1 Introduction to the packaging of pharmaceuticals and healthcare products

Introduction

Pharmaceuticals require more detailed packaging than do other sensitive products, such as foods, although there are several similarities in their requirements. Almost every type of modern packaging is used for the wide range of medications and devices now available, but the quantities involved are usually smaller than with foods. Security and integrity of the package are, however, more important and are controlled by licensing arrangements.

Definition

One of the best general definitions of pharmaceutical packaging was proposed by Dean [1]:

an economical means of providing protection, presentation, identification, information and convenience for a pharmaceutical product from the moment of production until it is used or administered.

Probably the most important function of pharmaceutical packaging is protection of the product. Physical damage and chemical deterioration from mechanical and climatic hazards, as well as changes caused by microorganisms must be prevented. The product and packaging materials must be compatible.

Additionally, modern packaging needs to be child resistant and tamper-evident. Advances in packaging technology have led to more complex testing requirements and hence a greater in-depth knowledge is required of traditional as well as newer packaging methods and materials. Convenience and ease of use, hygiene, package integrity, and new dispensing methods must now also be provided for patients.

Drugs need more care in their packaging than do most other products, because any failure in their packaging could result in changes in the drug that lead either to a failure to cure, to illness, to injury or even to death of the patient. A drug must be efficacious, for if it is only palliative then the drug and/or the package is a failure. Potency and bio-availability must both be demonstrated. Requirements in respect of Good Manufacturing
2 PACKAGING OF PHARMACEUTICALS AND HEALTHCARE PRODUCTS

Practice (GMP), improved microbiological standards and better ways of reducing possible contamination all play a part in the package design process.

Types of product

There are two major types of pharmaceutical product: ethical medicines and proprietary medicines (also called over-the-counter [OTC] drugs), and they require different treatment in respect of their packaging.

ETHICAL MEDICINES

Ethical medicines are sold to the public only on a prescription basis. In the USA, mainland Europe and the UK their sale in any other way is prohibited by law. There are some countries where such drugs can be obtained without prescription, but these are few. The principal users of packaging for ethical medicines are doctors, dentists, nurses, pharmacists and medical technicians. However, with the introduction of original pack dispensing (OPD), some ethical drugs are now dispensed to the patient in the same type of package as is used for over-the-counter products.

Requirements for the packaging of ethical medicines. Special attention is required, because both the container and closure must protect the medication from light, water vapour and oxygen, under the conditions of distribution and storage, which are often for longer periods than in the case of OTC products. Both the drug and the packaging must be approved by the regulating authority. While this is also true for OTCs, it is important to remember that OTCs often come in smaller quantities per pack and, as they have to meet the retail selling (marketing) challenge, they will require some display and convenience factors, e.g. transparency and easy opening, not required for ethical packages. A further difference is that OTCs often use more packaging per dose, in order to deliver the message and to get shelf space.

With certain exceptions, all ethical medicines, in whatever form (unit dose, prescription tablets, capsules, oral liquids, some ointments and some creams) were, until the introduction of OPD, always supplied to the pharmacist in bulk packages and repacked for dispensing according to the doctors’ instructions. Fifty years ago, almost all drugs were in liquid form and were contained in stoppered glass bottles. The great majority were also administered in hospitals. Currently, there is great emphasis on solid dosage forms, a decrease in liquid forms and the appearance of many new forms such as inhalers and transdermal patches. The development of new forms presents sophisticated challenges for packing developers.