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Data Sheet Compendium 1978

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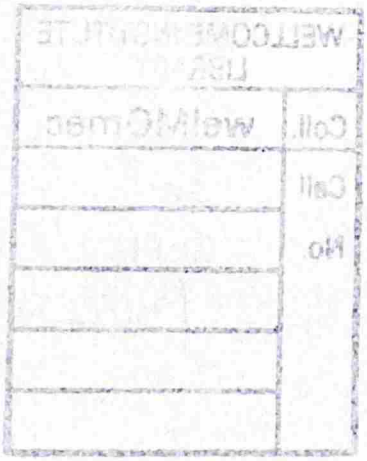

Pharmind Publications Limited
162 Regent Street London W1R 6DD

The compendium

An Alphabetical index of products, an index of non-proprietary names and a directory of participating companies (together with their telephone numbers) are provided in the tinted section at the back of the compendium.

Data sheets

Data sheets are supplied to practitioners in order to comply with the requirements of the Medicines Act 1968.

They are prepared by the individual companies concerned and, in consequence, vary somewhat in style. All follow, however, the requirements which are laid down by 'The Medicines (Data Sheet) Regulations 1972'.

Participation in the compendium is open to all companies manufacturing medicinal products intended for use under medical supervision.

Further information

The regulations which relate to data sheets restrict the scope of the material which may be given under the heading 'Further information' and require insertion of the word 'Nil' in any data sheet where there is no entry under that heading. Manufacturers are, of course, none the less always willing to provide additional information on their products upon request.

Enquiries should be directed to the companies concerned.

Responsibility for accuracy

The individual companies concerned are responsible for the accuracy of the information given in their data sheets and for its compliance with the regulations. No responsibility is accepted either by the Association of the British Pharmaceutical Industry (ABPI) or by Pharmind Publications Limited.

Date of preparation

The data sheets included in this compendium were prepared or reviewed during the third quarter of 1977 and the compendium itself was published in January 1978.

Trade marks

An asterisk by the name of a product indicates that the name is a trade mark. The company symbols which appear in certain participants' sections are also trade marks.

Legal category

The legal categories which are given in the Compendium are those which will apply when Part III of the Medicines Act 1968 is implemented. At the time of going to press, it was anticipated that the new legal categories would be effective as from 1 February, 1978.

As, however, the relevant statutory instruments had not been made when the content of this publication was finalised, the information given is by way of guidance only.

The following abbreviations are used under the heading 'Legal category' in entries in the Compendium.

GSL A preparation which is included in the General Sale List.

P A pharmacy sale medicine which can be sold only from a retail pharmacy.

POM A prescription only medicine.

MDA A preparation containing a substance included in Schedule 2 to the Misuse of Drugs Regulations 1973 (Misuse of Drugs Act 1971).
Doctors are reminded that the Misuse of Drugs Regulations 1973 lay down special requirements relating to the writing of prescriptions for products coming within Schedule 2.

The reporting of adverse reactions

One of the functions of the Committee on Safety of Medicines is to collect and study reports of adverse reactions to medicines. All doctors and dentists in the United Kingdom are encouraged to report toxicity or side-effects that they observe or suspect.

Certain products, which are marked ▼, are recent introductions, and doctors are therefore particularly requested to report details of all suspected adverse reactions to the Committee on Safety of Medicines, preferably on the yellow card issued by the Committee. They are asked to continue to report serious or unusual reactions to all other products.

Even incomplete reports can be helpful and practitioners should not be deterred from reporting because some details are not known.

Special postage-paid forms ('yellow cards') are provided for reports. Supplies of these can be obtained from the Committee at Finsbury Square House, 33/37A Finsbury Square, London EC2A 1PP, telephone 01-638-6020.

The above statement and the symbols marking certain products have been included in the compendium at the request of the Medicines Division of the Department of Health and Social Security.

The individual companies concerned would find it helpful to be informed by practitioners of any adverse reactions to their products which are reported.

Code of Practice for the Pharmaceutical Industry

Fourth edition (January 1974)

For many years members of the Association of the British Pharmaceutical Industry have agreed to voluntarily observe the principles set out in a *Code of Practice for the Pharmaceutical Industry*; a Code which regulates the standards of conduct to be followed in the marketing of medicines intended for use under medical supervision.

The Code was first published in 1958 and has been regularly revised to take account of changes in marketing practices. A fourth edition was introduced in 1974 and, as in the case of previous editions, publication followed consultation with the British Medical Association. The Code embodies the basic principles and procedures which the pharmaceutical industry believes to be essential for the conduct of its marketing activities and for the maintenance of standards which are in the interests alike of the public, the medical and allied professions and the industry.

On occasion, the criticism has been made that members of the medical profession were not aware of the provisions of the Code and, consequently, that the Code had been less effective than might otherwise have been the case. To ensure that these provisions become better known, the fourth edition of the Code has been reproduced in its entirety below.

Those who feel that the promotion of a medical speciality product has fallen below the standards which are required by the Code may write, if they so wish, to the Secretary, Code of Practice Committee, Association of the British Pharmaceutical Industry, 162 Regent Street, London W1R 6DD, and ask that the matter be investigated.

At the time of going to press, the Code of Practice was under review.

INTRODUCTION

a This Code of Practice for the Pharmaceutical Industry has been drawn up after consultation with the British Medical Association.

b The Code owes its origin to the determination of the Association of the British Pharmaceutical Industry to secure the universal acceptance and adoption of high standards of conduct in the marketing of medical products designed for use under medical supervision.

c Medical products usually owe their existence to research carried out by their manufacturers or to the development by them of results of academic research. Before a medical product is placed on the market the manufacturer will have accumulated considerable toxicological, pharmacological and clinical evidence and will have met all the statutory requirements for the testing, manufacture, and marketing of that product. With the full co-operation of the industry there is now an abundance of legislation designed to safeguard the public by ensuring that all products marketed meet standards of purity, effectiveness and safety which are acceptable in the state of present knowledge and experience.

d It is necessary, however, for the manufacturer, operating as he does in a keenly competitive industry and serving a profession for which freedom of choice is essential, to draw attention to the existence and nature of a particular product; for example, by appropriate promotional measures and the dissemination of further knowledge and experience gained in widespread use.

e While it is possible to legislate satisfactorily for the testing, manufacture and control of medical products, appropriate standards of marketing conduct cannot be defined by the same means. For this reason responsible manufacturers have concurred in the promulgation of the Code of Practice and submitted to its restraints.

f The Code emphasises the importance in the public interest of providing the medical and allied professions with accurate, fair and objective information on medical products so that rational prescribing decisions can be made. Moreover, the Code accepts the principle that such information should be presented in a form and by ways and means which conform not only to legal requirements but also to professional standards of ethics and canons of good taste.

The industry recognises its obligation to provide information about medical products to the pharmaceutical profession and the principles set out in this Code, therefore, apply equally to communications addressed to that profession. However, there may be rare instances where compliance with every provision of the Code would be inappropriate; for example, in connection with promotional material the purpose of which is to convey information of a commercial nature to pharmacists or pharmaceutical distributors.

g The Code, therefore, represents an act of self-discipline. Acceptance and observance of its provisions are a condition of membership of the Association of the British Pharmaceutical Industry. Member companies also acknowledge that the Code itself is to be applied in the spirit, as well as in the letter.

Pharmaceutical companies outside the Association are invited to accept and observe the Code because it is considered that high ethical standards should be

followed throughout the whole industry if it is to maintain the confidence of all the interests which it serves.

h The Code is administered by a Committee set up by the Board of Management of the Association. The Committee, with an independent legally qualified Chairman from outside the industry, consists of twelve members who are drawn from senior management and includes at least three medical directors (or medically qualified persons of equivalent status) of member companies. The Committee can turn for advice to a Panel of medically qualified persons not engaged in the industry. In addition, the Chairman has general authority to obtain expert assistance in any field, and has an original and a casting vote.

i The Committee meets regularly to deal with complaints, to secure compliance with the Code, and to make such recommendations as it deems fit for the amendment of the provisions of the Code.

j An outstanding feature of the work of the Committee over the years has been the success of voluntary compliance with the provisions of the Code and acceptance of rulings of the Committee. It has not been found necessary in practice to apply sanctions to secure compliance because subscribing members of the industry are anxious to ensure that their marketing activities conform to the highest standard.

k It is important, therefore, that the Code should accurately reflect that standard and for this reason it is kept under constant review by the Board of Management and amended from time to time where necessary to clarify it and bring it up to date. Notes for the guidance of member companies are issued periodically to keep them informed of the rulings and recommendations of the Committee and of any alterations to the Code.

l This edition of the Code supersedes all previous issues and is the fourth edition since the Code was first established in 1958. It embodies the basic principles and provisions which the pharmaceutical industry believes are essential for the conduct of its marketing activities and for the maintenance of standards which are in the interests alike of the public, the medical and allied professions and the industry.

PROVISIONS OF THE CODE

1 Definition of certain terms

1.1 The term 'promotion' means those marketing activities, coming under the control of the manufacturer, the purpose of which is to encourage the prescribing or use of the manufacturer's products. It includes, for example, the activities of representatives; various aspects of sales promotion such as journal and direct mail advertising; the use of films and other audio-visual material and exhibitions; and the provision of samples, gifts or hospitality.

1.2 The term 'medical product' means any unbranded or branded pharmaceutical product intended for use in humans which is promoted and advertised to the medical profession rather than directly to the lay public.

2 Methods of promotion

Methods of promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.

3 Nature and availability of information

3.1 Upon reasonable request, the manufacturer shall promptly provide members of the medical profession with accurate and relevant information about the medical products which he markets.

3.2 Information about medical products should accurately reflect current knowledge or responsible opinion.

3.3 Information about medical products must be accurate, balanced and must not mislead either directly or by implication.

3.4 Information must be capable of substantiation, such substantiation being provided without delay at the request of members of the medical profession.

4 Claims and comparisons

4.1 Claims for the usefulness of a medical product must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly. Such claims must have prior medical review and approval.

4.2 Exaggerated claims should not be made and all-embracing claims and superlatives avoided. Claims should not imply that a medical product, or an active ingredient, has some special merit, quality or property unless this can be substantiated.

4.3 The word 'safe' must not be used without qualification and it must not be stated categorically that a product has no side-effects, toxic hazards or risk of addiction.

4.4 The word 'new' should not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been generally promoted, for more than 12 months in the United Kingdom.

4.5 Comparisons of products must be factual, fair, and capable of substantiation. In presenting a comparison, care must be taken to ensure that it does not mislead by distortion, by undue emphasis or in any other way.

4.6 Brand names of products of other manufacturers must not be used in comparison unless the prior consent of the manufacturers has been obtained.

5 Disparaging references

5.1 The products or services of other manufacturers should not be disparaged either directly or by implication.

5.2 The clinical and scientific opinions of members of the medical and allied professions should not be disparaged either directly or by implication.

6 Printed promotional material

6.1 The Medicines Act requires a pharmaceutical company to provide a practitioner with a data sheet before promoting a product directly to him. The content of such data sheets is determined by regulations made under the Medicines Act.

6.2 Manufacturers must include certain information, as specified in this Code, on all other printed material (including journal advertising) for promotional purposes which is issued by the manufacturer or appears with his consent.

6.3 Where the purpose of the printed promotional material is to provide the medical profession with sufficient information upon which to reach a decision for prescribing or for use, then the following information must be given clearly and concisely:

(i) A quantitative list of the active ingredients, using approved or other non-proprietary names, contained in each unit or dose.

(ii) Recommended dosage, method of use and route of administration.

(iii) Side-effects, precautions and contra-indications of the product in the recommended dosage.

(iv) A statement that additional information is available on request.

(v) The company name and address.

Note (a) Where a data sheet, prepared in accordance with the requirements of the Medicines Act, accompanies the promotional material, the requirements of Clause 6.3 (i)–(iii) will be satisfied by the inclusion of the information in the data sheet.

(b) Where a reference is made to dosage and if any of the information required under Clause 6.3 (i)–(iii) is omitted, a statement that full prescribing information is available or that a data sheet accompanies the promotional material should be displayed boldly and prominently.

6.4 Where the purpose of the printed promotional material is to remind recipients of the availability and of the main indication of a product, or where it is demonstrably and obviously impracticable to display legibly the full information required under Clause 6.3, the following minimum information must be given:

(i) The approved or other non-proprietary names of the active ingredients.

(ii) A statement 'full prescribing information is available'.

(iii) The company name and address.

6.5 Promotional material, such as mailings and journal advertisements, must not be designed to disguise its real nature.

6.6 Promotional material should conform, both in text and illustration, to canons of good taste and should recognise the professional standing of the recipients.

6.7 Doctors' names or photographs must not be used in a prominent manner in promotional material or in any other way that is contrary to the ethical code of the medical profession.

6.8 Promotional material should not imitate the devices, copy, slogans or general layout adopted by other manufacturers in a way that is likely to mislead or confuse.

6.9 Where appropriate, for example in technical and other informative material, the date of printing or of the last review should be stated.

6.10 Extremes of format, size or cost of printed material should be avoided.

6.11 Post-cards, other exposed mailings, envelopes or wrappers should not carry matter which might be regarded as advertising to the lay public or which could be considered unsuitable for public view.

6.12 Telegrams must not be used for promotional purposes.

7 References to the Committee on Safety of Medicines

Unless specific requirements with regard to distribution or use have been imposed, manufacturers should not include in any announcement or promotional material a statement that the marketing of the product has been approved by the Committee on Safety of Medicines.

8 References to the National Health Service

8.1 Where reference is made to the prescribing of a product under the National Health Service, the phrase 'freely prescribable' or similar phrases suggesting a lack of restriction or restraint must not be used.

8.2 The 'basic NHS cost' of products must be given in all promotional literature, except where references to this cost would clearly be inappropriate.

8.3 Reproductions of official documents, such as prescription form EC10, should not be used for promotional purposes unless the agreement of the appropriate Government department has been received.

9 Distribution of printed promotional material

9.1 Promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information can reasonably be assumed.

9.2 Any information designed to encourage the use of medical products in clinics, industrial concerns, clubs or schools must be addressed to the medical adviser or medical officer or to medical auxiliary staff.

9.3 Restraint should be exercised on the frequency of distribution and on the volume of promotional material distributed.

9.4 Mailing lists must be kept up to date. Requests from doctors to be removed from promotional mailing lists must be complied with promptly and no name may be restored except at the doctor's request or with his permission.

10 Reprints, abstracts and quotations

(such use is, of course, subject to the law of copyright)

10.1 Reprints of articles by members of the medical profession must not be included in mailings but may be supplied to individual doctors on request. It is permissible to include in promotional material reasonably brief abstracts of, or quotations from, articles by members of the medical profession and to include in such material references to doctors' names in a bibliography of published works. In no case, however, should doctors' names be used in a prominent manner in promotional material.

10.2 Quotations from medical literature, or from personal communications received from doctors, must accurately reflect the meaning of the author and the significance of the study.

11 Medical representatives

11.1 Representatives must be thoroughly trained and possess sufficient medical and technical knowledge to present information on the company's products in an efficient manner.

11.2 Representatives should at all times maintain a high standard of ethical conduct in the discharge of their duties.

11.3 Representatives must not employ any inducement or subterfuge to gain an interview.

11.4 Representatives must ensure that the frequency, timing and duration of calls on doctors, or on hospitals, together with the manner in which they are made, are such as not to cause inconvenience. The wishes of an individual doctor, or the arrangements in force at any particular establishment, must be observed by representatives.

11.5 Representatives must take adequate precautions to ensure the security of medical products in their possession.

11.6 Representatives must not use the telephone to promote products to the medical profession unless prior arrangement has been made with individual doctors.

12 Samples

12.1 Samples of products restricted by law to supply on prescription, and of any other products that it would be unsafe to use except under medical supervision, must not be sent to doctors except in response to their instructions.

12.2 The size and quantity of the sample supplied should be appropriate for either:

(a) Familiarisation with the presentation and appearance of a product.

or

(b) The provision to patients for immediate use of an initial small supply of a product.

or

(c) The conduct of an agreed clinical evaluation of the product by the doctor.

12.3 Where samples of products restricted by law to supply on prescription are distributed by a representative, the sample must be handed direct to the doctor or given to a person authorised to receive the sample on his behalf. A similar practice must be adopted for products which it would be unsafe to use except under medical supervision.

12.4 Samples of products restricted by law to supply on prescription, which are made available to representatives for distribution, should be strictly limited in quantity and an adequate system of accountability should be established.

12.5 Samples sent by post must be packed so as to be reasonably secure against the package being opened by young children.

12.6 Distribution of samples in hospitals should comply with individual hospital regulations, if any.

13 Gifts and inducements

13.1 Subject to Clause 13.2, no gifts or financial inducements shall be offered or given to members of the medical profession for purposes of sales promotion.

13.2 Gifts in the form of articles designed as promotional aids, whether related to a particular product or of general utility, may be distributed to members of the medical and allied professions provided the gift is inexpensive and relevant to the practice of medicine or pharmacy.

13.3 If a promotional aid of the type mentioned in Clause 13.2 incorporates more than the product name or a brief slogan, the requirements of Clause 6 shall apply.

14 Hospitality

Entertainment or other hospitality offered to members of the medical and allied professions should be modest in nature and cost and always secondary to the main purpose of the meeting. It should not extend beyond members of the profession; it should be appropriate and not out of proportion to the occasion.

15 Market research

15.1 Methods used for market research must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. The following provisions apply whether the research is carried out directly by the manufacturer or by an organisation acting on his behalf.

15.2 Access to respondents must not be gained by subterfuge.

15.3 Any incentives given should be kept to a minimum and be commensurate with the work involved.

15.4 Questions intended to solicit disparaging references to competing products or manufacturers must be avoided.

15.5 Market research must not be used as a form of disguised sales promotion.

16 Relations with the general public and lay communication media

16.1 Requests from individual members of the public for information or advice on personal medical matters must always be refused and the enquirer recommended to consult his or her own doctor.

16.2 Information about a scientific discovery or a medical product should normally be supplied only where it is desirable or necessary to do so in the public interest or where the object is to keep the public informed of scientific and medical progress. However, there may be circumstances where disclosure to the public as shareholders or as persons with some other special and valid interest may be required or be desirable.

16.3 Information must be presented in a balanced way to avoid the risk of raising unfounded hopes in the public mind from the results of treatment. Statements must not be made or designed for the purpose of encouraging members of the public to ask their doctor to prescribe a product.

16.4 Information about a new medical product must not be released to the general public by the manufacturer until the medical profession has been informed of its availability, except in so far as the circumstances in Clause 16.2 may apply.