EXPIRY DATES (NON-STERILE)

INTRODUCTION

A uniform policy on expiry dates should be adopted so that the present ad hoc arrangement may be given some basis upon which they can be justified. The rationale behind the expiry dates is based upon the following:

General Precautions

Physical degradation of the product
Chemical degradation of the product
Microbial contamination of the product
Initial status of the product
Environment in which the products is used

Factors influencing the above

Container and closure - Protect from light, moisture, oxygen, loss by evaporation and ingress of bacteria
Formulation - Antioxidants to prevent oxidation, suspending agents to prevent caking, preservatives to reduce microbial growth N.B. Stability may be compromised by the presence of unknown excipients e.g. from tablets
Manufacturing conditions - Prevent initial contamination
Environmental conditions of use – Stock bottles are at greater risk than patient own medicines used on wards which are at greater risk than when used in the home.

Products may be classified under the following headings in order to formulate a general expiry date policy.

Repackaged industrial products
- Oral liquids
- Oral solids
- Externals

B. Hospital prepared products
- Oral liquids
- Oral solids
- Externals

DISCUSSION

Most products prepared by the industry have expiry dates in excess of two years in their original packs. However if a realistic stock turn is taken into consideration two years should be taken as a maximum. It is acceptable to retain the original expiry date provided that none of the physical constraints applied to the product are compromised on repackaging e.g. blister packs. Overlabelled original packs should usually retain the original expiry date.

Hospital prepared oral liquid products are usually inappropriate for an extensive shelf life. This is normally due lack of proven preservative efficacy, the risk of physical degradation such as caking and the potential for chemical degradation of the product.

With the possible exception of unit dose and blister packs, there is no guarantee that, after dispensing, the physical constraints are not removed e.g. loose tops. It is also the case that many ward environments are contaminated with pathogens. In order to protect the product from such abuses it should be used within a relatively short period from the time of dispensing, oral liquids being the most vulnerable. In use shelf lives should be applied.

There are three different situations in which the products are stored and used after leaving a hospital pharmacy

Ward stock bottles
Patient own medicines, stored and used at the patient bed.
Discharge medicines

It would be unusual if deliveries were not made to wards at least weekly and I would suggest this as the date after which oral stock bottles of liquids, which are most at risk, should not be used since first opening. If it is found that a substantial proportion of the contents of such containers are not used after one week then the volume dispensed is inappropriate.

Oral solids are less liable to degradation and provided they are packed in a suitable container the shelf life should be in excess of two years.

Externals such as creams, ointments and liquids, which are liable to microbial contamination, and which by their pharmacological nature, would tend to mask patient infections, should be treated with greater care. These products, if packaged under suitable conditions should not have an expiry date any longer than three months. It would be preferable if they were dispensed in unit dose containers or collapsing tubes otherwise they should be used within one week of first opening.

All other externals may have an expiry date of one year. Most products would be stable for at least two years. However it would be bad practice were such products to be left at the point of use half finished for that length of time.

SUMMARY

The following are the advised expiry dates for non sterile products manufactured and assembled under suitable conditions. It is assumed that the product is chemically and physically stable. The dates may be reduced to take into account local circumstances i.e. poor conditions of assembly and storage or suspect containers etc.. Individual products should be classified according to the local Quality Controller.

All products should be considered to have expired on the last day of the month unless otherwise stated.

This document has not considered the reuse of previously used products.

Repackaged industrial products and original packs

Oral liquids - Two years or the manufacturers expiry which ever is less. Use within one month of first opening.
Oral solids - Two years or the manufacturers expiry which ever is less.

Externals - Products liable to contamination and those likely to disguise infections – Manufacturers expiry and use within one week of first opening
Others - One year

Hospital prepared products

Oral liquids –

Ward stock - Validated expiry or one month and use within one week of first opening
Patients own - Validated expiry or one month and use within one month of first opening
Discharge medication - Validated expiry or one month and use within one month of first opening

Oral solids - Two years or the manufacturers expiry which ever is less.

Externals - Products liable to contamination - Three months and use within one week of first opening
Others - One year

Summary table

Product Type		Allocated Shelf Life	In Use shelf life
Repackaged industrial products	Oral liquids	2 years or manufacture's expiry whichever is the less	Use within one month of first opening
	Oral solid dose forms - loose	2 years or manufacture's expiry whichever is the less	Use within one year of first opening
	Externals liable to contamination	Manufacturers expiry	Use within one month of first opening
	Externals	Manufacturers expiry	Manufacturers expiry
	Blister packs, unit doses e.g. amps.	Manufacturer's original	Manufacturer's original
Over-labelled industrial products	Oral Liquids	Manufacturer's original	Manufacturer's advice
Over-labelled industrial products	Oral solids	Manufacturer's original	Manufacturer's original
Hospital prepared products	Oral liquids – ward stock	Validated expiry or one month	Use within one week of first opening
	Oral liquids –Patient own	Validated expiry or one month	Use within one month of first opening
	Oral solids - discharge	Validated expiry or one month	Use within one month of first opening
	Externals - Products liable to contamination	Three months	Use within one week of first opening
	Externals- others	One year	Use within one month of first opening
Eye drops	with preservative	Discard after 14 days	Replace on discharge
	without preservative	Discard after 24 hours	

Lead Speciality

Quality control and production pharmacists

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MAXIMUM SHELF-LIFE FOR STERILE PRODUCTS FOR HUMAN USE AFTER FIRST OPENING OR FOLLOWING RECONSTITUTION

GENERAL STATEMENT:

This guidance applies to all sterile products for human use, with the exception of Radiopharmaceuticals and extemporaneously prepared or modified preparations.

Because it is difficult to predict all the possible conditions under which the product will be opened, diluted, reconstituted and stored, etc., the user is responsible for maintaining the quality of the product that is administered to the patient. In order to help the user in this responsibility, the applicant should conduct appropriate studies and provide the relevant information in the User Information Texts, (e.g. SPC, Package insert, labels) following the examples given in italics below.

The applicant should also take note of the recommendations contained in the European Pharmacopoeia, with respect to storage times and conditions for specific categories of sterile products, once opened.

This guidance relates to the time between opening the product and time of administration to the patient; it takes no account of the duration of the administration process itself

UNPRESERVED STERILE PRODUCTS

General

Chemical and physical in-use stability has been demonstrated for x hours/days at y ^{0}C.

From a microbiological point of view unless the method of opening/reconstitution/dilution precludes the risk of microbial contamination, the product should be used immediately.
If not used immediately, in-use storage times and conditions are the responsibility of the user.

Specific text for Preparations for Infusion or Injection

Chemical and physical in-use stability has been demonstrated for x hours/days at y ^{0}C.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 ^{0}C, unless reconstitution / dilution (etc) has taken place in controlled and validated aseptic conditions

AQUEOUS PRESERVED STERILE PRODUCTS (including antimicrobial preservatives or intrinsically self-preserving)
NON-AQUEOUS, E.G. OILY PREPARATIONS

*Chemical and physical in use stability has been demonstrated for x hours/days at y ^{0}C. From a microbiological point of view, once opened, the product may be stored for a maximum of z days at **t** ^{0}C. Other in-use storage times and conditions are the responsibility of the user.*
The applicant should justify the values of z and t on a case by case basis; z should not normally be greater than 28 days.