



Year-End Product Availability

GREEN PAPER

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Green Paper

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The Year-End Issue

The CAPDM Board of Directors mandated its Customer Service Committee (CSC) to review factors that affect product availability at year-end and to develop industry guidelines to promote continuous availability of products. The CSC is composed of representatives from Rx brand and generic manufacturers, non-prescription drug manufacturers, pharmacy wholesalers and other industry representatives. The CSC considered the HDMA White Paper “Addressing the Year-End Issue – Assuring Product Supply”. The resulting Green Paper was published in September 2006.

Two and a half years later, a review of processes and practices by the CSC concluded that, while the situation has improved, there are still problems of product shortages. This update to the Green Paper incorporates revisions to improve the rigour of trading partners in ensuring that product availability is not compromised in the critical months of December and January.

The objective is to promote collaborative relationships among trading partners so that products are continuously available at the required volumes -- including in December and early January – to ensure that patient safety is not jeopardized, and so that in the case of public companies, revenue is accurately recognized in accordance with Sarbanes-Oxley and comparable Canadian legislation.

CAPDM recommends the following 10-point process:

1. Every September, pharmacy wholesalers and self-distributing pharmacy chains should contact manufacturers to remind them about the importance of continuity and sufficiency in year-end supply. This contact should be in writing; other means such as email and phone can be used in addition, depending on the wholesaler’s preference. This timing allows manufacturers time to be closed on days surrounding legal holidays, while still ensuring an adequate supply of inventory and an effective communication and distribution plan so that pharmacy wholesalers and self-distributing pharmacy chains have access to products in anticipation of the closure or in the event of an emergency. A reminder may have to be sent in October.
2. Each wholesaler and self-distributing pharmacy chain, in follow-up communications with manufacturer contact people, should ensure that appropriate personnel are acting on the reminder and should pro-actively ask each manufacturer contact person to notify their relevant trading partners of the plan, if they have not already done so (see #3 below).
3. Each manufacturer should alert their trading partners as to warehouse closings during the year-end holiday season, and when the first delivery is expected, by depot.
4. Each manufacturer should list the process and contacts for emergency orders when manufacturer warehouses are closed.

5. Pharmacy wholesalers and self distributing pharmacy chains should use all stock available to them including transfers from their internal depots, along with short-dated products when no other stock is available.
6. If a manufacturer's distribution facility is closed for an extended period of time (other than statutory holidays) and pharmacy wholesalers or self-distributing pharmacy chains are forced to carry more inventory, manufacturers should grant appropriate concessions or extension to payment terms to compensate for the cost of the extra inventory.
7. If a manufacturer is involved in temperature sensitive products (e.g. cold chain) with a set schedule to manage these sensitive products, they should allow for extra inventory since it may be required to meet the trading partner's year-end stock requirements as a result of the firm delivery schedule.
8. Each pharmacy wholesaler should contact their customers to assure them that a plan is in place for adequate product supply and to provide relevant supporting information such as closing and opening dates.
9. The relevant managers of each stakeholder company should raise awareness with senior executives (e.g. CEO, CFO, COO) regarding the impact of year-end closings on the pharmacy supply chain.
10. A related business practice is to prevent the possibility of a product shortage from occurring at all by each manufacturer instituting either a continuous year-end monitoring procedure or investment buying (see page 4). Manufacturers can also build preventative policies into a Manufacturer's Product Assurance Position Statement.

The recommendations are meant to help achieve 100% service levels throughout the supply chain. This goal requires collaboration and information sharing among trading partners as well as the implementation of programs within each company to improve operating efficiencies.

In summary, product shortages continue to occur often at year-end, causing wholesalers and self-distributing pharmacy chains to experience delays – sometimes extreme – in receiving completed orders. In some instances, delays are due to natural disasters or inclement weather. In other instances, financial reporting decisions and sales allocations made by manufacturers and less-than-efficient inventory management programs hinder the wholesalers' and self-distributing chains' ability to obtain product to meet demands of their mutual customers. Manufacturers who close or do not ship orders during any part of the holiday season (late November – early January) cause an unnecessary disruption of product flow in the pharmacy supply chain. Inefficient inventory management not only limits the ability to provide critical items to customers and patients, but it also affects profitability and may negatively influence relationships with trading partners. In the most egregious circumstances, if the shipping decisions reflect manipulation of revenue recognition, the completeness and accuracy of financial reporting might be jeopardized, and the effectiveness of internal controls called into

question, resulting in corporate compliance issues and concomitant risks to the companies and their management.

The pharmaceutical industry is expected to fill the ordering needs of the patient 100% of the time throughout the year. Working collaboratively with trading partners to establish inventory management processes that include a strategic purchasing plan is mutually beneficial to all members of the pharmacy supply chain and, most importantly, ensures product is continuously available to patients and consumers. Successful inventory management processes require frequent communication and collaborative sharing across the pharmacy supply chain and internally, as well.

Develop a Year-End Order Plan

To achieve an effective year-end order plan, trading partners should communicate and/or meet well in advance of year-end to plan for supply replenishment. Two-way communication and collaboration is paramount to the interests of their mutual customers and patients.

I. Customer Communications

- Initial communication needs to be established early (e.g. at least by September).
- Follow-up communication needs to reiterate the company's year-end commitment to ensure that product is available to Canadian patients.
- Discuss commitment to ensuring adequate supply of product directly with account contact.
- Create a calendar of events detailing the specifics of:
 - The manufacturer's holiday schedules. This calendar should be used/completed to determine the appropriate ordering schedule to each individual account.
 - Appropriate staff should discuss any available details regarding the expectations and ordering schedules of the account's largest purchasing customers; any questions should be clarified and resolved quickly.
 - Staff with account responsibility to the large indirect retail and institutional purchasing customers should provide a letter of commitment and should use/complete the calendar of events after discussing inventory stocking strategies.
 - Calendars should be completed and submitted to the supply chain planners no later than November 15. A calendar of direct purchasing accounts' order schedules should be shared with the appropriate departments such as Trade Relations, Customer Service, Finance, and Supply Chain/Logistics.

II. Monitoring Orders and Inventory Management Levels

- To ensure the fair and equitable allocation of product at year-end, especially when supply is limited, manufacturers should be provided with weekly access to inventory information at the wholesaler and self-distributing retailer levels. This transparency should be a necessary component of an inventory management agreement developed for the year-end process.

As a problem preventer, some manufacturers have instituted either a continuous or year-end monitoring procedure for trading partner orders to avoid either inventory shortages or investment buying. These procedures generally monitor what is defined as average weekly purchases by a pharmacy wholesaler/self-distributing retailer from the manufacturer. The algorithms employed by manufacturers utilize purchasing history for each trading partner. This history can vary from a 52-week moving average to as little as the past 90-day moving average. No matter what the length of history, a percentage factor is then applied to average weekly purchases to determine the level at which the manufacturer might start holding orders. These percentages vary by manufacturer depending upon their inventory situation.

Order Planning

<i>Consideration</i>	<i>Recommendation</i>	<i>Explanation</i>
Current Average Purchases	In determining a customer's average purchases, manufacturers should adopt a policy of using the past 90-day customer purchases together with purchase trends and the same quarterly sales period from the year prior.	Another factor that comes into play frequently is that even though a manufacturer utilizes the 90-day-average-purchases algorithm, there are times when unusual circumstances arise that need to be considered. The most common occurrences are losing or being awarded Hospitals/Institutions/Prime Vendor contracts and/or gaining or losing new retail chain accounts.
New Business	<p>Manufacturers should take into consideration the new business/planned customer promotions in calculating an average pharmacy distributor/self-distributing retailer order.</p> <p>Wholesalers/self distributing retailers should exchange information on changes in contracts that would significantly change product supply.</p> <p>Any manufacturer product availability issues during the 90-day calculation should also be considered.</p>	<p>At year-end, a number of manufacturers have plant shutdowns for the holidays ranging from a few days to a period of two weeks. This situation can create hardships for many pharmacy wholesalers/self-distributing retailers as they are required to remain open to satisfy patient demand from their retail customers. In the case of retail chains, if the wholesaler/self-distributing retailer cannot supply product, they can incur performance penalties.</p> <p>Although most manufacturers have a policy of providing customer service during any holiday shutdown, the shipment of products during a shutdown is not as common. Trading partners should establish emergency order procedures to ensure consistent supply of product.</p>
Seasonal Purchasing	<p>Manufacturers should adopt a policy of notifying the wholesaler/self-distributing retailer of their year-end closing schedule 90 days prior to the planned shutdown. They should also start the planning process of establishing sufficient inventory levels to ensure adequate supply. The adoption of these practices should allow most pharmacy wholesalers/self-distributing retailers to ensure they have adequate inventories or at least to make the case to the manufacturer that they may not be able to meet patient demand.</p> <p>Manufacturers should have emergency order procedures to prevent stock-out and ensure seamless supply for Canadian patients.</p>	

Closing Summary

Advocating for a continuous and seamless supply system throughout the year is a core strategic objective for CAPDM. The lack of available products during year-end is an issue that surfaces each year as a problem in the industry, leaving customers frustrated and concerned about not being able to get product to their patients. As an industry, year-end shortages cannot be tolerated, and everything within our means must be done to eliminate this possibility.

As another year-end approaches, industry strives to meet the goal of ensuring product is continually available. The guidelines and recommendations presented in this **Green Paper** are some ongoing steps that should be taken to resolve this issue.

**Sample Letter: from Manufacturer to Wholesalers/Self-Distributing Pharmacy Chains
(Initial Communication)**

IMPORTANT HOLIDAY REMINDER!!!!

Dear Trading Partner:

XYZ Pharmaceuticals understands the difficulty in providing products through the holiday season. For this reason, we want to provide you with the following 200X holiday schedule.

All XYZ Pharmaceutical offices will be closed from 5:00 p.m. **(date) through (date)**. However, to maximize the availability of our products, XYZ Pharmaceuticals has made arrangements for shipping during this period. All phone/fax/mail orders received by noon EST on **(date)** will be scheduled for delivery on or prior to **(date)**. (Electronic orders must be transmitted no later than 5:00 p.m. EST on **(date)** to schedule a December delivery.) To enable timely shipment of your orders, we must be notified if your receiving docks will be closed anytime between **(date)** and **(date)**.

XYZ Pharmaceuticals will resume normal business hours on **(date)**. All orders received during the holiday period will be shipped as soon as possible.

Emergency orders procedures for injectable products will remain in effect during the holiday period.

Please adjust your ordering procedures to assure adequate inventory during the holiday period.

Thank you for your assistance.

Sincerely,

[Name]
[Title]
[full contact info]

V. 200X Holiday Schedule	VI. Time/Date
Deadline for EDI orders to be delivered prior to 00/00/00 (Orders received after these times/dates will be delivered on 00/00/00)	5:00 p.m. EDT 00/00/00
Deadline for Phone/Fax/Mail orders to be delivered prior to 00/00/00 (Orders received after these times/dates will be delivered on 00/00/00)	Noon EDT 00/00/00
All XYZ Pharmaceutical offices closed	5:00 p.m. EDT 00/00/00
All XYZ Pharmaceutical offices re-open	8:00 p.m. EDT 00/00/00

**Sample Letter: from Wholesaler/Self-distributing Pharmacy Chain to Manufacturers
(Initial Communication)**

IMPORTANT HOLIDAY REMINDER!!!

Dear Valued Trading Partner:

Every December and early January brings challenges that affect our ability to service our mutual customers in a timely and cost-effective manner. Therefore, we wish to collaborate with your team to plan for year-end continuous availability of products in order to meet the needs of Canadian patients. To successfully handle year-end inventory ordering, we will share, if necessary, whatever data is needed with the manufacturing community to show that the inventory we need is to meet current needs of our customers.

{COMPANY NAME} understands the issues surrounding year-end closings. It is our request that we act together to ensure the supply chain is not disrupted in any manner during December and January. Strategic, mutually-agreed purchasing plans are critical to the success of meeting customers' demand requirements.

We request that your company not hold orders this coming year-end. Held orders result in extended lead-times, false demand, backlogs in receiving the first days of January, and very frustrated customers.

If you do elect to hold orders, please contact {COMPANY NAME} by {DATE} to discuss alternative purchasing strategies so that {COMPANY NAME} can maintain satisfactory inventory levels throughout the year-end period. If I have not heard from you by this date, I will contact you within X days to discuss your plans for shipping or not shipping during the year-end holiday period, our requirements for inventory levels by depot, and the possibility of extended payment terms in line with the number of additional days' inventory we may be required to carry if you elect to not ship during the holidays. Please forward this email to your Customer Service Manager, Sales Forecasting and Finance so they are aware of our intentions. Please note that if Finance deems it necessary, they should look to increase the credit limit for this period.

Thank you for your understanding and cooperation on this important matter for our mutual customers who will expect nothing less than high levels of service this year-end.

Sincerely,

[Name]
[Title]
[full contact info]

This document represents a suggested position for dealing with the year-end product availability issue as determined by CAPDM based on the input from the Customer Service Committee, key associations and CAPDM members. The Green Paper provides voluntary guidelines and procedures on the subject matter of this document. CAPDM encourages its members to consider these and adopt them into their everyday operations, where appropriate. Each member is, however, responsible for using his or her own judgment. In no event will CAPDM or its directors, employees, agents or advisors be liable for any direct, indirect, special or consequential damages resulting from the use of this information by any member or third party.