4 Developing packaging for medical preparations

Introduction

The packaging of pharmaceuticals is inevitably conservative and because of this new developments tend to originate in other areas and then develop into the fields of medicine. Specialised packages for pharmaceutical products are somewhat slow to develop and tend to be associated with new methods of administering drugs or such specific trends as the unit dose form or methods of bettering compliance.

The Packaging Decision Making process [1]

Apart from the statutory and legal requirements (which will be discussed later) there are a number of general guidelines for all developments in the packaging of pharmaceutical products which are similar to packaging for almost all types of product.

In selecting packaging for any kind of product we must consider the answers to four basic questions:

- What must the packaging achieve?
- What types of packaging are available?
- What are the advantages and disadvantages of any specific package in relation to the available alternatives?
- What costs will result from the choice of each possible packaging, taking into account the other elements of production, marketing and distribution?

Once we have answered the first three questions, which are largely technical, and made sure that we can meet the legislative and statutory regulations in all respects, the final decision will most likely be made on economic grounds, preferably on the basis of the total cost equation and not on the cost of the packaging alone. But whatever the result the process of development will have proceeded along similar lines.

The design of packaging for any product involves three separate but related development areas:

- The structure and form of the package and the packaging materials needed
- The development of the packaging equipment and machinery for
erecting or forming the primary package, filling and closing it, collating and preparing the result for transport and distribution, i.e. the packaging line engineering.

- The labelling, text and graphics requirements to identify and market the product

**Materials and structure of the package**

One of the major requirements for many pharmaceutical products is that sterilisation is required for the product after it has been placed in its primary package. The materials used must therefore withstand whatever method of sterilising is employed.

**Sterilisation of materials [2]**

The special needs of drugs and healthcare products have resulted in the rapid development of a large number of newer packaging systems and materials. In the rapid growth era of sterile medical packaging, these new materials have changed the packaging scene considerably. Spunbonded olefin sheet (Tyvek), and plastics (rigid containers, semi-rigid thermoforms and films) are now replacing the traditional primary packaging materials for medical products – glass, metal, paper and paperboard.

In pharmaceutical terms, sterilisation means the destruction and removal of *all* viable microorganisms (bacteria, viruses or fungi) in order to prevent their gaining access to the human body. It should be remembered that, unlike commercial sterilisation in foods, sterility of medical products is not a matter of degree. A device or medication is either sterile (i.e. absolutely devoid of microorganisms) or it is not.

The chosen method of sterilisation depends not only on the nature of the medication concerned but also upon the packaging, no part of which must be adversely affected by it. Ideally, sterilisation is best carried out after the product has been packaged but this is not always possible and then packaging and product must be sterilised separately, and the filling and closing of the packages is then carried out under aseptic conditions.

The main sterilisation processes are:

- Heat sterilisation (wet and dry)
- Gas sterilisation
- Irradiation (IR, UV, gamma- and electron (E)-beam)
- Sterilisation by chemicals

*Heat sterilisation.* Heat is one of the most effective and reliable means of sterilisation and may be applied in a number of ways.