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edited by
D A Dean E R Evans I H Hall

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11 New Fetter Lane
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Tel: +44 (0)20–7583 9855
Fax: +44 (0)20–7842 2293

29 West 35th Street
New York, NY 10001, USA
Tel: +1 (212) 216 7800
Fax: +1 (212) 564 7854

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Edited by

D.A.Dean
Packaging Consultancy, Education and Training, Nottingham, UK

E.R.Evans
Pharmaceutical Quality Assurance Consultant, Wiltshire, UK

I.H.Hall
Packaging Consultant for Pharmaceuticals and Security, Buckinghamshire, UK

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CONTRIBUTORS

P.L.Corby
(BA, F.Inst.Pkg.)
Retired **D.A.Dean**
(B.Pharm., F.R.Pharm.S., FSS, DBA, F.Inst.Pkg., FIP, SA)
Consultant
Dixie Dean Packaging Consultancy
Education and Training **E.R.Evans**
(F.Inst.Pkg., MIQA)
Consultant
Pharmaceutical Quality Assurance **Dr N.Frampton**
(Ph.D., C.Chem., MRSC)
Business Development Manager
Ernest Jackson Ltd **Dr J.Glasby**
(Ph.D., B.Pharm., BA (Law), M.R.Pharm.S.)
Managing Director
Kendle International Ltd **I.H.Hall**
(BA, M.I.Mgt., M.Inst.Pkg.)
Consultant
Packaging Consultants for Pharmaceuticals and Security

PREFACE

For many years, the role of packaging has been low-profile and rarely understood by the general public who, other than at the point of sale, have considered it almost invisible. However, the increasing publicity associated with environmental issues had tended to identify packaging as environmentally unfriendly. This masked the more important and essential roles of the pack, i.e. its influence on product shelf life and the protection it provides against the various hazards which might cause the product to deteriorate.

Although for many years pharmaceutical packaging has been thought to have a rather dull and negative role, it is now being increasingly realised not only that the pack has a very important function, but that pharmaceutical packaging requires an intensity of testing which exceeds that required for all other products. This is necessary to safeguard both the end user, i.e. the professional person or patient, and the company under the general 'product liability' requirements. It is particularly relevant with certain higher risk products, (i.e. IV solutions, injections and implants) and where the pack is increasingly involved in terms of product administration. Often in these circumstances product and pack cannot be segregated.

In trying to provide a broad overview of packaging for pharmaceuticals it will be inevitable, as with any technical or scientific subject, that certain aspects will quickly become out of date. This is especially likely in the area of directives, guidelines, compendial standards, national standards, etc. where attempts to harmonise, standardise and rationalise are constantly ongoing.

The situation is complicated by the fact that the world can be divided according to its purchasing power. This means that the most profitable areas (EU, Japan, USA, etc.) form a significant part of the pharmaceutical market as the more expensive drugs cannot be purchased in developing countries. In terms of packaging, technical weaknesses can be readily highlighted by the fact that problems found and solved in the developed world (even 30–40 years ago) tend to repeat themselves in the less developed territories (e.g. those associated with moving from glass to plastics). This book, therefore, endeavours to span the historical detail of the past as well as giving insight into the trends of tomorrow for the developed world. For example, the problem of environmental stress cracking was experienced in the mid-1950s when detergent solutions moved from metal and glass packaging into plastic. However, the same problem was found 35 years later in a developing country on a very large scale, as people there were unaware of the problem and its solution. Thus while international travel (to the masses) was virtually non-existent before 1960 but is well accepted today, it is suggested that a book on pharmaceutical packaging must involve at least a similar period of history, as learning must start with a certain level of basic knowledge. For example, glass packaging 60 years ago was in an era of long necks, square corners, sunken panels, heavy in weight, to achieve adequate distribution of wall thickness and closed with corks or ground glass stoppers. Today most of these features would be associated with antiquity and poor design. However, some of these designs can still be found in developing countries being manufactured on second- and third-hand equipment which started its life in the developed world. This is common to many industries.

In this book I have drawn from the past 50 years of experience in the packaging industry together with valuable contributions from P.L.Corby, E.R.Evans, N. Frampton, J.Glasby and I.Hall, which in total will provide an in-depth background for the next generations.

One inevitable conclusion is that the subject of pharmaceutical packaging can only become more complex with the passage of time, and hence will need even greater attention to detail.

D.A.Dean

Technical editor's note

Technology is synonymous with change and this is as true of pharmaceutical packaging as it is of electronics.

As this book is finalised for publication, I have seen advisory notices on several new British Standards (e.g. BS EN 12377: 1999, Packaging flexible tubes—test methods for the airtightness of closures; and BS EN 14632:1999, Extruded sheets of polyethylene, requirements and test methods). There has been further reference to increased legislation (e.g. regulatory

control of suppliers of pharmaceutical starting materials), and I can anticipate that the impending launch of ISO 9000, in its ISO 9000:2000 format, will result in increased customer demands on suppliers.

Compared with the relative price stabilty of oil throughout the 1990s, the year 2000 has been accompanied by continuing price escalation which, if it continues, will eventually filter through to increased plastic costs and the possible decline in some applications where there are alternatives.

A further, possibly even greater change concerns the rationalisation of the pharmaceutical industry where well-known companies apparently disappear and are lost within a new derived company identity. Here it seems too easy to lose the accumulated data, wisdom and experience that went into the creation of a specification, a standard or even a product.

The modern history of packaging is one of change, often but not always leading to improvement, and the readers of this book, particularly those with a career in the supply or use of packaging materials, must above all maintain an awareness of changes to materials, specification, standards and regulatory legislation.

Lastly, a close technical relationship with the supplier(s) is essential, not only for operational efficiency but also to ensure the supplier's/suppliers' appreciation of the implication of uncontrolled change on the stability of the pharmaceutical product.

E.R.Evans