



4 Medicines for Human Use: Labelling, Advertising and Devices



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4.1 LABELLING OF MEDICINAL PRODUCTS

The containers of relevant medicinal products sold or supplied in the United Kingdom must be labelled in accordance with the Medicines (Marketing Authorisations etc) Regulations 1994 as amended. Medicines not classed as relevant medicinal product and therefore not covered by this legislation should be labelled in accordance with the Medicines (Labelling) Regulations 1976, as amended.

Those medicinal products that are Schedule 2 or 3 Controlled Drugs must also be labelled in accordance with the Misuse of Drugs (Northern Ireland) Regulations 2002 (see relevant section). The labelling of medicines has become much more complex following the adoption of European Directives. The main labelling activities that may be embarked upon by pharmacists are described below. Any pharmacist who undertakes any other labelling of medicinal products should seek advice from the DHSSPS.

See separate section (1.4) on labelling requirements in the event of a pandemic (page 35). For labelling requirements for Medicines for Veterinary Use, and Non-Medicinal Poisons, please refer to relevant sections of the Guide to Legal Requirements.

The following guidance on legal requirements for the labelling of medicinal products is divided into the following sections:

- Labelling of dispensed medicinal products
- Labelling of assembled (pre-packaged medicines)
- Labelling of chemists' nostrums
- Labelling of relevant medicinal products
- Labelling of dispensed non-relevant medicinal products/unlicensed medicines
- BANs and rINNS
- Warnings and other special labelling requirements
- Labelling of General Sale List Products
- Labelling of products for pharmacy sale only
- Labelling of Prescription Only Medicines

Refer to Glossary section of the Guide to Legal Requirements for definitions of terms used.

Labelling of dispensed medicinal products

A dispensed medicinal product, so far as a pharmacist is concerned, is defined as:

- a medicinal product prepared or dispensed by a practitioner or prepared or dispensed in accordance with a prescription given by a practitioner, or
- a medicinal product for use by being administered to human beings where that

medicinal product has been sold or supplied by a doctor or dentist for administration to a particular patient of his and that doctor or dentist sells or supplies that medicinal product to that patient or to a person under whose care that patient is, or

- a medicinal product prepared or dispensed in a registered pharmacy by, or under the supervision of, a pharmacist in the circumstances set out in sections 10(3) or 10(4)(a) of the Medicines Act, (those items prepared by the pharmacist either in accordance with a specification furnished by the customer, or after the patient has asked the pharmacist to use his judgement as to the most appropriate medicine), or
- a medicinal product where the person selling or supplying the medicinal product sells or supplies it for administration to a particular person after being requested by, or on behalf of, that person and in that person's presence to use his own judgement as to the treatment required (i.e., counter prescribed).

The labelling requirements for dispensed relevant medicinal products are taken from the Medicines (Marketing Authorisations etc) 1994 SI No. 3144, as amended.

The labelling requirements for dispensed non-relevant medicinal products are taken from the Medicines (Labelling) Regulations 1976, as amended.

Examples of such products are chemists' nostrums and unlicensed medicines.

The labelling requirements for dispensed relevant and for non-relevant medicinal products are the same. The only additional requirement for dispensed non-relevant medicinal products is item (d) below.

The container of a dispensed medicinal product must be labelled to show the following particulars:

- the name of the person to whom the medicine is to be administered;
- the name and address of the person who sells or supplies the medicinal product;
- the date of dispensing;
- directions for use (these may be omitted if the product is one made to the specification of the person for whom it is prepared or dispensed); the words "Keep out of the reach of children" or words of direction bearing a similar meaning*;
- where the medicinal product has been prescribed by a practitioner such of the following particulars as he may request namely,
 - i the name of the product,
 - ii directions for use,
 - iii precautions relating to the use of the product,

If the pharmacist is of the opinion that any of those particulars are inappropriate and he is unable to contact the prescriber, he may substitute other particulars of the same kind;

- the phrase “For external use only” within a rectangle if the product is not on a General Sale List and is an embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external use only;
- if the product contains hexachlorophene, either the words “Not to be used for babies”, or a warning that the product is not to be administered to a child under two years except on medical advice. This wording must be within a rectangle within which there is no other matter.

*It is recommended that the phrase “Keep out of the reach and sight of children” should be placed on dispensing labels. This requirement is one of good practice and is not currently a mandatory requirement.

Where several containers of medicinal products of the same description are supplied in a package, the particulars required under (f) need only appear on the package containing all the products, or may appear on only one of the individual containers or packages. All the remaining containers must, however, be labelled with all the other particulars. A container need not be labelled if it is enclosed in a package that is labelled with the required particulars (except for hexachlorophene warnings that are required on both container and package).

Other information may be added if the pharmacist considers it to be necessary.

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 within 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. Pre-packing at the request of a medical practitioner is not permitted without an assembly licence.

The particulars that are required are:

- the name of the medicinal product;
- the appropriate quantitative particulars of the medicinal product (the ingredients);
- the quantity of the medicinal product in the container;
- any special requirements for the handling and storage of the medicinal product;
- the expiry date;
- the batch reference, preceded by the letters “BN” or “LOT” or other letters indicating a batch reference.

All medicines assembled in such a way must be re-labelled before being supplied to a patient, either as a dispensed medicinal product, or with the standard labelling particulars.

Labelling of chemists' nostrums

The following requirements apply to medicinal products that are prepared in a registered pharmacy for retail sale from that pharmacy **and that are not advertised**. (Such products are familiarly known as "chemists' nostrums". See Section 10 of the Medicines Act). The preparation and the sale or supply must be carried out by or under the supervision of a pharmacist.

The label of the container of such a medicinal product and any package immediately enclosing it must show the following standard labelling particulars:

- name of the product;
- pharmaceutical form;
- appropriate quantitative particulars;
- quantity;
- directions for use;
- handling and storage requirements (if any);
- expiry date;
- the words "Keep out of the reach of children" or words of a similar meaning; where appropriate, the words "Warning. Do not exceed the stated dose", in a rectangle in which there is no other matter (this would be necessary where one or more of the ingredients are Prescription Only Medicines, incorporated in such a way as to exempt it from Prescription Only control);
- the name and address of the seller;
- the letter P in a rectangle.

Labelling of relevant medicinal products

A relevant medicinal product is required to be labelled with the following particulars:

- the name of the product followed by its strength and pharmaceutical form, where the product contains one active ingredient and its name is an invented name, by the common name;
- 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; the pharmaceutical form of the product;
- the contents of the product by weight, by volume or by number of doses of the product;
- a list of excipients known to have a recognised action or effect. In relation to products that are injectable or are topical or eye preparations, all excipients; the method and, if necessary, the route of administration of the product;
- a special warning that the product must be stored out of the reach and sight of children;
- any special warning required by the Marketing Authorisation for the product concerned;

- the expiry date of the product (stating the month and year) in clear terms;
- any special storage precautions for the product;
- any special precautions for the disposal of any unused products or waste materials derived from such products;
- the name of the holder of the Marketing Authorisation of the product;
- the address of the holder of the Marketing Authorisation of the product; any Marketing Authorisation number as allocated by the licensing authority; the manufacturer's batch reference;
- 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;

- legible and indelible;
- comprehensible; and
- 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 symbol or pictogram designed to clarify the above particulars;
- other information compatible with the summary of product characteristics that is useful for health education.

There must not be any labelling of a promotional nature.

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 that is liable to be confused with the common name.

Labelling of dispensed non-relevant medicinal products/unlicensed medicines

A non-relevant medicinal product is essentially an unlicensed medicine, for example a medicine extemporaneously prepared by a pharmacist under Section 10 of the Medicines Act 1968 against a prescription.

The requirements for the dispensing label for non-relevant medicinal products are the same as the requirements for the dispensing label of a relevant medicinal product (see section above). The only exemption to this is when a pharmacist extemporaneously prepares a product in accordance with a specification furnished by a person to whom the product will be sold or supplied, under Section 10 (3) (a) of the Medicines Act 1968. In this case the "directions for use" may be omitted from the dispensing label.

BANs and rINNS

European law requires the use of the Recommended International Non-Proprietary Name (rINN) for medicinal substances. In many cases the British Approved Name

(BAN) and the rINN are identical. Where the two differ, the BAN has been modified to agree with the rINN. The list of BANs and rINNs is given in the current BNF and is also available on www.mhra.gov.uk.

Warnings and other special labelling requirements

For dispensed medicines see "Labelling of Dispensed Medicinal Products". In addition to the labelling particulars shown for chemists' nostrums and relevant medicinal products above, there are certain other particulars, warnings and phrases that must be shown on the labels of containers and packages of certain medicinal products. Different requirements apply to General Sale List products, Pharmacy medicines and Prescription Only Medicines.

Labelling of General Sale List products

Relevant medicinal products, on a General Sale List when sold or supplied by retail in addition to appropriate particulars above, must be labelled as follows:

- (1) If containing aloxiprin, aspirin or paracetamol, with the words "If symptoms persist, consult your doctor" and the recommended dosage (unless the product is for external use).
- (2)
 - (a) if containing aloxiprin, with the words "Contains an aspirin derivative";
 - (b) if containing aspirin, with the words "Contains aspirin" (unless "aspirin" is included in the name of the product or if the product is for external use)
 - (c) if containing aspirin or aloxiprin, with the words "Do not give to children aged 16 years or under, unless on the advice of a doctor". (The PIL should read: "There is a possible association between aspirin and Reye's syndrome when given in children. Reye's syndrome is a very rare disease that can be fatal. For this reason, aspirin should not be given to children under 16 years unless on the advice of a doctor).
 - (d) if containing paracetamol, with the words "Contains paracetamol" (unless "paracetamol" is included in the name of the product);
 - (e) children's formulations: preparations wholly or mainly intended for children of 12 years of age and younger should carry two warnings as follows:
 - i "Do not give with any other paracetamol-containing product"; and
 - ii either "Immediate medical advice should be sought in the event of an overdose, even if the child seems well" (if there is an accompanying PIL) or "Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed serious liver damage" (if there is no accompanying PIL).

- (f) adult formulations: preparations mainly intended for adult use should carry two warnings as follows:
- i "Do not take with any other paracetamol-containing product" ; and
 - ii either "Immediate medical advice should be sought in the event of an overdose, even if you feel well" (if there is an accompanying PIL) or "Immediate medical advice should be sought in the event of an overdose, even if you feel well, because of the risk of delayed serious liver damage" (if there is no accompanying PIL).

N.B. Where more than one of the phrases in (a), (b), (c), (d), (e) and (f) above apply, they may be combined, for example, "Contains aspirin, and aspirin derivative and paracetamol". Those phrases must be surrounded by a rectangular box within which there is no other matter and must be in a prominent position.

- (3) If containing paracetamol, the words "Do not exceed the stated dose". Those words must appear adjacent to either the directions for use or the recommended dosage.

Labelling of products for pharmacy sale only

Medicinal products, including relevant medicinal products, for pharmacy sale only, when sold or supplied by retail in addition to appropriate particulars above, must be labelled as follows:

- (1) With the capital letter "P" in a rectangle containing no other matter. (That also applies to sales by wholesale.)
- (2) If containing aspirin, aloxiprin or paracetamol, in the manner described above for medicinal products on a General Sale List.
- (3) If exempt from Prescription Only control by reason of the proportion or level in the product of the Prescription Only substance, with the words "Warning. Do not exceed the stated dose". (This does not apply to products for external use or products containing any of the substances set out in 5 below.)
- (4) If for the treatment of asthma or other conditions associated with bronchial spasm or if they contain ephedrine or any of its salts, with the words "Warning. Asthmatics should consult their doctor before using this product". (This does not apply to products for external use.)
- (5) If containing any of the antihistaminic or similar substances or any of their salts or molecular compounds with the words "Warning. May cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink". (This does not apply to products for external use.)
- (6) If the product is an embrocation, liniment, lotion, liquid antiseptic or other liquid preparation or gel and is for external application, with the words "For external use only".
- (7) If the product contains hexachlorophene, either with the words "Not to be used for babies" or a warning that the product is not to be administered to a child under two years except on medical advice.

The relevant warning phrase or phrases described under “Labelling of General Sale List Products” and “Labelling of Products for Pharmacy Sale Only” above must be in a rectangle within which there is no other matter. That does not apply to the phrases “Do not exceed the stated dose” or “If symptoms persist consult your doctor” on the labels of products required to be labelled because of their aspirin, aloxiprin or paracetamol content.

Where more than one of the phrases (1) to (7) in this section (Labelling of products for pharmacy sale only) is applicable to a particular product, the phrases may be together within a rectangle although the wording must not be altered or combined except that the word “Warning” need only appear once.

Labelling of Prescription Only Medicines

The container and package of every “Prescription Only Medicine”, in addition to appropriate particulars above, must be labelled:

- except in the case of a dispensed medicine to show the letters POM in capitals within a rectangle within which there shall be no other matter of any kind;
- if the product is an embrocation, liniment, lotion, liquid antiseptic, or other liquid preparation or gel and is for external application, with the words “For External Use Only”;
- if the product contains hexachlorophene, either with the words “Not to be used for babies” or a warning that the product is not to be administered to a child under two years except on medical advice.

The phrases described above must be within a rectangle within which there is no other matter of any kind.

4.2 ADVERTISING AND PROMOTION OF MEDICINES

Acceptance of gifts and inducements to prescribe or supply

The Medicines (Advertising) Regulations 1994 govern the supply, offer or promise of gifts to healthcare professionals, including pharmacists, by drug manufacturers and distributors. Pharmacists accepting items such as gift vouchers, bonus points, discount holidays, sports equipment etc., would be in breach of Regulation 21. Pharmacists are, therefore, advised not to participate in such offers.

4.3 MEDICAL DEVICES

The Medical Devices regulations have implemented into national law various European Directives that provide for mandatory CE marking of all devices covered by them, including sutures, some dressings and contact lens care products.

A CE marking means that a manufacturer claims that his product satisfies the requirements essential for it to be considered safe and fit for its intended purpose and should be regarded as equivalent to marketing authorisation. For all except the simplest devices, this CE Marking is checked by a certification organisation known as a notified body, of which there are over 80 across Europe, each designated by their national competent authority.

Further information can be obtained directly from the DHSSPS or the Medicines and Healthcare Products Regulatory Agency (MHRA). For example, principles of appropriate procurement, safe use, maintenance and repair and guidance on reporting device related adverse events are set out as a series of practical check lists on 'Devices in Practice' available from the MHRA website (www.mhra.gov.uk).

4.4 CLINICAL TRIALS

From May 2004, the Clinical Trials Directive 2001/20/EC is effective for all clinical trials conducted in the UK.

For full details see The Medicines for Human Use (Clinical Trials) Regulations SI No. 1031 2004. www.opsi.gov.uk/legislation

The Website of the MHRA also contains a wide range of useful information and links to information sources about Clinical Trial authorisations:

<http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Legislationandguidancedocuments/index.htm>

4.5 USE OF FLUTED BOTTLES

A liquid medicinal product that is for external use must be sold or supplied in a bottle, the outer surface of which is fluted vertically with ribs or grooves recognisable by touch, if the product contains any of the substances listed below.

- Aconite; alkaloids of.
- Adrenaline; its salts.
- Amino-alcohols esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid or the derivatives of these acids; their salts.
- p-Aminobenzenesulphonamide; its salts; derivatives of p-Aminobenzenesulphonamide having any of the hydrogen atoms of the p-amino group or of the sulphonamide group substituted by another radical; their salts.
- p-Aminobenzoic acid; esters of; their salts.
- Ammonia except in medicinal products containing less than 5% weight in weight of ammonia.
- Arsenical substances, the following: arsenic sulphides; arsenates; arsenites; halides of arsenic; oxides of arsenic; organic compounds of arsenic.

- Atropine; its salts.
- Cantharidin; cantharidates.
- Carbachol.
- Chloral; its addition and its condensation products other than alpha chloralose; their molecular compounds.
- Chloroform except in medicinal products containing less than 1% volume in volume of chloroform.
- Cocaine; its salts.
- Creosote obtained from wood except in medicinal products containing less than 50% volume in volume of creosote obtained from wood.
- Croton, oil of.
- Demecarium bromide.
- Dyflos.
- Ecothiopate iodide.
- Ephedrine; its salts except in medicinal products containing less than the equivalent of 1% weight in volume of ephedrine.
- Ethylmorphine; its salts.
- Homatropine; its salts.
- Hydrofluoric acid; alkali metal bifluorides; potassium fluoride; sodium fluoride; sodium silicofluoride except in mouth washes containing not more than 0.05% weight in volume of sodium fluoride.
- Hyoscine; its salts.
- Hyoscyamine; its salts.
- Lead acetates except in medicinal products containing lead acetates equivalent to not more than 2.2% weight in volume of lead calculated as elemental lead.
- Mercury, oxides of; nitrates of mercury; mercuric ammonium chloride; mercuric chloride; mercuric iodide; potassium mercuric iodide; organic compounds of mercury; mercuric oxycyanide; mercuric thiocyanate except in medicinal products containing not more than 0.01% weight in volume of phenylmercuric salts or 0.01% weight in volume of sodium ethyl mercurithiosalicylate as a preservative.
- Nitric acid except in medicinal products containing less than 9% weight in weight of nitric acid.
- Opium.
- Phenols (any member of the series of phenols of which the first member is phenol and of which the molecular composition varies from member to member by one atom of carbon and two atoms of hydrogen); compounds of phenol with a metal except in;
 - (a) medicinal products containing one or more of the following:
 - Butylated hydroxytoluene
 - Carvacrol.
 - Creosote obtained from coal tar.
 - Essential oils in which phenols occur naturally.
 - Tar (coal or wood), crude or refined.

- tert-Butylcresol.
- p-tert-Butylphenol.
- p-tert-Pentylphenol.
- p-(1,1,3,3-tetramethylbutyl) phenol
- Thymol;

(b) mouthwashes containing less than 2% weight in volume of phenols;

(c) liquid disinfectants or antiseptics not containing phenol and containing less than 2.5% weight in volume of other phenols;

(d) other medicinal products containing less than 1% weight in volume of phenols.

- Physostigmine; its salts.
- Picric acid except in medicinal products containing less than 5% weight in volume of picric acid.
- Pilocarpine; its salts except in medicinal products containing less than the equivalent of 0.025% weight in volume of pilocarpine.
- Podophyllum resin except in medicinal products containing not more than 1.5% weight in weight of podophyllum resin.
- Solanaceous alkaloids not otherwise included in this Schedule.

Some exceptions to fluted bottle requirements

The fluted bottle requirements do not apply where:

- medicinal products are contained in bottles with a capacity greater than 1.14 litres;
- medicinal products are packed for export for use solely outside the UK;
- medicinal products are sold or supplied solely for the purpose of scientific education, research or analysis;
- eye or ear drops are sold or supplied in a plastic container;
- where the Marketing Authorisation or clinical trial certificate otherwise provides.

4.6 CHLOROFORM: SALE AND SUPPLY

The Medicines (Chloroform Prohibition) Order (NI) 1979, No.382 as amended 1980/263, 1989/1184, prohibits the sale or supply of any medicinal product consisting of or containing chloroform, which is for human use, except in the following circumstances.

A sale or supply may be made:

- (1) a. by a doctor or dentist to a patient of his, where the medicinal product has been specially prepared by that doctor or dentist for administration to that particular patient, or
- b. by a doctor or dentist who has specially prepared the medicinal product at the request of another doctor or dentist for administration to

- a particular patient of that other doctor or dentist, or
- c. from a registered pharmacy or hospital or by a doctor or dentist where the medicinal product has been specially prepared in accordance with a prescription given by a doctor or dentist for a particular patient, or
- (2) a. to a hospital, a doctor or a dentist for use as an anaesthetic, or
- b. to a person who buys it for the purpose of reselling it to a hospital, a doctor or a dentist for use as an anaesthetic, or
- (3) a. where the medicinal product contains chloroform in a proportion of not more than 0.5% (w/w) or (v/v), or
- b. where the medicinal product is solely for use in dental surgery, or
- c. where the medicinal product is solely for use by being applied to the external surface of the body, which for the purpose of this Order does not include any part of the mouth, teeth or mucous membranes, or
- (4) where the medicinal product is for export, or
- (5) where the medicinal product is sold for use as an ingredient in the preparation of a substance or article in a pharmacy, a hospital or by a doctor or dentist.

