Understanding the Drivers of Expired Pharmaceutical Returns

HDMA
Healthcare Distribution Management Association

The Healthcare Distribution Management Association (HDMA) is the national association representing primary, full-service healthcare distributors. Each business day, the member companies of HDMA are responsible for ensuring that more than eight million prescription medicines and healthcare products are safely delivered to 145,000 pharmacies, hospitals, nursing homes, physician offices, clinics, government and other providers in all 50 states. This essential public health function is provided with tremendous efficiency, saving the nation's healthcare system nearly $32 billion each year. HDMA and its members are the vital link in the healthcare system, working daily to provide value, remove costs and develop innovative solutions to deliver care safely and effectively.

Recommendations in this report, *Understanding the Drivers of Expired Pharmaceutical Returns*, are intended to help distributors, manufacturers, healthcare providers and service providers identify opportunities to improve inventory management and ultimately reduce the volume of expired returns in the reverse supply chain. All stakeholders involved in the project have a shared vision to reduce total supply chain costs associated with unsaleable returned goods while preserving or improving the safety and security of the healthcare supply chain.

This report identifies several product-related and demand-related drivers of expired pharmaceutical returns. This report also contains examples of process improvements that may help companies address and reduce the quantity of expired products returned, as well as track their progress in making these improvements. Moving forward, the adoption of track-and-trace technologies may enable companies to have more control in managing inventory and ultimately limit the volume of expired pharmaceutical returns. A company may wish to consider using the information in this report in its own, individual business practices or in conjunction with its trading partners in order to reduce the quantity of returns.

This report and its associated project are key components of HDMA's vision and ongoing efforts to promote enhanced data sharing within the healthcare supply chain. These efforts are part of an overall strategy to advance best business practices and improve supply chain security and patient safety.

Understanding the Drivers
of Expired Pharmaceutical Returns

Reducing the Quantity of Expired Pharmaceuticals
in the Healthcare Supply Chain

Developed for the

HDMA
Healthcare Distribution Management Association

Returns Task Force

Prepared by

R2 Raftery Resource Network, Inc.

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OVERVIEW

This report describes the major causes that contribute to unsaleable pharmaceutical returns, actions an individual company may take to decrease its unsaleable returns and ways to evaluate progress in decreasing unsaleable returns. The report covers unsaleable pharmaceutical returns which are expired, about to expire or will eventually expire before they can be sold. The report explores two points in the supply chain – the pharmacy and the warehouse – to determine where and why pharmaceutical returns typically occur.

Understanding the Drivers of Expired Pharmaceuticals Returns includes:

- Recommendations that may help a company address the causes of and reduce expired pharmaceutical returns.
- An evaluation tool that a distributor or manufacturer could use to determine what opportunities a company has to improve and to measure the progress it has made.

Relevant information from previous HDMA publications is included in this report, as well.

This report describes factors and practices within the healthcare supply chain that may increase the amount of unsaleable pharmaceuticals, i.e., the drivers of expired pharmaceutical returns. It also contains information about what an individual company, or a company in conjunction with its trading partner, might wish to do in order to reduce expired returns. In this report, the term "distributor" refers to wholesalers, but may also include self-distributing retailers and any other company that processes and/or stores pharmaceutical products, such as mail order fulfillment centers.

Each company must develop its own, individual returns management practices, and must individually choose how to deal and contract with its industry partners, suppliers and customers.

HDMA RETURNS TASK FORCE

This report was developed by the HDMA Returns Task Force (RTF), whose mission is to identify best practices and develop recommendations that address key issues and improve processes and technology efficiencies for returned and/or unsaleable healthcare products. Raftery Resource Network, Inc. (R2N), an independent consulting firm with subject matter expertise, facilitated the report.

The RTF is comprised of representatives from major segments of the healthcare industry, including manufacturers and distributors of healthcare products and service providers to the healthcare supply chain. For this report, the RTF has expanded the scope of its work effort to include healthcare providers, as well. Many members of the RTF, along with representatives of retail and institutional pharmacies, provided subject matter expertise for this report.

PROJECT TEAM

HDMA recognizes the following individuals and companies who invested their time and expertise as project team members to assist in developing this report through participation in facilitated focus group discussions, qualitative interviews and collective review.

Ms. Joanne Cooper, Manager, Corporate Relations, AmeriCares
Mr. Michael Kody, Vice President, Supply Chain Strategy, AmerisourceBergen Drug Company
Ms. Margaret Kinder, Senior Returns Analyst, Baxter Healthcare
Mr. Frank Harkins, Associate Director, Credit & Collections, Boehringer Ingelheim Pharmaceuticals, Inc.
Mr. Neil Warren, Vice President, Industry & Supplier Relations, Cardinal Health, Inc.
Ms. Samantha Trudeau, Logistics Analyst, Cephalon Inc.
Ms. Tiffany Rowley, Trade Relations Manager, Covidien - Mallinckrodt
Ms. Lisa Fowler, Pharm. D., Director Management and Professional Affairs,
National Community Pharmacists Association
Ms. Martha Greene, Senior Operations Manager, Genentech USA
*Mr. Thomas Bloemeke, Manager, Returns and Recalls, GlaxoSmithKline
Mr. Robert J. Schaltenbrand, Director, Strategic Development, Guaranteed Returns
Mr. Thomas J. Twitty, Vice President, Operations, H. D. Smith
Mr. Steven Marcus, R.Ph., MBA, Executive Vice President, Health One Management Company
Mr. Cray Lester, Pharmacy Supply Chain, HEB
Ms. Jennifer Mauldin, Executive Vice President, Inmar, Inc.
*Mr. Scott Bradford, Vice President, Reverse Logistics, McKesson Corporation
Ms. Diane Staub, Director of Sales, Support, and Operations, Novartis Pharmaceuticals Corporation
Mr. Robert Weston, Customer Service/Logistics Manager, Procter & Gamble Pharmaceuticals
Mr. Ed Crimmins, Senior Director, Pharmacy Returns, Rite Aid Corporation
Mr. Frank Lee, Director, Performance Development, Smith Drug Company
Mr. Bob Breetz, The Kroger Company
Mr. Tim Harris, Senior Director, Pharmacy Logistics, Wal-Mart Stores, Inc.
Mr. Thomas Hervey, Logistics Operations Coordinator–Pharmacy, Wal-Mart Stores, Inc.

*Project Team Leads

Advisor to the Returns Task Force:
Mr. Daniel J. Raftery, President, Raftery Resource Network, Inc.

INTRODUCTION

Like many other industries, manufacturers of pharmaceutical products have historically created returned goods policies that offer credit for unsold products that meet specific criteria. These policies assist in sales efforts to distributors and retailers, particularly during the launch of new products.

Addressing returned goods in the healthcare supply chain offers an opportunity for total system cost reductions. In the past, for instance, the industry has developed and improved methods for removing expired products from pharmacies and other dispensers. However, this also has led some to rely on the returns process rather than on more proactive inventory management efforts.

Several unavoidable circumstances influence demand for pharmaceuticals, which can subsequently result in pharmaceuticals expiring, or nearing expiration, while still within the supply chain. Examples include:

- Patients decide to obtain drug therapy elsewhere (from a different pharmacy, clinic or mail order) or otherwise move on.
- Patients shorten or end their prescribed regimen ("patient non-compliance").
- Patients are moved to a generic equivalent or a different course of treatment.
- Retailers compete aggressively for patients' business.
- Negative information about a drug product arises (e.g., adverse events, manufacturing problems).

Returns systems serve several useful purposes; the most important is to guard patient safety through a controlled reverse logistics process. Trading partners have many opportunities to improve inventory management processes and the timing of events and communications. The combined efforts of manufacturers, distributors, retailers and dispensers can contribute to reducing the overall quantity of expired pharmaceutical products.

THE OPPORTUNITY

Distributors, manufacturers and pharmacies have a significant opportunity to individually reduce costs by lowering the number of selling units that become expired.
The projected value of all Rx products returned in the U.S. for which manufacturer credit is requested is estimated to be $2.6 - 4.2 billion[1]. Excluding recalls and overstock returns, the value of pharmaceutical products returned to distributors by their retail and institutional customers averaged $15,918,825 per distribution center in 2007[2]. In addition, handling, transportation and storage costs are associated with these returned goods.

2008-2009 HDMA Factbook Data	2006	2007
Percent of all Rx selling units returned to distributor (median)	1%	1%
Percent of all Rx selling units returned to manufacturer (median)	2%	2%

[1] See Appendix C.

[2] See the *2008-2009 HDMA Factbook*.

Data from the annual *2008-2009 HDMA Factbook* survey show relatively consistent percentages of pharmaceutical returns for distributors and manufacturers over the most recent two consecutive years.

Although these data reflect multiple causes for returns, among those on the RTF who process pharmaceutical returned goods, product expiration is generally considered to be the main cause. According to 26 manufacturers participating in the *2008-2009 HDMA Factbook* survey, 72 percent of all returns are either "out dated or short dated."

INVENTORY VISIBILITY

The focus of this report is to understand what causes pharmaceuticals to remain unsold before their expiration dates – identifying the "drivers" of returns. A critical first step for a company that wants to reduce the quantity of expired products under its control is to be able to identify how much inventory exists at various points in its supply chain and how much is dispensed.

Distributors function as the focal point or consolidator for both forward and reverse distribution of healthcare products sold from their own inventory. However, after products leave the distribution warehouse, the distributor's awareness of the inventory currently in the distribution pipeline is limited. This lack of total supply chain visibility inventory limits problem-solving and forecasting efforts by manufacturers and distributors.

Typically, a manufacturer becomes aware of the existence of expired products when the products begin the journey back to the manufacturer through the reverse distribution pipeline. The following steps may help individual supply chain participants address the volume of returned goods:

- Analyzing "morgue" inventory in pharmacies, institutions and warehouses (i.e., products with inadequate shelf-life according to the owner's standards for distribution and which do not qualify for manufacturer credit until a later date).
- Collecting "reason code" data (i.e., details about the condition of the product or the reason it is being returned) and lot number and expiration date.
- Communicating these data with appropriate supply chain partners, using advanced Electronic Data Interchange (EDI) technologies where possible (e.g., in addition to many other applications, the 852 EDI transaction set can be used for unsaleable returns inventory; the 867 EDI transaction set can be used to see retail sales and returns; the 180 EDI transaction set can be used for a return authorization request or notification; and the 812 EDI transaction set can be used for credit/debit adjustments).

Although the basic collection of these data will not by itself reduce the quantity of expired products and could require capital investments, a company with this information can support procedural improvements by identifying where and why expiration occurs in the supply chain and evaluating its efforts to reduce the occurrence of product expiration. Morgue inventory levels and reason codes are currently being used by several companies to track and communicate improvement opportunities. As more companies compile, analyze and apply these data, the entire supply chain will benefit.

RETURNS DRIVERS: SUMMARY

These eleven drivers of expired pharmaceutical returns are listed in a sequence developed by the HDMA Project Team that represents the most significant and feasible for a company to address[3]. These drivers are discussed in more detail in the following section.

Demand- and Inventory-Related Drivers

Primary Drivers of Expired Pharmaceutical Returns

Driver	Description	Possible Actions for a Company
1. Pharmacy stock rotation	Pharmacies generally stock 3,500-4,000 SKUs. Most pharmacy inventory is organized alphabetically. Highly manual process to collect expiration information. Many SKUs are very slow movers and are stocked with fast movers.	Conduct periodic checks on dating and rotate inventory. Cycle through entire inventory over defined period. Transfer excess inventory to actively dispensing stores. Exception: certain acute medications. Some retail systems show all inventory in a district. Pharmacist can direct patient to store today or arrange for a transfer tomorrow.
2. Alignment of manufacturer and distributor ship life policies with manufacturer production and inventory practices	In general, retailers and distributors want Rx product with 1 year or more shelf life and do not ship to stores with less than 6 months. Biotech (with 3 month efficacy) is an exception. As a result of FDA actions, a new batch could have longer dating than prior batch.	Manufacturers should consider 12 months minimum ship life. Alert distributor and retailer to shorter life. Might include written approval to ship. Develop special communications for slow-movers to alert pharmacies.
3. Retail pharmacy practices for short-dated products	Retailers often pull products off the shelf 90 days prior to expiration. Distributors usually ship with at least 6-7 months shelf life remaining. Short shelf life situation with biotech or specialty products, e.g., 3 months.	Monthly inventory inspections for expiration date can find items in stores with less than 90 days shelf life. Special order specialty products with short shelf life as needed. Educate patients about expiration date and efficacy.
4. Drop in demand for seasonal Rx products	Products need to be in store when patients arrive. Inventory build-up may occur. If season is soft, return rates are higher. Fall-off rate can be very steep; high sales volume exists until the end of season.	Hold inventory in distribution center (DC) vs. store for quick response to increased dispensing needs. Intra-company transfers move product from "cold" to "hot" dispensing locations. DC to DC transfers accommodate regional demand variations.
5. Warehouse stock rotation	Larger distributors generally carry 36,000-40,000 total SKUs. Service Level Commitments cover any patient request at pharmacy level. Broad variety of products: brand/generic; slow movers/fast movers; maintenance/acute.	Rationalize SKUs based on demand. Service levels may decline as trade-off. Slow movers, such as maintenance drugs, could be sourced via wholesaler or dispensed via mail order. Use expiration date data in warehouse management systems.
6. Investment buying/ forward buying at retail and by institutions	Distributor service agreements between individual trading partners have generally curtailed this activity. Exception: seasonal items require forward buying. Tiered contracts at institutions may cause some forward buying to get rebate at end of quarter.	Additional actions might be identified through discussions with trading partners and legal counsel.

[3] See Appendix B for more information.

Primary Drivers of Expired Pharmaceutical Returns (cont.)

Product-Related Drivers

Driver	Description	Possible Actions for a Company
7. New product failures	Market share forecasts drive production and distribution. Communications to prescribers may lag behind distribution. Actual demand may be lower than pre-launch forecasts.	Manufacturer should consider coordinating product delivery with communications to prescribers. Instructions from manufacturer to distributor should cover the complete product lifecycle. Retailers and distributors could evaluate new item performance and rebalance inventory.
8. Unit of dispensing is not standardized.	Prescribing practices often differ from how product is packaged. Most scripts are written in multiples of 30. Many are for 28. Multiple ways to order (e.g., 30, 100 or 1,000). No standard practice for mixing lots. Dispensing practices vary by channel.	Some chains like unit-of-use packaging, e.g., 30 or 28. Some manufacturers have developed new products in multiples of 30 counts (e.g., 180). Consider seeking FDA approval for unit-of-use packaging when it makes sense.
9. Generic product introductions	Generic launches cause increased returns of branded products. If supply chain partners do not properly anticipate the launch, returns can be substantial. A single generic item can be supplied by multiple vendors.	Manufacturers should forecast for branded returns after patent expiration. The pharmacy, distributor and manufacturer should increase communications prior to and immediately after generics launch. Distributors could include potential impact on returns in independent company decisions to change generic suppliers.
10. National Drug Code conversions	Product acquisitions and divestitures among manufacturers result in NDC conversions of the product. Sales of old NDC may stop before inventory is depleted.	Old and new NDCs for identical products can be linked in inventory management systems so that new inventory is not sold until old inventory is depleted. Some states allow the dispensing of both NDCs in the same prescription, under certain conditions.
11. Government actions, such as FDA enforcement actions	For drugs marketed without FDA approval, FDA might issue a "do not sell past X date" rule. Inventory can remain in the supply chain. State regulations about redistribution vary.	Some manufacturers work with FDA to obtain approvals or extend transition period. These events can be treated as if they were recalls or staged withdrawals.

Note: These drivers are presented from a total supply chain perspective. Each driver could be more or less important to an individual company, depending upon that company's position in the supply chain and the amount of progress already made on these returns drivers.

RETURNS DRIVERS: DETAILS

This section describes the conditions and practices in the supply chain which define or contribute to each driver of returns. Recommendations are included for how manufacturers, distributors, retailers and institutions can reduce the quantity of pharmaceutical returns.

The relative impact on the amount of expired pharmaceuticals in the supply chain and difficulty in changing practices also are shown for each driver as:

- ↑ Indicates above average impact/difficulty.
- ↓ Indicates below average impact/difficulty.

The "average" is a highly qualitative mid-point among these drivers as estimated by the RTF. The impact and difficulty may be different for individual companies than these general industry estimates.

Demand- and Inventory-Related Driver #1

Pharmacy stock rotation

↑ IMPACT ↓ DIFFICULTY

In order to be prepared to fill any customer's prescription at any time, a typical pharmacy can hold 3,500 - 4,000 Rx items in stock. Many of those items have very low volume. Storeroom inventory is typically arranged alphabetically, with the "slow movers" and higher velocity items stocked together. Service level agreements between individual trading partners generally reinforce the importance of minimizing stock-outs.

Managing this inventory relies heavily on manual processes including physical inspection and record-keeping by pharmacy personnel. Lack of standardization in the presentation of expiration information complicates this activity, requiring the pharmacy personnel to handle the product in order to locate the information.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Conduct regular and periodic inspections of pharmacy inventory, cycling through the entire storeroom over a defined period such as one week or one month.

b. Transfer excess inventory to actively dispensing pharmacies, except for acute medications.

c. Provide individual pharmacies with visibility into inventory at other nearby stores (within a given retail chain operator) so that pharmacists can direct patients to another store for an immediate prescription fill, or arrange for an inter-store transfer.

d. Use inventory management techniques that have proven successful for better inventory control of "slow movers" in other product categories. Examples include special tags (possibly a unique color) for inventory with short shelf-life remaining. (Note: temporary low-adhesive tags would not damage product labels).

e. Consider "rationalizing" product variety in a given pharmacy based on actual demand, except for acute medications.

Demand- and Inventory-Related Driver #2

Alignment of manufacturer and distributor ship life policies with manufacturer production and inventory management practices

IMPACT DIFFICULTY

Distributors typically want to buy prescription drug products with one year or more of shelf-life and do not ship to stores with less than six months of shelf-life. There are some reasons that products are shipped to retail or distributor with 12 months of shelf-life (or close to 12 months). Exceptions for shipping with less than 12 months of shelf-life are products in limited supply or biotech products (with three month efficacy).

Variations in expiration dates can occur for different batches of a given product, especially those requiring FDA approval for each batch. For example: When an order is placed with a manufacturer, the best dating available is X. A new batch is in the queue for approval by the FDA. After the order is placed, the new batch is released to the marketplace and has a longer expiration on it (X + 6 months, for example). In this example, a distributor could be holding inventory of the same product with two very different shelf lives, which would require special attention.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Consider shipping products from the manufacturer with 12 months or longer remaining shelf-life.

b. In the event of less than 12 months remaining, alert the distributor and/or retailer. Obtain a formal approval to ship the short-dated product to expedite the receiving process.

c. Develop communication practices for slow-movers with short shelf-lives to alert pharmacies about the situation. For example, an auxiliary label can be temporarily applied, indicating “best date available” in bright colors. Closed-loop supply chains such as self-distributing retailers can use internal systems to evaluate sales velocity for short-dated products.

Demand- and Inventory-Related Driver #3

Retail pharmacy practices for short-dated products

IMPACT ↑ DIFFICULTY ↓

Retailers often pull short-dated products off the shelf 90 days prior to expiration. Distributors usually work with a six month window (shipping at seven months). Biotech or specialty products generally have shorter shelf lives, e.g., three months. In addition, some states may have requirements regarding the date on which the prescription is filled as it relates to expiration date. These conditions and practices can result in expired products being returned to manufacturers for credit after being held in a "morgue" inventory location until they expire.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Conduct monthly inventory inspections to find items with less than 90 days shelf-life remaining.

b. Special order specialty medications with short shelf-life, as needed, rather than holding inventory in pharmacies.

c. Educate patients through pharmacy interaction about the relationship between expiration date and medication efficacy.

Demand- and Inventory-Related Driver #4

Drop in demand for seasonal Rx products

IMPACT ↑ DIFFICULTY ↓

For highly seasonal products such as cough/cold medications, allergy remedies or influenza vaccines, retail pharmacies build inventory well ahead of the start of the season. As a result, products are already in the store when patients need them. This build-up to meet anticipated demand may result in high rates of return at the end of the season, especially if actual demand has been soft. Inventory management for flu vaccine is further complicated by the variations in strain and severity from year to year. Seasonal products generally have short shelf lives and experience very high demand volume until the end of the season. Volume fall-off rates can be extreme for seasonal pharmaceuticals.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Hold some inventory in the distributor's or retailer's warehouse in order to respond quickly to dispensing surges.

b. Transfer inventory from dispensing locations with low sales to locations with high sales volumes via intra-company transfers.

c. Transfer inventory among warehouses to accommodate regional demand variations.

d. In addition to current resources (e.g., Centers for Disease Control forecasts), use new information resources to support forecasts (e.g., Google's geographic flu reports at: www.google.com/flutrends/).

e. Collaborate with individual trading partners to forecast regional dispensing demand.

f. After the start of the season, replenish based on demand rather than on forecasts.

g. Use historical data to forecast when the season will end.

h. Monitor demand and inventory levels weekly for key seasonal items and conduct analyses to forecast the end of season. In companies without highly automated inventory tracking technology, manual observation and communication may be necessary to monitor seasonal products at individual pharmacies (e.g., manual inspection and phone calls or emails).

i. Set seasonal minimums and maximums for ordering of seasonal items in computer-assisted ordering systems and return the limits to non-seasonal values in the last weeks of the season.

j. Consider developing a range of multipliers for order points of seasonal items, organized by demand variability. Each demand group can have a multiplier for in-season and one for out-of-season.

Demand- and Inventory-Related Driver #5

Warehouse stock rotation

IMPACT DIFFICULTY

In order to satisfy Service Level Commitments, many types of products are included in warehouse inventory, such as branded and generic, slow movers and fast movers, maintenance and acute medications. For example, larger healthcare distributors typically carry 36,000 - 40,000 total items in their inventory. All distributors, regardless of their size, generally follow the philosophy that any item that any patient may request at any pharmacy they service needs to be in the distributor's warehouse.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Use pharmacy-level demand to rationalize which items to carry in the warehouse, recognizing that service level may decline as a trade-off.

b. Rationalize warehouse inventory based on product velocity and consider alternative source options for slow-moving maintenance medications or alternative dispensing options (e.g., mail order delivery) where available.

c. Include expiration date data in the warehouse inventory management system and use expiration date to "age" case-level inventory in systems with this capability.

At this time, most fundamental warehouse inventory management systems use date of receipt to control the "First In, First Out" flow of products. Some newer systems can accommodate expiration date data, which currently are captured at the receiving dock. Companies considering investing in newer systems should also consider the cost of collecting the data at the receiving dock.

Demand- and Inventory-Related Driver #6

Investment buying/forward buying at retail and by institutions

↓ IMPACT ↓ DIFFICULTY

Retail pharmacies or institutions may protect against future price increases by purchasing extra inventory for certain drugs. Whereas this practice was more prevalent in the past, Distributor Service Agreements between individual trading partners have become a normal industry practice and generally have curtailed investment buying.

The primary exception is seasonal products, which are driven by forecasts and require large inventory to meet anticipated demand. Another exception may occur when price-tiered contracts between institutions and distributors result in some forward-buying, incentivized by volume-related rebates. Retailers generally recognize that this practice ties up too much capital in inventory investment. In addition, regulatory requirements make sales of excess inventory more difficult for retailers.

Recommendations

If a company wishes to focus further on these issues, it might consider speaking with its counsel and trading partners about additional private contractual arrangements that could address these practices in more detail.

An Example of Industry Progress in Inventory Management

The healthcare distribution industry has made progress in controlling unsaleables in several areas. Companies have improved business practices in order to reduce the quantity of products that expire. One example involves the supply-side counterpart to investment buying.

In the past, manufacturer sales representatives often were compensated based on their gross sales, without accounting for the portion of those sales that expired before they could be dispensed. As a result, incidents of "channel loading" occasionally occurred. Current Service Agreements between individual trading partners generally address "channel loading" practices so manufacturers more often track net sales (e.g., gross sales minus returns and unsaleables) in compensation and performance evaluations.

Product-Related Driver #7

New product failures

IMPACT ↑ DIFFICULTY ↑

In preparation for the launch of a new product, manufacturers develop market share projections which, in turn, drive production and distribution volume. While educational communications with prescribers about the new drug occur near the launch and often generate interest in prescribing, legal requirements limit what a manufacturer may communicate about a new drug prior to obtaining FDA approval.

In some cases, prescribers' knowledge about a new drug lags behind the drug's distribution. As a result, some pharmacies may return the new item to the distributor for lack of prescriptions, only to encounter a delayed demand after reducing their inventory. Additionally, for a variety of reasons, actual demand for a new product may not be as high as the pre-launch forecasts.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. A launching manufacturer could try to coordinate the delivery of new product inventory to coincide with the communication to prescribers about the new drug, following appropriate legal requirements and codes of conduct for prescriber communications.

b. Communications from manufacturer to distributor should cover the complete product lifecycle process, including the end-of-life procedures.

c. Retailers and distributors could evaluate the sales performance of a new item after an appropriate period, such as 16 weeks. If the initial inventory remains in the system, a retailer or distributor could consider balancing inventory.

Communications with prescribers about unapproved drugs and any other issues regarding the marketing of drugs prior to FDA approval should comply with all FDA and state laws and regulations. The complex issues regarding the permissible communications about a drug prior to FDA approval and at launch are beyond the scope of this report. For additional information regarding FDA's requirements for prescription drug promotion, go to: http://www.fda.gov/cder/ddmac/.

Product-Related Driver #8

Unit of dispensing is not standardized

IMPACT DIFFICULTY

Prescriptions are often written for quantities in multiples of 30 and many are for 28. For some medications, such as antibiotics, the prescribed quantities can be as low as five, six or seven. Manufacturers often package a given pharmaceutical in quantities of 30, 100 or even 1,000. When the pharmacist fills a prescription from a larger quantity package, the remaining product often must be relabeled. Practices vary across the industry regarding this residual inventory (a.k.a. "partials"). Regardless of the practice, partials are often returned to manufacturers for credit or are destroyed.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Manufacturers could consider seeking FDA approval for "unit-of-use" packaging (quantities of 30 or 28) when possible, economically feasible and consistent with approved labeling.

b. Manufacturers could consider seeking FDA approval for new products in packaging in multiples of 30 (e.g., 180) for products usually prescribed in that quantity.

c. Manufacturers could consider conducting research into expected prescribing practices prior to FDA approval of a given drug to support labeling and packaging configurations.

d. Manufacturers could consider educating prescribers further about efficacy, optimum dosage and expected unit of use.

Product-Related Driver #9

Generic product introductions

↑ IMPACT ↑ DIFFICULTY

After the expiration of the branded patent, several manufacturers may have FDA approval to supply the generic equivalent. This is a natural consequence of free market competition. However, there is a potential hidden cost.

The introduction of generic equivalents creates an increase in the quantity of returns of the branded product which was previously protected by patent(s). If supply chain partners do not properly anticipate this event, the returned quantity can be substantial. Trading partner communication prior to the release of generic equivalents also is critical to ensure product availability.

Whereas the generic product's efficacy is the same among the various manufacturers, reimbursement practices and policies are not. Retailers often look at manufacturer policies regarding who may reimburse for returns, including who may reimburse for partials. Reimbursements for partials, formulary changes or contract pricing changes are examples of some of the factors that individual distributors may consider when choosing a generic supplier. In addition to manufacturer reimbursement practice variations, changing suppliers can cause an increase in returned product, due to variations in a tablet or capsule size, shape, color, etc., which can be confusing to the consumer.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. The brand manufacturer could re-forecast brand sales as soon as it knows about the launch of generic equivalents and anticipate some cost associated with branded product returns.

b. Supply chain partners (pharmacy, distributor and manufacturer) should increase the frequency and quality of communications about branded product inventory levels during the transition to generic product availability.

c. A wholesaler or self-distributing retailer could include potential impact on costs associated with returns in its decision to change suppliers of a generic product.

Product-Related Driver #10

NDC conversions

IMPACT ↓ DIFFICULTY ↑

National Drug Code (NDC)[4] conversions (i.e., a change in a drug's NDC number) cause similar challenges in the supply chain. Product acquisitions and divestitures among manufacturers result in NDC conversions for what is otherwise generally considered the same item. When the product with the new NDC begins selling, the old one may stop. Some retail systems only show the new NDC, causing the old NDC inventory to expire without system visibility.

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Link old and new NDCs of identical products with the same form and strength in inventory management systems and switch to dispensing the new one after inventory of the old one is depleted.

b. Use two bottles when dispensing a product with both old and new NDC in the same prescription and fill, except where state laws or insurance reimbursement practices prohibit. Consider using an auxiliary label (i.e., a patient advisory sticker) to communicate to patients that the new NDC product is the same as the old one, when appropriate.

c. Communicate with supply chain trading partners about the amounts and location of inventory in the pipeline and about when the NDC conversion will occur. Address system database limitations on a retailer-by-retailer basis with manual efforts.

[4] See www.fda.gov/cder/ndc for more information about NDC.

Product-Related Driver #11

Government actions, such as FDA enforcement actions

IMPACT | DIFFICULTY

Some prescription drugs are marketed without FDA-approved applications. The FDA will sometimes take action against these drugs and issue an order that the drug or drugs may not continue to be marketed until the manufacturer submits a New Drug Application and The FDA approves that application. Under these circumstances, drugs without approved applications must be withdrawn from the market. However, the unapproved drug may remain in "morgue" inventory in the reverse logistics supply chain after the "do not sell" date. Manufacturers usually issue instructions to distributors and retailers regarding the disposition of unapproved drug products; however, there is significant variability. Examples include FDA action against timed release drugs containing guaifenesin (May 2007) and topical drugs containing papain (September 2008) and certain prescription narcotics (March 2009).

Recommendations

A company could consider the following actions to reduce the quantity of expired pharmaceuticals related to this driver:

a. Manufacturers should educate retailers and distributors about those products they handle that may become involved in future FDA enforcement actions.

b. In the event of an FDA action, manufacturers may work with the FDA to obtain approvals or extend the transition period.

c. Treat these events as if they were recalls or staged withdrawals. Be ready for a potential recall at a later date.

This report is intended to address individual company actions and to improve communications among trading partners in the healthcare supply chain, which may reduce the quantity of returned products. The complex issues regarding the marketing of drugs without FDA approval are beyond the scope of this report. For additional information regarding FDA's unapproved drugs initiative, go to: http://www.fda.gov/cder/drug/unapproved_drugs/default.htm

APPENDIX A

LEADERS IN RETURNED GOODS MANAGEMENT

In 1997, HDMA (then called National Wholesale Druggists Association) published *Returned Goods Scorecard*, a self-evaluation tool for manufacturers and distributors of pharmaceuticals. The report described five levels of success in managing key aspects of returned goods.

Not surprising to those involved with returned goods management, many returns practices of highly successful companies continue to apply today. The following table summarizes the top-level practices for reducing unsaleables from the 1997 report.

The HDMA Returns Task Force recommends that distributors and manufacturers refer to these leading company practices, along with the other recommendations in this report, as diagnostic tools that help to identify opportunities to reduce incidents of pharmaceutical product expiration and to track progress.

Leading Company Practices		
Returned Goods Processing		
M	D	**Top-level management** supports the company's returned goods control process. Reductions in returned goods costs are documented; ROI responsibility is assigned.
M	D	**Cross-functional resources** are dedicated to routinely manage costs. Cost reductions are documented by function.
M	D	**Internal education** is complete. Process for improvement is in place.
M		**Policy** supports corporate objectives, is understandable and covers all customers and products. Policy is reviewed periodically and revised based on experience.
M		**Policy updates** and revisions are successfully communicated and implemented internally and externally. Collaboration with customers improves policy.
M	D	**Disposition** occurs as defined in policy for all products. Options are reviewed and changed based on experience.
M	D	**Information technology** is used to process returned goods claims. No unauthorized deductions exist for returned goods.
M	D	**Returned goods data** are used and benchmarked internally and externally. Reduction in returned goods expenses is documented through regular use of data.

M = Generally considered a manufacturer's practice.
D = Generally considered a distributor's practice.

APPENDIX A

Leading Company Practices (cont.)		
Returned Goods Prevention		
M	D	**Top-level management** supports and is involved in returned goods management activities, e.g., annual business reviews. Actively supports industry efforts with returned goods issues. Initiates improvement initiatives and actions.
M		**Brand P&L** includes returned goods costs within an Activity-Based Management framework. Quantity of returned goods is lower due to changes in product development practices.
M		**Customer P&L** includes returned goods costs within Activity-Based Management framework. Quantity of returned goods is lower due to changes in marketing and sales practices.
M	D	**New technology** is used to reduce product damage and costs within supply chain.
M	D	**Warehousing standards** are changed to reduce returned goods (e.g., reduce damages).
M	D	**Loading practices** are improved to reduce damage.
M	D	**EDI transactions** are used to improve supply chain inventory management.
M	D	**Order and inventory management** are linked to demand and supplier inventory management systems (e.g., Vendor Managed Inventory or VMI).
M		**Returns data** are used in **package redesign** to lower unsaleability.
M		All **packages** are bar-coded and visually differentiable.
M	D	All **shipping containers** are bar-coded and follow recommendations from *Voluntary Shipping Container Guidelines* (1997) and *Case Marking: A Common Language for Shipping Containers* (1996).
M	D	All **shipping platforms** incorporate *Recommendations from the Grocery Industry Pallet System* (1992).

M = Generally considered a manufacturer's practice.
D = Generally considered a distributor's practice.

APPENDIX B

IMPACT AND DIFFICULTY OF RETURNS DRIVERS

Members of the HDMA Project Team contributed their perspectives about the major drivers of expired Rx returns. They rated each driver for its potential impact on the industry and the degree of difficulty in incorporating actions for improvement. Following is a summary of the ratings of distributors, manufacturers, retailers and service providers:

Impact and Difficulty Rating for Each Driver

	Product-Related	Demand- and Inventory-Related
MORE DIFFICULT	7. New product failures. 8. Unit of dispensing is not standardized. 9. Generic product introduction.	1. Pharmacy stock rotation. 2. Alignment of manufacturer and distributor ship life policies with manufacturer production and inventory management practices. 3. Retailer pharmacy practices for short-dated products. 4. Drop in demand for seasonal Rx products.
LESS DIFFICULT	10. National Drug Code conversions. 11. Government actions, such as FDA withdrawals.	5. Warehouse stock rotation. 6. Investment buying/forward buying at retail and by institutions.

MORE IMPACT

LESS IMPACT

Note: These drivers are presented from a total supply chain perspective. Each driver could be more or less important to an individual company, depending upon its position in the supply chain and the amount of progress already made on these returns drivers.

APPENDIX C

INDUSTRY PROJECTION FOR VALUE OF EXPIRED Rx RETURNS

Two methods were used to estimate the annual expired Rx returns. The *2008-2009 HDMA Factbook* was used as the main source of data for both methods.

Method 1 - Based on HDMA Distributor Member Survey Data	
$15,918,825	Average returns per DC (mean)[1]
x 125	Total DCs in survey
$1,989,853,125	
÷ 76%	% of industry sales through distributors[2]
$2,618,227,796	Total value of industry returns

Method 2 - Based on HDMA Manufacturer Member Survey Data	
$291,000,000,000	Total industry sales[3]
x 2%	Annual Rx selling units returned to mfrs.[4]
$5,820,000,000	
x 72%	Outdated and short dated returns[5]
$4,190,400,000	

Comparison	
$291,000, 000,000	Total industry sales[3]
1%	Distributor returns %[1]
$2,910,000,000	Distributor returns

Conservative estimate: Industry Rx returns related to expired product was $2.6 to $4.2 billion in 2007.

[1] From Table 88, *2008-2009 HDMA Factbook*. Data are for FY 2007. Total annual dollar value of returns for credit requested from manufacturers, excluding recalls or overstock returns.

Note: The median is reported as $6 million. This large variance from the mean may be driven by "0s" in the data.

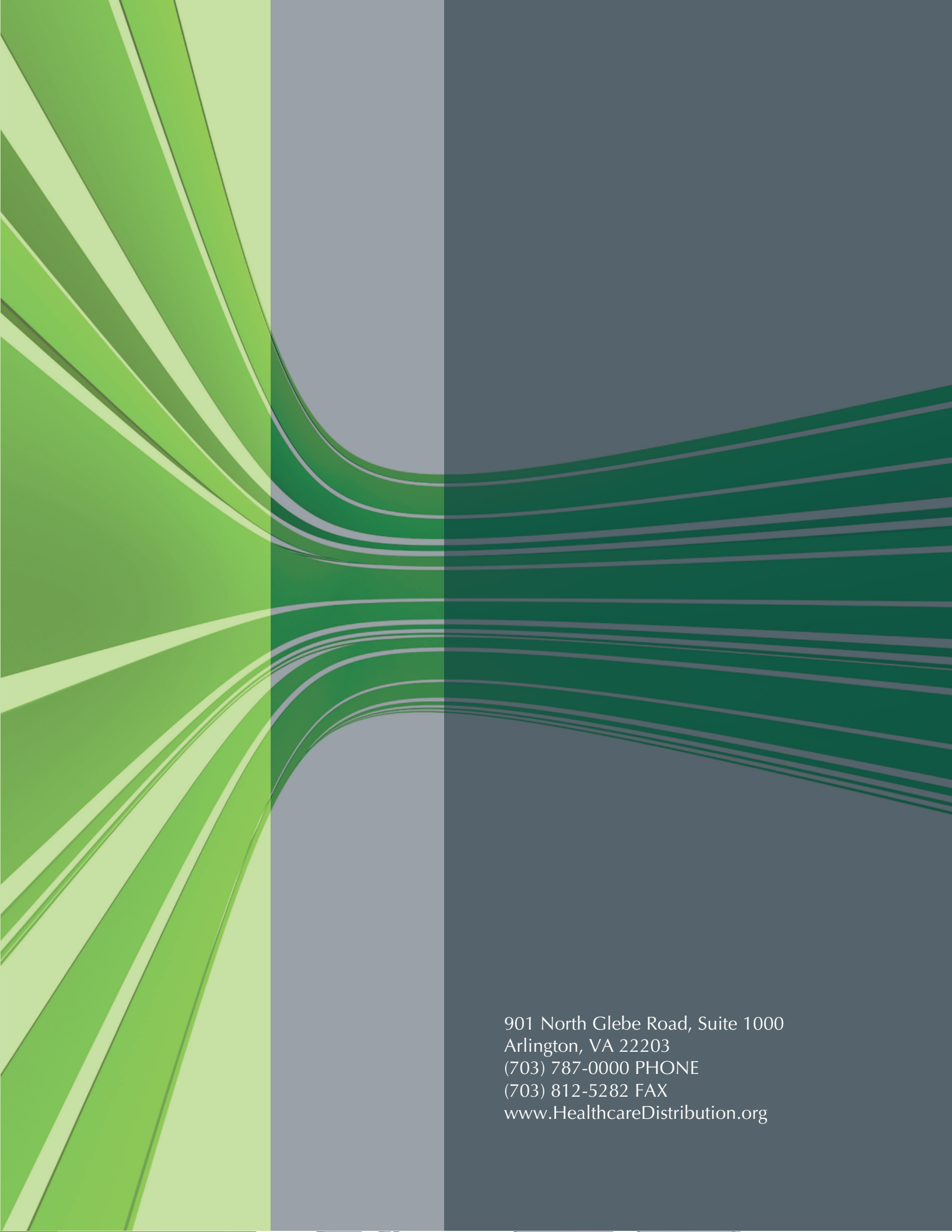
A large variance also exists between the number of responses to this question (63) and to the question about annual dollar value of returned Rx product (116). Table 93 reports that 51% of returns to distributors are overstocks, which is very close to the relationship between annual dollar value of returned product ($29,891,000) and $15,918,825. This is interpreted as validation that the mean and not the median is a more representative value to use in this estimate.

[2] The estimated percent of industry sales through distrbutors was nearly 76% in 2007, from Table 1, *2008-2009 HDMA Factbook*.

[3] Total US Prescription Market, 2008, Source: *IMS Health, IMS National Sales Perspectives™*

[4] From Table 89, *2008-2009 HDMA Factbook*. Data are for FY 2007.

[5] From Table 93, *2008-2009 HDMA Factbook*. Data are for FY 2007. Excludes recalls and withdrawals.



901 North Glebe Road, Suite 1000
Arlington, VA 22203
(703) 787-0000 PHONE
(703) 812-5282 FAX
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