAIT DE PRODUIT

ATTENTION : Toutes les pharmacies et tous les grossistes/distributeurs
(selon le niveau du retrait)

Date :

Fabricant :

Désignation du produit
:

Produit/concentration	Format	DIN	CUP	Numéro de lot	Date de péremption	Date de la première vente

Raison du retrait :

Classification du retrait :

Niveau I – Avis public à l'intention des patients plus :	<input type="checkbox"/>
Niveau II – Avis à l'intention des pharmacies plus;	<input type="checkbox"/>
Niveau III – Avis à l'intention des grossistes/distributeurs;	<input type="checkbox"/>
Niveau IV – Retrait volontaire	<input type="checkbox"/>

Instructions particulières :

Note à l'intention du pharmacien :

On demande aux consommateurs et aux professionnels de la santé de signaler tout effet indésirable présumé lié à l'utilisation de ces produits à *<Fabricant>* ou à Santé Canada, dont les coordonnées sont les suivantes :

Programme canadien de surveillance des effets indésirables des médicaments (PCSEIM)
 Direction des produits de santé commercialisés
 SANTÉ CANADA
 Indice de l'adresse :
 Ottawa (Ontario) K1A 1B9
 Ligne sans frais (téléphone) : 1 866 234-2345
 Ligne sans frais (télécopieur) : 1 866 678-6789
cadmp@hc-sc.gc.ca

Directives de retour :

Grossistes/distributeurs :
 Toute distribution des lots identifiés ci-dessus doit cesser. Veuillez retourner immédiatement tout stock touché avec la mention « **Produit retiré – Ne pas utiliser** » par messagerie en port dû. Veuillez communiquer avec *<votre service de messagerie>*, mentionner le compte *<numéro de compte>* et demander un ramassage de colis. Envoyez votre retour à l'adresse suivante :

**Directives de retour :
(suite)**

Pharmacies:

Toute distribution des lots identifiés ci-dessus doit cesser. Veuillez retourner immédiatement tout stock touché avec la mention « **Produit retiré – Ne pas utiliser** » **par messagerie en port dû**. Veuillez communiquer avec *<votre service de messagerie>* , mentionner le compte *<numéro de compte>* et demander un ramassage de colis. Envoyez votre retour à l'adresse suivante :

**Politique de crédit et
dédommagement au
pharmacien :**

Tous les stocks retirés seront entièrement crédités en fonction du prix courant de *<Fabricant>* . *<Fabricant>* dédommagera les pharmaciens directement touchés par ce retrait en leur versant des honoraires professionnels de *<X>* \$ pour chaque ordonnance de *<Nom du produit>* retournée et remplacée. Pour faciliter ce processus, nous vous demandons de remplir le formulaire de retour ci-joint et de l'annexer à la marchandise retournée. Veuillez noter que *<Fabricant>* acceptera les retours de marchandises et les réclamations d'honoraires professionnels jusqu'au *<Date : 30 jours suivant l'envoi de l'avis>* .

Nota : Avant de nous retourner un produit, nous vous demandons de retirer tout renseignement destiné au patient de chaque ordonnance retournée.

Si vous désirez obtenir de plus amples renseignements au sujet du retour des stocks touchés, veuillez communiquer avec le Service à la clientèle de *<Fabricant>* au *<Numéro de téléphone>* .

<NOM DU PRODUIT ET CONCENTRATION> FORMULAIRE DE RETOUR – RETRAIT DE PRODUIT

Nom et n° de la pharmacie : _____ N° de compte client <Fabricant> : _____
 Adresse : _____ OU
 _____ Nom du grossiste : _____
 _____ N° de compte du grossiste : _____

N° de référence ou de la demande de retrait : _____ Nom du pharmacien : _____
 Date : _____ N° de téléphone : _____

PHARMACIE SEULEMENT				GROSSISTE SEULEMENT
N ^{bre} d'unités de <Produit> retournées par vos patients	Honoraires professionnels de \$ (pour les retours de vos patients seulement)	N ^{bre} d'unités de <Produit> retournées en provenance de vos stocks	Format	N ^{bre} d'unités de <Produit> retournées en provenance de vos stocks
			<Nom du produit et concentration>	
Total :	Total :	Total :		Total :

**VEUILLEZ JOINDRE CE FORMULAIRE AUX PRODUITS ET RETOURNER LE TOUT
AVANT LE**
 <Date : 30 jours suivant l'envoi de l'avis>

Si vous avez des questions au sujet de cet avis de retrait, veuillez communiquer avec le Service à la clientèle de <Fabricant> au <Numéro de téléphone> .

Retourner à : <Adresse> _____

Product Recall/Withdrawal Glossary of Terms

Average Invoice Line Handling Cost (AILHC)

Is a measure of cost to deliver product to a customer i.e. pick, pack and ship. CAPDM has reviewed this cost with their membership and will do so annually. To see the items included in this cost, please consult the italic items on the Pharmacy Distributor Activity Checklist.

Current Selling Price

The current selling price is the price that the distributor would sell an item for today.

Customer

Refers to all store type locations that a distributor sells product to.

Distributor

The reference to "distributor" throughout the green paper refers to a traditional pharmacy distributor/wholesaler and a self-distributing retailer.

Recall/withdrawal

With respect to a product, other than a medical device, means a firm's removal from further sales or use, or correction, of a marketed product that violates legislation administered by the Health Protection Branch.

Purchasing Unit

A purchasing unit is the lowest purchase multiple in which the buyer acquires the stock. For example, if the buyer purchases the stock in multiples of 36 – however sells to the retail customer in singles, the purchase multiply would be 36

CAPDM Distributor members who have been involved in the development, support and have endorsed the green (position) paper are as follows:

Company	Name	Title	Telephone	Fax
AmerisourceBergen Canada	Susan Coleman	QA/QC Director	613-546-9201	800-567-6674
Kohl & Frisch Limited	Ken Rubin	Nat. Bus. Mgr. Pharma/RA	905-761-2391	905-660-0404
McKesson Canada	Heather Thullner	National Recall Coordinator	514-832-8192	514-832-8109
uniPHARM Wholesale Drugs Ltd	Stuart Ross	Buyer	604-276-5235	604-270-9728
UPE Group of Companies	Roger Irmen	Pharmaceutical Buyer	306-956-2108	306-244-0680

CAPDM Self-Distributing Retailers Members

Company	Name	Title	Telephone	Fax
The Jean Coutu Group (PJC)	Sandra Batista/Odette Poirier	Coordinator - Diabetes/Rx Inventory	450-646-9611	450-646-2991
London Drugs	Jim Rama	Pharmacy Operations Manager	604-272-7119	604-272-7157
Sobey's Pharmacy Group (including Lawton's)	Carolyn Brackett	Procurement Manager Pharmaceuticals	902-468-4637	902-468-3432
Shoppers Drug Mart	Esther Law	Pharmaceuticals Manager	416-493-1220 x. 5087	416-490-2858

Non-Member Contact List

Company	Name	Title	Telephone	Fax
Centre Distribution Racine Inc.	Rosaire Blouin/Julien Bernier	Director	418-661-9326	418-661-9326
Dispensaries Wholesale Ltd.	Barry Turner	Manager	780-426-1664	780-425-6721
Familiprix	Anik St-Helaere	Coordinator	418-847-5300 x. 2244	418-847-2619
Loblaws/Westfair	Caroline Sayer	Category Manager	905-459-2500 x. 6108	905-861-2608
McMahon Distributor Inc.	Sylvie Renaud/Richard Laforest	Buyers	514-356-4611 x. 4609	514-355-7472
Medical Pharmacies	Catherine Cahill	Warehouse Manager	905-420-7335	905-420-8571
Nu-Quest Distribution Inc.	Ed Ledrew	Pharmaceutical Consultant	709-745-8884	709-745-8288
Prairie Supply Co-op	Heather Russell	Executive Assistant	403-255-0091 x. 221	403-212-5054
Procurity Pharmacy Services	Jason Halick	Category Manager Pharma	204-631-3507 x. 3520	204-694-7278
Rep Pharm Inc.	Monique Faibish	Front Shop Manager	905-339-2000 x. 214	905-339-2286
Value Drug Mart	Dan Kratko	Purchaser	780-453-1701 x. 220	780-454-7720

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