

# **EXPIRY DATES**

## ***GREEN PAPER***

### **Issue Statement**

Consumers are receiving products that will expire prior to normal/expected usage.

### **Issue Analysis**

1. **There are no expiry date standards for returns by category from pharmacy distributors and retailers.** This problem is exacerbated by the fact that there is considerable confusion in determining when a short-dated product becomes unsaleable. It can be deemed unsaleable when it becomes unacceptable for purchase by a consumer. However, consumers vary on when the “unacceptable” point is reached. For some it is determined by assessing whether it is likely that it will be consumed within the remaining expiry period. For others it may be determined by immediate necessity. It is also category specific.
2. **There are no standard manufacturers’ expiry date returns policies.** Some manufacturers do not want product back until it expires. Others would like to receive in-date product returned even if it is short-dated. Procedures for handling product that is deemed unsaleable vary:
  - Pharmacy distributors/retailers may keep it until it expires;
  - Pharmacy distributors/retailers may send it back;
  - Pharmacy distributors/retailers may receive a percentage discount and be asked to dispose of it; and,
  - Pharmacy distributors/retailers may have a contract with the company which provides for a percentage of annual sales returns policy.
3. **There is poor inventory management/stock rotation throughout the supply chain.** This is due to:
  - Year-end loading;
  - Promotional loading;
  - Lack of adherence to FIFO (first in, first out);
  - Recycling of returns;
  - Poor product lifecycle forecasting;
  - Formulary changes/regulatory changes;
  - Rx to OTC switches;
  - Dramatic shifts in market share due to genericization or addition of “me too” drugs;
  - Poor SKU rationalization due to number of packages/sizes/format; and,
  - Assumption that last received is the freshest.

4. **There is an absence of expiry date tracking capability.**
5. **Short-dated product exists and there will always be some short-dated product in the supply chain.** Manufacturers will ship shortest date product to those who will accept it. Consumers would often rather have short-dated product than no product. Therefore there needs to be an exception handling procedure.

## **Goals**

Provide consumers with product with acceptable dating (the freshest possible product).  
Minimize non-value-added costs and disruption in the supply chain.  
Improve partner relationships by minimizing misunderstandings and deductions, communicating what should be reasonable consumer expectations by category and communicating what should be reasonable pharmacy distributor/retailer expectations with respect to specific product dating.

## **Options/Alternatives**

Recommend expiry date standards by category for pharmacy distributors and retailers.

Recommend good inventory/stock rotation practices.

Look at published documents from the Health Protection Bureau to be used as part of a communications strategy.

Educate stakeholders (pharmacy distributors, chain drugstore distribution centres, and retailers) on what to expect vis-à-vis the breadth/range/variability of expiry dates by category.

Provide background information on why some products have shorter or longer expiry dates.

Investigate development of a formula for calculation of minimum stocking expiry dates, which takes into account the entire supply chain through to consumer consumption time.

## Discussion

It is very difficult to set standards for expiry dates by categories for pharmaceutical products. For example, a company may manufacture one injectable in a category with 60 months expiry dating and another in the same category with 12 months expiry dating. Similarly the company could have tablets in the same category with expiry dates varying from 24 months to 60 months. It is possible to make some generalizations regarding the fact that creams and liquids tend to have shorter expiry periods and that antibiotics rarely have more than 24 months expiry dating. However, even in these categories there may be exceptions.

Producing smaller batches of short dated and slow moving products may help. However, the economics related to batch size may make this difficult. In the case of consumer products, manufacturers may discontinue slow moving products.

For short dated and slow moving product, managing effective distribution can be difficult.

Manufacturers are motivated to try to improve on dating if stability data permits. They generally file for an extension on expiry data if stability data exists. This is an automatic and painless process for products that have been on the market for a number of years. It is more difficult for new products since stability data does not exist to justify granting of an extension.

Manufacturers are more motivated to apply for extensions on short dated product so that they can respond to changes in the market, (e.g. drop off of growth).

Currently, there are products where the best available expiry dating will never meet some retailers' acceptable expiry dating policies. For example, some retailers will not accept product that has expiry dating less than one year. However, for products with short expiry dates necessary due to stability assessment, the one-year policy is unrealistic. This means the products will always be "exceptions". Unfortunately, some retailers are unable to flag these exceptions on a regular basis in their systems. This results in increased costs to the supply chain since the retailers' receivers either do not accept delivery of the product or must make inconvenient calls to the manufacturer. Alternatively, manufacturers have to call the retailers each time one of these regularly short-dated products is being shipped.

Product at the pharmacy distributor is set aside if it doesn't meet acceptable expiry dating guidelines. The buyer then typically calls the manufacturer to determine whether it is the best dating they can acquire. Based on the response they decide whether they will keep the product or return it for fresher product.

Generally, product with 3 months dating or less is considered by many to be obsolete at both manufacturing and pharmacy distribution facilities.

## Recommendations

1. There should be standardized threshold “stop ship” dates for regularly listed products. These stop ship dates should differentiate between consolidated shipments (wholesaler or chain with warehouse) and those shipments directly to pharmacy.

	<b>Rx Products</b>	<b>OTC products</b>
<b>Shipments to consolidators</b>	<b>9 months*</b>	<b>12 months*</b>
<b>Shipments to pharmacies</b>	<b>6 months*</b>	<b>9 months*</b>

**\*Minimum requirements (in months) of expiry dating remaining on product before stop shipments occur.**

2. A recommended guideline between manufacturer and pharmacy distributor needs to be developed that addresses the communication flow when the only product available does not meet the guidelines outlined above.
3. Manufacturers should publish a list of “regular” exceptions. This could be done by including the number of days of normal available expiry for regularly short dated products on the manufacturers’ price lists and new product information sheets. The lists of regular exceptions and the retailers’/consolidators’ ability to flag them will help to improve order cycles by taking into account lead times.
4. Retailers and consolidators should recognize that exceptions exist and adjust their internal systems to accept “regular” exceptions and note other expected exceptions.
5. Manufacturers should, where economically possible, produce smaller batches of short-dated and/or slowing moving pharmaceutical products.
6. An exception list should be included in the ECCnet catalogue.

## Evaluation Criteria

To aid in implementation, the CAPDM pharmacy distributors are encouraged to utilize the evaluation criteria chart below. Once implemented, the evaluation chart can be used to measure the performance of a manufacturer in regards to expiry dates.

### Expiry Dates Green Paper Evaluation Criteria

	Unacceptable	Acceptable	Best Practice
<b>Expiry Dates</b>	Manufacturer has no defined policy. Routinely ships products with less than required dating remaining. Provides no notification prior to shipping short dated merchandise.	Manufacturer has a published policy that does not meet CAPDM minimum standard. Manufacturer does not provide communication prior to shipping short dated stock.	Manufacturer has a policy that meets CAPDM minimum standard. Occasionally ships product with less than required dating. Provides communication prior to shipping short dated stock.
	Mfr. policy exceeds CAPDM standard. Rarely ships short dated. Communicates all short dating issues prior to shipping. Replaces short dated with fresh stock when available.		
	Comment/Action:		