



Royal Pharmaceutical Society Of Great Britain

Legal and Ethical Advisory Service Fact Sheet: Three

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, and the effect thereof

Introduction

This is an information sheet designed to be of assistance to pharmacists and others with like interests. The contents have not been issued as Council policy, but it is intended as a resource which pharmacists may use to review their practices and policies. It is not intended to interpret the law, the Code of Ethics or Council policies, but offers common sense guidance on issues of topical interest

All of the issues addressed will be within the enforcement jurisdiction of the Department of Health via the Medicines and Healthcare Products Regulatory Agency. A list of contact telephone numbers can be found at the end of this fact sheet.

If any further queries arise, please do not hesitate to contact the Legal and Ethical Advisory Service on 020 7572 2308 for further clarification. Email queries may be sent to leadvice@rpsgb.org.

The Legislation

On 1st January 1994 **The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994** came into force. (Hereinafter referred to as "The Regulations"). These Regulations implemented into national law a number of European Council Regulations and Directives relating to medicinal products in the European Community.

The underlying principle of The Regulations is laid down in Regulation 3. Regulation 3 states that, subject to a limited number of exemptions, except where a marketing authorisation has been granted in accordance with the relevant Community provisions by the licensing authority *no relevant medicinal product shall be placed on the market or distributed by way of wholesale dealing.*

The Labelling of Relevant Medicinal Products

Relevant medicinal products are those to which Chapters II to V of the 65/65 European Directive applies. In essence, all medicinal products which are commercially produced fall within the definition, and must be labelled as shown below. The labelling directive came into effect on January 1, 1994, since when all new licensed medicinal products and all those products undergoing renewal of their product licences are required to comply. Since January 1, 1999 all commercially produced medicines have been required to comply with the following. The particulars required are:

- a) the name of the product followed, where the product contains one active ingredient and its name is an invented name, by the common name; where a product is available in several pharmaceutical forms and/or several strengths, the pharmaceutical form and/or strength must be included in the name.
- b) a statement of the active ingredients of the product expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using the common names of the ingredients;
- c) the pharmaceutical form of the product;
- d) the contents of the product by weight, by volume or by number of doses of the product;
- e) a list of excipients known to have a recognised action or effect. In relation to products which are injectable or are topical or eye preparations, all excipients;
- f) the method and, if necessary, the route of administration of the product;
- g) a special warning that the product must be stored out of reach of children;
- h) any special warning required by the product licence for the product concerned;
- i) the expiry date of the product (stating the month and year) in clear terms;
- j) any special storage precautions for the product;
- k) any special precautions for the disposal of any unused products or waste materials derived from such products;
- l) the name of the holder of the product licence of the product;
- m) the address of the holder of the product licence of the product;
- n) any product licence number as allocated by the licensing authority which relates to the product preceded by the letters "PL" in capital letters or other abbreviation of the expression "product licence;"
- o) the manufacturer's batch reference;
- p) where a product is intended for self-medication, any instruction on the use of the product.

All labelling of containers and packages of relevant medicinal products shall be:

- a) legible and indelible;
- b) comprehensible; and
- c) either in the English language only or in English and in one or more other languages provided that the same particulars appear in all languages used.

Containers and packages of relevant medicinal products may be labelled to show:

- a) a symbol or pictogram designed to clarify the above particulars;
- b) other information compatible with the summary of product characteristics which is useful for health education. There must not be any labelling of a promotional nature.

In any case where a relevant medicinal product is available in more than one pharmaceutical form or strength; and the name of that product does not include the pharmaceutical form and the strength of the product, in a place where the label prominently shows the name of the product there shall be added immediately after the name, in the same style and size of letters as the name, a statement of the pharmaceutical form or strength of that product; in this paragraph "strength" means the suitability of the product for a baby, child or adult. The requirement for a container or package of a relevant medicinal product to be labelled to show its name is not met by the container or package being labelled to show an invented name which is liable to be confused with the common name.

The Requirement for Patient Information Leaflets

The Regulations place various obligations on the holders of marketing authorisations for relevant medicinal products, one of which has been discussed in relation to their labelling. Another obligation is the requirement for a patient information leaflet which complies with the specifications laid down in the Regulations and the various European Directives.

Schedule 3 paragraph 12 to The Regulations states the following:

Where in relation to a relevant medicinal product-

- a) *the labelling of the product, or any package leaflet accompanying the product, does not comply with; or*
- b) *the product is not accompanied by a package leaflet required to be provided by virtue of,*

the applicable requirements of Council Directive 92/27 EEC or Schedule 5, any person, other than the holder of the marketing authorisation for that product, who in the course of a business carried on by him, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe that the labelling does not so comply or, as the case may be, that the product is not so accompanied, shall be guilty of an offence.

Each time a pharmacist makes a supply of or sells a relevant medicinal product, be this in the community, to hospital outpatients, hospital inpatients or to discharge patients then this section applies.

It follows that if the marketing authorisation of the product in question requires a patient information leaflet to be supplied and one is not supplied then an offence is committed under The Regulations.

There is, at the time of preparation of this fact sheet, considerable variation in the availability of patient information leaflets, with manufacturers' packs. As the most important reason for supplying a leaflet is patient information and patient safety, every effort should be made to supply a leaflet. In the first instance, pharmacists should contact manufacturers directly to try and obtain additional copies of leaflets. Pharmacists should also be aware of web based versions of leaflets. Although not yet fully comprehensive, leaflets are available through the Electronic Medicines Compendium. (www.emc.medicines.org.uk). These could be printed out and supplied by pharmacists with dispensed medicinal products to ensure compliance with the Regulations. As a last resort, pharmacists may have to consider photocopying manufacturers'

leaflets if practicable. This could breach copyright, but pharmacists may be left with no alternative. Pharmacists may therefore wish to seek independent legal advice before undertaking any photocopying. In any event, copies must only be supplied with that manufacturer's product and care must be taken to ensure that only the latest version of a leaflet is copied.

Other information produced in addition to the PIL which is not a requirement of the Regulations may have to be considered under The Medicines Advertising Regulations 1994. Regulation 6 of which prohibits the issue of an advertisement, which is likely to lead to the use of a relevant medicinal product for the purpose of treatment, prevention or diagnosis of any disease, specified in Schedule 1. This covers many of the diseases treated in hospital. Pharmacists should therefore exercise caution before producing their own information leaflets. A self-made patient information leaflet cannot replace the marketing authorisation holders PIL which still must be supplied in accordance with the Regulations. Pharmacists may wish to discuss the matter with their respective legal advisers.

Patient Information Leaflets in Hospitals

The Department of Health has stated that medicines used in hospitals are recognised as falling into a special category. PILs are not required to be included in the packaging of hospital dispensed products for inpatients, but should be held in the pharmacy or on the ward so that the PIL can be provided to the patient or prescriber on his or her request. The patient should be aware of his or her right to see the PIL. For outpatients a PIL should be provided in each case.

Even where a product is used outside the terms of its marketing authorisation for an unlicensed indication, the PIL should be supplied in the packaging in order to meet the requirements of Article 6 of Directive 92/27 EEC.

The requirements of the Directive do not extend to extemporaneously prepared products which are not covered by a marketing authorisation.

Packing down Relevant Medicinal Products from Bulk

The Medicines Act 1968 Section 10 provides various exemptions for pharmacists from the formal licensing requirements detailed in the Act. Section 10 states the following:

“... the restrictions imposed do not apply to anything which is done in a registered pharmacy, a hospital or health centre and is done there by or under the supervision of a pharmacist of a pharmacist and consists of:-

- a) preparing or dispensing a medicinal product in accordance with a prescription given by a practitioner, or
- b) assembling a medicinal product (provided that where the assembling takes place in a registered pharmacy)
 - i. it shall be in a registered pharmacy at which the business in medicinal products carried on is restricted to retail sale or to supply in circumstances corresponding to retail sale and the assembling is done with a view to such sale or supply either at that registered pharmacy or at any other such registered pharmacy forming part of the same retail business; and

- ii. the medicinal product has not been the subject of any advertisement.”

This section must though be read in the light of what has already been said about the labelling and leafleting of relevant medicinal products. A pharmacist packing down a relevant medicinal product for a sale over the counter would find it difficult to provide a patient information leaflet or indeed label in accordance with all the requirements of the Directive. It is for this reason that pharmacists are advised against packing down relevant medicinal products from bulk into smaller containers for over the counter sale, for example 100 Ferrous Sulphate. Commercially available patient packs should be obtained which come labelled and leafleted appropriately, where available.

The Labelling of Assembled (Pre-packed Medicines)

Some pharmacists assemble medicines by breaking down bulk containers into quantities more appropriate for use against prescriptions. This, technically, falls into the definition of assembly, and all medicines should be properly labelled. Medicines repackaged in this way can only be sold or supplied from that pharmacy or from another pharmacy under the same ownership.

Note: Packaging pre-packs at the request of medical practitioners is not permitted without an assembly licence.

The labelling particulars which are required are those stated in Article 2(1) of Directive 92/27/EEC as applicable (see section: Labelling of Relevant Medicinal Products)

All medicines assembled in such a way must be re-labelled before being supplied to a patient as a dispensed medicinal product

APPENDIX

Department of Health contacts

(1) The Medicines and Healthcare Products

Regulatory Agency (Tel: 020 7084 2000)

Post Licensing Division (Head of Division: Dr June Raine)

National Yellow Card Information Service - 0800 731 6789

Reclassification: Mrs Williams - 020 7084 2523

Advertising & Leaflets and Labels: Mrs MacDonald – 020 7084 2267

Inspection and Enforcement (Head of Division: Dr Gordon Munro)

Manufacturers' Licences: Ms Baloch – 020 7084 2442

Wholesale Dealers' Licences: Ms Baloch – 020 7084 2442

Enforcement: Mrs Scammell – 020 7084 2665

Borderline Products: Mr Carter – 020 7084 2613

Executive Support (Head of Division: Mr Roy Alder)

Herbal Products: Mr Brittain – 020 7084 2604

(2) The Office of the Chief Pharmacist (Tel: 020 7210 5483)

Chief Pharmacist: **Dr Jim Smith**

Principal Pharmacists: **Miss Diane Kennard, Mrs Sue Faulding**