

GENERAL LEGAL REQUIREMENTS



A Guide for Pharmacists in Northern Ireland 2010 Edition



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A Guide for Pharmacists in Northern Ireland

2010 Edition

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GENERAL LEGAL REQUIREMENTS

INTRODUCTION

This publication provides a practical guide to all pharmacists on the legal requirements for the sale or supply of medicinal products, poisons and chemicals.

While every possible care has been taken in the compilation of this guide, no responsibility can be accepted for any errors or for any consequences of such errors. The aim has been to present as clear and concise a summary of the law as possible and to interpret the various orders and regulations so as to decide the categories into which individual products should be classified. On any question of interpretation, however, it should be borne in mind that only the courts can give a legally binding decision.

Every effort has been made to ensure the accuracy of this publication at the time of print. However, as legislation is dynamic, please refer to the website of the Pharmaceutical Society of Northern Ireland for updates on changes to legislation.

The Medicines Act 1968 and the Poisons (NI) Order 1976, together with the Misuse of Drugs Act 1971, and subsequent regulations and amendments regulate all retail and wholesale dealings in medicines and poisons. Certain non-medicinal poisons and chemicals are also subject to the labelling requirements of the Chemicals (Hazard Information and Packaging for Supply Regulations (Northern Ireland) 2009.

It is important to appreciate that the Medicines Act 1968 applies only to substances when they are used as medicinal products or as ingredients in medicinal products.

It should be noted that there is no statutory list of Pharmacy medicines, that is, of medicines that may be sold over the counter only in registered pharmacies. The basic principle of the Medicines Act is that all medicines may be sold or supplied by retail only from registered pharmacies except those that are included on a General Sale List. The other principal statutory list is the list of Prescription Only Medicines, which can be supplied from pharmacies only in accordance with a practitioner's prescription.

Medicines that are not Prescription Only Medicines and are not included in the General Sale List are Pharmacy medicines, that is, medicines that may only be sold from a registered pharmacy under the supervision of a pharmacist.

The Medicines Act applies to all medicines for human use but no longer applies to veterinary medicines. In 2005 the Veterinary Medicines Regulations published by the Veterinary Medicines Directorate came into force and cover veterinary medicines. These regulations are updated annually in October.

Similarly there are substances used in medicines that also have non-medicinal uses. Several of these substances are included (together with other non-medicinal poisons) in the Poisons List made under the Poisons (NI) Order 1976.

In producing this guide, we are grateful to the Royal Pharmaceutical Society of Great Britain, for those sections that have made use of previously published advice in the Medicines, Ethics and Practice (MEP) Guide. The Pharmaceutical Society of Northern Ireland is also grateful to the members of the Legislation, Standards and Practice Committee, the Department for Health, Social Services and Public Safety, the Health and Safety Executive, and the Veterinary Medicines Directorate, for their time in reviewing and amending the document.

DEFINITIONS

The following are definitions of terms used in the Medicines Act 1968 and the Misuse of Drugs Regulations 2002, as amended, or are interpretations of terms used in these sets of legislation, that are not explained in the main text of the guide:

Accountable Officer is a fit, proper and suitably experienced person appointed or nominated by a designated body to ensure the safe management and use of controlled drugs within that Designated Body and by any person acting on behalf of, or providing services under arrangements made with, that Designated Body.

Additional supply optometrist means a person who is registered as an optometrist, and against whose name particulars of the additional supply speciality have been entered in the relevant register.

Appropriate date means:

(a) in the case of a health prescription, the date on which it was signed by the practitioner giving it or a date indicated by him as being the date before which it shall not be dispensed, and

(b) in every other case, the date on which the prescription was signed by the practitioner giving it; and, where a health prescription bears both the date on which it was signed and a date indicated as being that before which it shall not be dispensed, the appropriate date is the later of those dates.

Appropriate non-proprietary name

European Law requires the use of the Recommended International Non-Proprietary Name (rINN) for medicinal substances. In most cases The British

Approved Name (BAN) and rINN are identical. Where differences occurred, the BAN has been modified to accord with the rINN. See current British National Formulary or the most up to date British Pharmacopeia.

Appropriate quantitative particulars means:

Briefly, the quantity of each active ingredient (or that part of the active molecule responsible for the therapeutic or pharmacological activity) identified by its appropriate non-proprietary name and expressed in terms of weight, volume, capacity or, for certain products, in units of activity or as a percentage.

The quantity to be shown is:

- (a) the quantity in each dosage unit (for pastilles and lozenges only, it can be shown as a percentage), or
- (b) if there is no dosage unit, the quantity of each active ingredient in the container, or
- (c) if the product contains any active ingredient that cannot be definitively characterised, the quantity of the ingredient present in the highest proportion (diluent, excipient, etc., need not be stated).

The quantity of antimicrobial preservative added to a biological medicinal product must be stated. This applies to antigens, toxins, antitoxins, sera, antisera and vaccines.

The quantity can be expressed in terms of the dilution of the unit preparation for a homoeopathic product (that is, a product prepared in accordance with the methods of homoeopathic medicine or similar system which is sold or supplied as a homoeopathic product and is so described by the person who sells or supplies it).

Clinical Management Plan

This means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by:

- (a) the patient to whom the plan relates,
- (b) the doctor or dentist who is party to the plan, and
- (c) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan.

Common name in relation to a relevant medicinal product means the Recommended International Non-proprietary Name (rINN). See current British National Formulary or the most up to date British Pharmacopeia..

Community practitioner nurse prescriber means a person:

- (d) who is a registered nurse or a registered midwife, and
- (e) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from

the Nurse Prescribers' Formulary for Community practitioners in the current edition of the BNF.

Container means, briefly, the inner receptacle that holds the medicinal product. A package is every other outer receptacle.

Cosmetic means any substance or preparation intended to be applied to the various surfaces of the human body including epidermis, pilary system and hair, nails, lips and external genital organs, or the teeth and buccal mucosa wholly or mainly for the purpose of perfuming them, cleansing them, protecting them, caring for them or keeping them in condition, modifying their appearance (whether for aesthetic purposes or otherwise) or combating body odours or normal body perspiration.

Dispensed medicinal product includes a medicinal product prepared or dispensed by a practitioner (doctor, dentist or veterinarian) or prepared or dispensed in accordance with a prescription given by a practitioner and a medicinal product prepared or dispensed in a registered pharmacy by, or under the supervision of, a pharmacist, either in accordance with a specification furnished by the purchaser (for example, a customer's recipe) or in accordance with the pharmacist's own judgement as to the treatment required for a person present in the pharmacy (that is, counter-prescribing).

See also the full definition in the Labelling of Dispensed Medicinal Products section of this Guide to Legal Requirements.

Dosage unit means:

- (a) where the medicinal product is in the form of a tablet or capsule or is an article in some other similar pharmaceutical form, that tablet, capsule or other similar article, or
- (b) where the medicinal product is not in the form as aforesaid, that quantity of the medicinal product which is used as the unit by reference to which the dose of the medicinal product is measured.

European Economic Area (EEA) healthcare professional means:

- (a) a doctor who is lawfully engaged in medical practice in a relevant European state, or
- (b) a dentist who is lawfully engaged in dental practice in a relevant European state (including a person whose formal qualifications as a doctor are recognised for the purposes of the pursuit of the professional activities of a dental practitioner under Article 37 of the European Directive 2005/36/EC) where "relevant European state" means an EEA state, other than the United Kingdom, or Switzerland.

Effervescent, in relation to a tablet, means containing not less than 75 per cent, by weight of the tablet, of ingredients included wholly or mainly for the purpose of releasing carbon dioxide when the tablet is dissolved or dispersed in water.

Expiry date means the date after which, or the month and year after the end of which, the medicinal product should not be used, or the date before which or the month and year before the beginning of which, the medicinal product should be used.

External use means application to the skin, hair, teeth, mucosa of the mouth, throat, nose, ear, eye, vagina, or anal canal when a local action only is intended and extensive systemic absorption is unlikely to occur, and references to medicinal products for external use shall be read accordingly except that such references shall not include throat sprays, throat pastilles, throat lozenges, throat tablets, nasal drops, nasal sprays, nasal inhalations or teething preparations.

Food includes beverages, confectionery, articles and substances used as ingredients in the preparation of food, and includes any manufactured substance to which there has been added any vitamin and which is advertised as available and for sale to the general public as a dietary supplement.

General Sale List medicine means a medicine for which all active ingredients are listed in the Medicines (Products Other Than Veterinary Drugs) (General Sale List) Order (NI) (1984), as amended.

Health prescription means a prescription issued by a doctor, dentist, a supplementary prescriber, a district nurse/health visitor prescriber or extended formulary nurse prescriber under, or by virtue of:

- (a) in England and Wales, the National Health Service Act 1977;
- (b) in Scotland, the National Health Service (Scotland) Act 1978;
- (c) in Northern Ireland, the Health and Personal Social Services (Northern Ireland) Order 1972.

IRME practitioner means in relation to a medical exposure, a practitioner for the purposes of the Ionising Radiation (Medical Exposure) Regulations 2000.

Maximum daily dose (mdd) means the maximum quantity of the substance contained in the amount of the medicinal product for internal use which it is recommended should be taken or administered in any period of 24 hours.

Maximum dose (md) means the maximum quantity of the substance contained in the amount of the medicinal product for internal use which it is recommended should be taken or administered at any one time.

Maximum strength (ms) means either:

- (a) the maximum quantity of the substance by weight or volume contained in a dosage unit of a medicinal product;
- (b) the maximum percentage of the substance contained in a medicinal product calculated in terms of weight in weight (w/w), weight in volume (w/v), volume in weight (v/w) or volume in volume (v/v) as appropriate;
- (c) the maximum number of units of activity contained in a dosage unit or a weight of a medicinal product.

Medicinal product means any substance or article (not being an instrument, apparatus or appliance) that is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways, that is to say:

- (a) use by being administered to one or more human beings or animals for a medicinal purpose;
- (b) use as an ingredient, by a practitioner or in a pharmacy or in a hospital or in a business comprising the sale of herbal remedies, in the preparation of a substance or article that is to be administered to one or more human beings or animals for a medicinal purpose.

Medicinal purpose means any one or more of the following purposes, that is to say:

- (a) treating or preventing disease;
- (b) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition;
- (c) contraception;
- (d) inducing anaesthesia;
- (e) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way.

Nurse independent prescriber means a person:

- (a) who is a registered nurse or a registered midwife, and
- (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber

Operating department practitioner means a person who is registered under the Health Professions Order 2001 as an operating department practitioner.

Optometrist independent prescriber means a person:

- (a) who is registered optometrist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as an optometrist independent prescriber.

Parenteral administration means administration by breach of the skin or mucous membrane.

Pharmacist independent prescriber means a person:

- (a) who is a pharmacist, and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber.

Prescriber identification number means the number recorded against a person's name by the relevant National Health Service agency for the purposes of that person's private prescribing.

Prescription means a prescription issued by a doctor for the medical treatment of a single individual, by a nurse independent prescriber for treatment of a single individual, by a supplementary prescriber for the medical treatment of a single individual, by a dentist for the dental treatment of a single individual or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment.

Prescription Only Medicine means a medicine that is specified in the Prescription Only Medicines (Human Use) Order 1997 or the Medicines (Veterinary Drugs) (Prescription Only) Order 1991.

Private prescribing means issuing prescriptions other than health prescriptions, where the definition of "prescription" has effect as if the words "or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment" were omitted.

Professional register means the register maintained by the Nursing and Midwifery Council, as laid down in paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001.

Professional registration number means the number recorded against a person's name in the register of any body that licenses or regulates any profession of which that person is a member.

Registered chiropodist/podiatrist means a person who is registered in part 2 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Radioactive medicinal product means a medicinal product which is, which contains or which generates a radioactive substance and which is, contains or generates that substance in order, when administered, to utilise the radiation therefrom.

Radiopharmaceutical means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose.

Registered dietitian means a person who is registered in part 4 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered midwife means a person registered in the Midwives' Part of the professional register.

Registered nurse means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register.

Registered occupational therapist means a person who is registered in Part 6 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered optometrist means a person whose name is entered in the register of optometrists maintained under section 7 of the Opticians Act 1989.

Registered orthoptist means a person who is registered in part 7 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered orthotist and prosthetist means a person registered in Part 10 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered paramedic means a person who is registered in part 8 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered pharmacy means premises for the time being entered in the register required to be kept under the Medicines Act 1968 by the Registrar of the Pharmaceutical Society of Northern Ireland (or of Royal Pharmaceutical Society of Great Britain*, as appropriate).

*In September 2010 the regulatory remit of the Royal Pharmaceutical Society of Great Britain will transfer to the new General Pharmaceutical Council, who will then maintain the register of pharmacies, pharmacists and pharmacy technicians in Great Britain.

Registered physiotherapist means a person who is registered in Part 9 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered radiographer means a person who is registered in Part 11 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Registered speech and language therapist means a person who is registered in Part 12 of the register maintained by the Health Professions Council under article 5 of the Health Professions Order 2001.

Relevant medicinal product means a medicinal product for human use to which the provisions of the 2001/83/EC Directive apply other than:

- (a) a traditional herbal medicinal product, or
- (b) a homoeopathic medicinal product that fulfils the conditions laid down in Article 14(1) of the 2001 Directive

(This definition is taken from the Medicines (Marketing Authorisations etc) Regulations 1994 as amended.)

Repeatable prescription means a prescription that contains a direction that it may be dispensed more than once.

Retail pharmacy business means a business (not being a professional practice carried on by a practitioner) that consists of, or includes, the retail sale of medicinal products other than medicinal products on a General Sale List (whether medicinal products on such a list are sold in the course of that business or not).

Specified publication means the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex (or other official compendia that may in the future be produced under the Medicines Act).

Strength in relation to a relevant medicinal product means the content of active ingredient in that product expressed quantitatively per dosage unit, per unit volume or by weight, according to the dosage form.

Supplementary prescriber means:

- (a) a registered nurse,
- (b) a pharmacist,
- (f) a registered midwife, or
- (g) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001 relating to:
 - i chiropodists and podiatrists;
 - ii physiotherapists;
 - iii radiographers: diagnostic or therapeutic; or

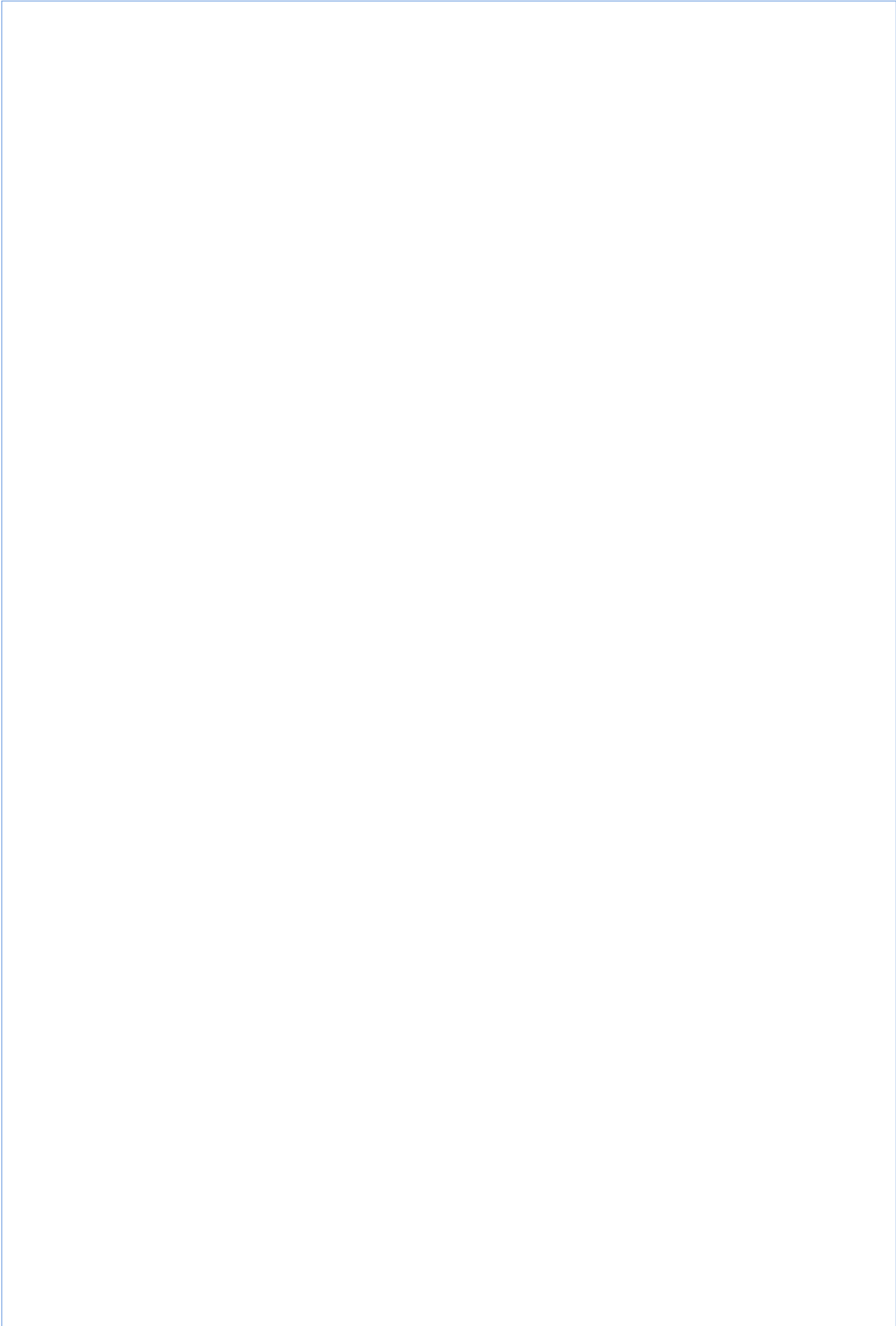
- (h) a registered optometrist
against whose name is recorded in the relevant register an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber.

Unit preparation means a preparation, including a mother tincture, prepared by a process of solution, extraction or trituration with a view to being further diluted tenfold, or serially in multiple powers of ten, in an inert diluent and then used either in this diluted form or, where applicable, by impregnating tablets, granules, powders or other inert substances for the purpose of being administered to human beings.

Veterinary medicinal product means:

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals; or,
(b) any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.

Veterinary requisition means a requisition which states, in accordance with Article 14 (2) (a)(ii) of the Misuse of Drugs Regulations 2002 as amended that the recipient is a veterinary surgeon or veterinary practitioner.





1 Medicines for Human Use: POM, P, GSL & General Pharmacy Regulations



1 MEDICINES FOR HUMAN USE **POM, P, GSL & General Pharmacy Regulations**

Classes of medicinal products

Those medicinal products that, in the opinion of the appropriate Ministers, can, with reasonable safety, be sold or supplied otherwise than by or under the supervision of a pharmacist are known as General Sale List (GSL) medicines and are listed in the General Sale List Order or are so classified in their marketing authorisation.

Other medicinal products that may be sold or supplied only from pharmacies in accordance with a prescription given by a practitioner are specified in the Prescription Only Order or are so classified in their marketing authorisation. Any medicinal product that is not a Prescription Only Medicine or a General Sale List medicine is a Pharmacy medicine.

There are, therefore, three classes of products under the Medicines Act 1968, namely:

- (1) General Sale List medicines (GSL).
- (2) Pharmacy medicines (P).
- (3) Prescription Only Medicines (POM).

The legal requirements that apply to the sale, supply, dispensing and labelling of each class are dealt with separately below.

Meaning of "retail sale" and "wholesale dealing"

The selling of a medicinal product constitutes "wholesale dealing" if it is sold to a person for the purpose of:

- (a) selling or supplying it, or
- (b) administering it, or causing it to be administered to one or more human beings, the sale, supply or administration being in the course of a business carried on by the purchaser.

Any sale that does not fall within this definition of "wholesale dealing" is a retail sale. The restrictions on the retail sale of medicinal products also apply to supply and to supplying "in circumstances corresponding to retail sale", which includes the dispensing of prescriptions under the Health Service.

1.1 GENERAL SALE LIST MEDICINES (GSL)

All General Sale List medicines, except those that have been designated as foods or cosmetics, must be licensed products (it should be noted that a medicinal product, made up in a pharmacy for sale from that pharmacy without a marketing authorisation, is classified as a Pharmacy medicine even though all its ingredients are in the GSL Order).

Products not on general sale

Part of the GSL order specifies certain classes of medicinal products for human use that shall not be available on general sale. They are medicinal products promoted, recommended or marketed:

- (a) for use as anthelmintics,
- (b) for parenteral administration,
- (c) for use as eye drops,
- (d) for use as eye ointments,
- (e) for use as enemas,
- (f) for use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum,
- (g) for administration wholly or mainly to children being a preparation of aloxiprin or aspirin.

Foods and cosmetics

Medicinal products that are for sale or supply either for oral administration as a food or for external use as a cosmetic are General Sale List medicines. This does not include products that are Prescription Only Medicines, eye drops or eye ointments, or any product that contains either:

- (a) vitamin A, vitamin A acetate or vitamin A palmitate with a maximum daily dose equivalent to more than 7,500 international units of vitamin A or 2,250 micrograms of retinol;
- (b) vitamin D with a maximum daily dose of more than 400 units of antirachitic activity.

Retail sale of GSL medicines

Medicinal products on a General Sale List may only be sold by retail, offered or exposed for sale by retail, or supplied in circumstances corresponding to retail sale either at registered pharmacies, or in circumstances where the following conditions are fulfilled:

- The place at which the medicinal product is sold, offered, exposed for sale or supplied, must be premises at which the person carrying on the business is the occupier and which he is able to close so as to exclude the public. Sales from automatic machines should only be made from machines located in premises that the occupier is able to close so as to exclude the public.
- The medicinal product must have been made up for sale in a container elsewhere and not have been opened since the product was made up for sale in it.

In 2005 amendment SI No. 766 amended the Medicines (Pharmacy and General Sale-Exemption) Order 1980 to permit the supply of general sale medicines by a prison officer to a prisoner for the purpose of treatment of that prisoner.

Pharmacy Only (PO)

A PO medicine is a product that is licensed as a GSL medicine, but is restricted to sale through pharmacies only. PO medicines do not need to be sold under the supervision of a pharmacist. These medicines may be available for self-selection by members of the public.

1.2 PHARMACY MEDICINES (P)

A Pharmacy medicine means a medicinal product that is not a Prescription Only Medicine and is either:

- not a medicinal product on a General Sale List, or
- a product referred to in Regulation 8 of The Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations (NI) 1980.

The products referred to in Regulation 8 include the following:

- (a) products for human use containing aloxiprin, aspirin, paracetamol or salicylamide that are offered or exposed for sale by retail in packs containing:
- i in the case of effervescent tablets,
 - a) which do not contain aspirin, or where the amount of aspirin in each tablet does not exceed 325 milligrams, more than 30 tablets;
 - b) where the amount of aspirin in each tablet exceeds 325 milligrams, but does not exceed 500 milligrams, more than 20 tablets;
 - ii in the case of tablets that are not effervescent, where they are enteric-coated tablets, containing more than 75mg aspirin only, more than 28 tablets, or where they contain aloxiprin or paracetamol or a combination of any or all of these substances, more than 16 tablets;
 - iii in the case of powder or granules, more than 10 sachets;
 - iv in the case of capsules, where they contain aloxiprin, aspirin or paracetamol or a combination of any or all of those substances, more than 16 capsules;
 - v in the case of liquid preparations of paracetamol, intended for persons aged 12 years and over, more than 160 ml, intended for persons less than 12 years, individual doses of more than 5 ml each, or more than 20 unit doses;
- (b) tablets for human use containing bisacodyl that are offered or exposed for sale by retail in containers or packages containing more than 40 tablets;
- (c) products for human use containing ibuprofen that are offered or exposed for sale by retail in containers or packages containing:
- i in the case of tablets, more than 16 tablets;
 - ii in the case of capsules, more than 16 capsules;
 - iii in the case of powders or granules, more than 12 sachets;
 - iv in the case of a product for topical use, more than 2.5g of ibuprofen;

- v in the case of liquid preparations, unit doses of more than 5mls each, or more than 20 unit doses.
- (d) products for topical human use containing clotrimazole that are offered or exposed for sale by retail in containers or packages containing more than 500 milligrams of clotrimazole;
- (e) products for human use containing sodium picosulphate in a container or package of more than 60 ml of the product;
- (f) products for human use containing loperamide hydrochloride in a container or package of more than 6 tablets or capsules;
- (g) Omeprazole 10mg;
- (h) Statins - simvastatin 10mg;
- (i) products for human use containing ranitidine hydrochloride in a container or package of more than 12 tablets;
- (j) products for human use containing famotidine in a container or package of more than 12 tablets;
- (k) products for human use containing heparinoid in a container or package of more than 20g of the product;
- (l) products for human use containing ibuprofen lysine in a container or package containing more than 16 tablets.

Pharmacy medicines may not be sold, offered or exposed for sale by retail, or supplied in circumstances corresponding to retail sale in the course of a business carried on by any person, unless:

- that person is, in respect of that business, a person lawfully conducting a retail pharmacy business;
- the product is sold, offered or exposed for sale, or supplied on premises that are a registered pharmacy; and
- that person, or, if the transaction is carried out on his behalf by another person, then that other person, is, or acts under the supervision of, a pharmacist.

The products referred to in the previous paragraph, i.e. large packs of products containing aspirin, aloxiprin, paracetamol and salicylamide are not subject to the legal requirement for Pharmacy medicines in that they need not be sold by or under the supervision of a pharmacist; however, there is a professional requirement that these large packs be supervised.

The process of reclassification of medicines from POM to P and P to GSL is an ongoing one and the above list is therefore not exhaustive. When a product is reclassified, pharmacists must be aware of the actual product(s) that are licensed, the indications for use, the strength of the product allowed and any additional restrictions that might apply to the sales of such products.

Information is available on www.pjonline.com/reclassification or MHRA web site www.mhra.gov.uk.

Matters around the classification and regulation of medicines may also be subject to change in the event of a national health emergency, when specific legislation may be enacted. See page 35 for more information.

1.3 PRESCRIPTION ONLY MEDICINES (POM)

Prescription Only Medicines are those medicinal products described as such in the Prescription Only Order.

The main classes of Prescription Only Medicines are as follows:

- (1) medicinal products in respect of which a marketing authorisation has been granted and in the marketing authorisation are classified as being prescription only medicines;
- (2) medicinal products in respect of which no marketing authorisation has been granted consisting of, or containing, a substance listed in Column 1 of Schedule 1;
- (3) medicinal products that are for parenteral administration;
- (4) medicinal products that are Controlled Drugs unless a marketing authorisation has been granted in respect of that medicinal product whereby the product is classified as being a Pharmacy or General Sale List Medicine;
- (5) cyanogenetic substances, other than preparations for external use;
- (6) medicinal products that on administration emit radiation or generate any substance that emits radiation, in order that radiation may be used;
- (7) medicinal products in respect of which marketing authorisation has been granted consisting of, or containing, aloxiprin, aspirin, or paracetamol in the form of non-effervescent tablets or capsules that are classified as being pharmacy only or general sale list medicines.
- (8) Medicinal products in respect of which a marketing authorisation has been granted consisting of or containing pseudoephedrine salts or ephedrine base or salts in all pharmaceutical forms which in the marketing authorisation are classified as being pharmacy only medicines.

There are a number of exemptions from prescription only control and pharmacists should check if any exemption exists.

Exemptions from Prescription Only Medicine status

Some medicines are exempt from Prescription Only control only when in the form of particular licensed medicines. For example, hydrocortisone is a Prescription Only Medicine, but when in the form of a licensed product, for which the indications fall within the terms specified for an exemption, the product is licensed as a Pharmacy medicine. No other hydrocortisone products can be sold without prescription, and the licensed products must only be sold within the terms of their licence (they cannot, for example, be mixed with other medicinal products, even where they are Pharmacy only or even General Sale List medicines).

Extemporaneously prepared medicines or nostrums containing a Schedule 5 Controlled Drug, eg, pholcodine is classed as a prescription only medicine and cannot therefore be sold over the counter. Pharmacists may not re-package Schedule 5 Controlled Drugs from a dispensing pack into smaller quantities for over the counter sale.

It is unlawful to sell or supply a product or products containing more than 720mg of pseudoephedrine salts or more than 180g ephedrine base (or salts) to a person at any one time (i.e. in one transaction) except in accordance with a prescription. A sale or supply without a prescription may be made of more than one product containing only one of these substances, provided that the total amount sold does not exceed the above limit. However, it is unlawful to sell or supply a pseudoephedrine-containing product at the same time as an ephedrine-containing product in one transaction.

Some medicinal products are exempted from Prescription Only status when sold or supplied for the treatment of specified conditions and at dosages not exceeding stated maxima. The labelling of such products is complex and pharmacists are therefore advised to sell only licensed products that are specifically packed for over the counter sale.

Administration of Prescription Only Medicines

The legislation provides that no one may administer a parenteral Prescription Only Medicine otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner.

The following list of medicines for use by parenteral administration are exempt from this restriction when administered for the purpose of saving life in an emergency.

- Adrenaline injection (1 in 1000)
- Atropine sulphate injection
- Atropine sulphate and obidoxime chloride injection
- Atropine sulphate and pralidoxime chloride injection
- Atropine sulphate, pralidoxime mesilate and avizafone injection
- Chlorphenamine injection
- Dicobalt edetate injection
- Glucagon injection
- Glucose injection 50%
- Hydrocortisone injection
- Naloxone hydrochloride injection
- Pralidoxime chloride injection
- Pralidoxime mesilate injection
- Promethazine hydrochloride injection

- Snake venom antiserum
- Sodium nitrite injection
- Sodium thiosulphate injection
- Sterile pralidoxime*

*At the time of print, the MHRA were considering whether to amend the list of Prescription Only Medicines which can be administered parenterally by anyone for the purpose of saving life in an emergency under Article 7 of the POM Order. (MLX 367) The above list may therefore be updated in the next edition of this guide.

Administration of smallpox vaccine

The legislation provides that no one may administer a parenteral Prescription Only Medicine otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner. Smallpox vaccine for parenteral administration to human beings is exempt from this restriction where either:

1. (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by:
 - i the Secretary of State,
 - ii the Scottish Ministers,
 - iii the National Assembly for Wales,
 - iv the Department of Health, Social Services and Public Safety, for Northern Ireland
 - v an NHS body; and
 (b) the vaccine is administered for the purpose of providing protection against smallpox virus in the event of a suspected or confirmed case of smallpox in the United Kingdom, or:
2. (a) the vaccine has been supplied by, or on behalf of, or under arrangements made by Her Majesty's Forces;
 (b) the vaccine is administered for the purpose of providing protection against smallpox virus to:
 - i members of Her Majesty's Forces; or
 - ii other persons employed or engaged by those Forces.

For the purposes of this section, "NHS body" means in a Northern Ireland context:

- the Health and Social Care Board;
- the Business Services Organisation (BSO);
- the public health agency; or,
- an HSC Trust,

Administration by operators

The legislation provides that no one may administer a parenteral prescription-only medicine otherwise than to himself, unless he is a practitioner or is acting in accordance with the directions of a practitioner.

This restriction does not apply to:

- 1 a radioactive medicinal product, administration of which results in a medical exposure; or,
- 2 any other prescription only medicine if it is being administered in connection with a medical exposure.

The following conditions must be satisfied:

- The radioactive medicinal product or other prescription only medicine is administered by an operator acting in accordance with the procedures and protocols referred to in regulation 4(1) and 4(2) of the Ionising Radiation (Medical Exposure) Regulations 2000;
- The medical exposure has been authorised by an IRME practitioner or, where this is not practicable, by an operator acting in accordance with written guidelines issued by an IRME practitioner;
- The IRME practitioner is the holder of a certificate granted under the Medicines (Administration of Radioactive Substances) Regulations 1978;
- The radioactive medicinal product or other prescription only medicine is not a Controlled Drug; and
- In the case of a prescription only medicine which is not a radioactive medicinal product, it is specified in the protocols (see subsection (a)) in connection with a medical exposure.

Administration of Prescription Only Medicines in hospital

The Medicines Act 1968 does not specify that the directions of a practitioner need be in writing in order to authorise administration. Nevertheless, it is good practice to ensure that, whenever a Prescription Only Medicine is administered, it has been authorised in writing by a practitioner before administration takes place. Some hospitals have formulated policies to permit administration in an emergency on the telephoned or verbal request of a practitioner, usually involving two nurses checking one another. Some hospitals have also formulated policies for the routine administration of Prescription Only (and Pharmacy and General Sale List) medicines. Such a policy should be carefully considered and agreed by medical, nursing and pharmaceutical staff to ensure that patients are not put at risk. If in doubt, the Department of Health should be consulted along with the legal advisors of the hospital.

Guidance given in booklet Use and Control of Medicines 2004

www.dhsspsni.gov.uk/

Prescriptions for Prescription Only Medicines

A Prescription Only Medicine may be sold or supplied by retail only in accordance with a prescription given by an appropriate practitioner. United Kingdom registered doctors and dentists are appropriate practitioners for all Prescription Only Medicines, as are doctors and dentists registered in an EEA country or Switzerland. EEA or Swiss healthcare professionals are not permitted to issue prescriptions for

Schedule 1-5 Controlled Drugs and medicines that do not have a UK marketing authorisation.

Pharmacists may telephone the General Medical Council, Tel No. 0845 357 3456, to confirm that a doctor is registered and the General Dental Council, Tel No. 020 7887 3800, to confirm that a dentist is registered.

For EEA medical prescribers, a list of competent international medical regulatory authorities is available on the website of the International Association of Medical Regulatory Authorities. This provides links to the websites of the national regulator and its contact details: <http://www.iamra.com/memberlist.asp>

For EEA dental prescribers, the General Dental Council website hosts a list of competent dental authorities in each EEA Member State, which likewise provides links to the websites of the national regulator and its contact details:

<http://www.gdc-uk.org/NR/ronlyres/C3814151-872A-445D-9A86->

[E417E6037974/58174/ContactdetailsforcompetentauthoritiesineachMemberS.doc](http://www.gdc-uk.org/NR/ronlyres/C3814151-872A-445D-9A86-E417E6037974/58174/ContactdetailsforcompetentauthoritiesineachMemberS.doc)

* See guidance by the Pharmaceutical Society of Northern Ireland on dispensing EEA prescriptions (July 2010)

Supplementary prescribers are appropriate prescribers for all prescription only medicines, a limited number of Controlled Drugs in specific circumstances and unlicensed medicines unless the unlicensed medicine is part of a clinical trial that has a clinical trial certificate or exemption.

Supplementary prescriber status can be checked, by contacting the professional body with whom the supplementary prescriber is registered.

Community nurse practitioner prescribers are appropriate practitioners for the descriptions and classes of prescription only medicines specified in Schedule 3 of the POM order.

Nurse independent prescribers are appropriate practitioners for the descriptions and classes of medicinal products specified in Article 3A (1) of the POM Order.

Pharmacist independent prescribers are appropriate practitioners for the descriptions and classes of medicinal products in Article 3 of the POM Order, other than medicinal products that are Controlled Drugs.

Optometrist independent prescribers are appropriate practitioners in relation to the descriptions and classes of medicinal products specified in Article 3 of the POM order, other than medicinal products that are Controlled Drugs or for parenteral administration or both.

NB: Legislation came into force on the 1st April 2008 with respect to the prescribing of CDs by nurse independent prescribers and pharmacist

independent prescribers – SI No 464. Further amendments will be made to the Misuse of Drugs Regulations (NI) 2002 and the Pharmaceutical Services Regulations in order to implement these changes.

To be valid a prescription issued by an appropriate practitioner:

- (a) shall be signed in ink with his own name by the practitioner giving it;
- (b) shall be written in indelible ink (this includes typewriting and computer generated prescriptions). A health prescription, which is not for a Controlled Drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations, can be written by means of carbon paper or similar material but must be signed in indelible ink by the practitioner giving it;
- (c) shall contain the following particulars:
 - i the address of the practitioner giving it,
 - ii the appropriate date,
 - iii such particulars as indicate whether the appropriate practitioner giving it is a doctor, a dentist, a supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor or an EEA or Swiss Dentist,
 - iv where the appropriate practitioner giving it is a doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor or an EEA or Swiss Dentist, the name, address and the age, if under 12, of the person for whose treatment it is given*;
- (d) shall not be dispensed after the end of the period of six months from the appropriate date, unless it is a repeatable prescription in which case it shall not be dispensed for the first time after the end of that period nor otherwise than in accordance with the direction contained in the repeatable prescription;
- (e) in the case of a repeatable prescription that does not specify the number of times it may be dispensed, shall not be repeated on more than one occasion unless it is a prescription for oral contraceptives, in which case it may be dispensed a total of six times (i.e. five repeats) before the end of the period of six months from the appropriate date.

Pharmacists should bear in mind that in the case where a part dispensing has occurred against a prescription, then that prescription cannot be returned to the patient for the balance to be dispensed in another pharmacy or on a later occasion. Instead an 'owing slip' or similar arrangement should be made.

In the case of a repeatable prescription, the prescription must be retained for two years from the date of the final supply made on it.

A prescription, other than a health prescription for a Controlled Drug listed in Schedule 1,2 or 3 of the Misuse of Drugs Regulations 2002 may still be valid

where it is created in an electronic form, is signed with an advanced electronic signature and is sent to the person who is dispensing it as an electronic communication.

The advanced electronic signature must be uniquely linked to the signatory and to the data to which it relates in such a manner that any subsequent change of data is detectable. In this case the signatory is the appropriate practitioner issuing the prescription. In addition, the signature must be capable of identifying the practitioner and be created in such a way that the practitioner can maintain it under their sole control.

When a Prescription Only Medicine is also a Controlled Drug listed in Schedule 2 or 3 of the Misuse of Drugs (Northern Ireland) Regulations 2002 a prescription must also be written in accordance with the requirements of those regulations.

Note: repeats are not permitted for Controlled Drug prescriptions (S2, S3).

Prescriptions Written by Practitioners from other EEA Member States

The Pharmaceutical Society of Northern Ireland has published a useful guidance document for pharmacists on dispensing prescriptions originating from other EEA member states.

This can be accessed via the following URL:

<http://www.psni.org.uk/documents/589/Dispensing+European+Economic+Area+prescriptionsJuly2010.pdf>

Validity of dental prescriptions

A dentist is an appropriate practitioner for the purpose of prescribing Prescription Only Medicines. A prescription written by a dentist is valid under the Medicines Act 1968 even where the item prescribed is not in the Dental Formulary. Under the terms of service, a National Health Service prescription written by a dentist is valid only if the medicinal products ordered are on the dental formulary, but a private prescription can order any Prescription Only (or Pharmacy or General Sale List) medicine.

Dentists are required by their registration body to restrict their prescribing to areas in which they are competent, and this would therefore mean that a dentist should generally prescribe only medicines that have uses in dentistry.

Facsimile transmission of prescriptions

A "fax" of a prescription does not fall within the definition of a legally valid prescription (see above) because it is not written in indelible ink and has not been signed by an appropriate practitioner. A fax can, however, confirm that at the time of receipt, a valid prescription is in existence.

Any pharmacist who decides to dispense a Prescription Only Medicine against a fax, without sight of the original prescription, must ensure that adequate safeguards exist to ensure that the integrity of the original prescription is maintained and that the prescription will be in his possession within a short time. Any doubt as to the content of the original prescription, caused by poor reproduction, must be overcome before the medicine is supplied.

As it is possible to fax a prescription many times, the pharmacist is advised to ensure that no dispensing against a fax takes place unless the system used for the sending or receipt of faxes is secure.

Under no circumstances can medicines listed in Schedules 2 or 3 of the Misuse of Drugs (Northern Ireland) Regulations 2002 be dispensed against a fax.

Directions to supply POMs in hospitals

The Medicines Act 1968 does not specify that the directions of an appropriate practitioner need to be in writing, in order to authorise administration. Nevertheless, it is good practice to ensure that whenever a prescription-only medicine is administered it has been authorised in writing by an appropriate practitioner before administration. Such a direction does not need to comply with the requirements specified for prescriptions but does need to relate to a specific patient.

The intention is to permit the sale or supply of medicines against the patient's bed card or patient notes. Most entries on a patient's bed card are directions to administer. However, providing the wording is clear, the entry can be taken as authority to make a supply, for example as take home medication. Providing the entry fulfils the requirements the details can be transposed onto an order form to be used in pharmacy to prepare the take home medication. It is good practice for the transposition to be carried out by a pharmacist. By carrying out this transcription the pharmacist is not prescribing, as the original written direction to supply was made by a practitioner.

Some hospitals have formulated policies that permit the supply of Prescription Only (and Pharmacy and General Sale List) medicines, without a practitioner being directly involved in each transaction. Such policies are often loosely described as "blanket directions" because they authorise the supply of a limited range of medicines to any patient once all the specified requirements are met. These protocols must be drawn up very carefully to ensure that there can be no possibility of misinterpretation and so that all contra-indications or precautions are covered. It is necessary to check with the Department of Health and Social Services before adopting such a policy, especially if there are any concerns about its appropriateness.

See guidance given in booklet Use and Control of Medicines 2004, DHSSPSNI
www.dhsspsni.gov.uk

Patient Group Directions

The legislation now permits the supply of prescription only medicines under patient group direction (PGD).

A PGD is a written direction relating to supply and administration or administration only of a prescription only medicine to persons generally (subject to specific exclusions) and is signed by a doctor, dentist and by a pharmacist.

The following is a list of the persons who are permitted under the Regulations to supply or administer under a PGD:

- Registered paramedics or individuals who hold a certificate of proficiency in ambulance paramedic skills issued by the Secretary of State, or issued with his approval;
- Pharmacists;
- Registered dental hygienists
- Registered dental therapists
- Registered dietitians;
- Registered midwives;
- Registered nurses;
- Registered occupational therapists;
- Registered optometrists;
- Registered orthotists and prosthetists;
- Registered speech and language therapists;
- Registered chiropodists;
- Registered orthoptists;
- Registered physiotherapists;
- Registered radiographers.

There are THREE main types of PGD:

- 1 where this allows authorised healthcare professionals to supply medicines on behalf of an NHS body;
- 2 where it is to assist a doctor or dentist providing primary care NHS services
- 3 where the NHS body authorises a PGD for the supply of a POM by a named person lawfully conducting a retail pharmacy business (i.e. the owner of the pharmacy).

In addition supply of POMs under a patient group direction can be made on behalf of an independent clinic/hospital or medical agency, a prison service or a police force.

A helpful flowchart on PGDs is available on www.groupprotocols.org.uk. For examples of PGDs see www.rpsgb.org.uk/.

See also supply of specified Controlled Drugs under PGDs in Controlled Drugs section.

Forged Prescriptions

It can be extremely difficult to detect a forged prescription, but every pharmacist should be alert to the possibility that any prescription calling for a product liable to misuse could be a forgery. In many instances, the forger may make a fundamental error in writing the prescription or the pharmacist may get the instinctive feeling that the prescription is not genuine because of the way the patient behaves.

If the prescriber's signature is known, but the patient has not previously visited the pharmacy, or is not known to be suffering from a condition which requires the medicinal product prescribed, the signature should be scrutinised and, if possible, checked against an example on another prescription known to be genuine. Large doses or quantities should be checked with the prescriber in order to detect alterations to previously valid prescriptions.

If the prescriber's signature is not known, the prescriber must be contacted and asked to confirm that the prescription is genuine. The prescriber's telephone number must be obtained from the telephone directory, or from directory enquiries, not from the headed notepaper, as forgers may use false letter headings.

A list of matters which should alert a pharmacist to making further checks is given below. The list is not exhaustive.

- 1) Unknown prescriber
- 2) New patient
- 3) Excessive quantities
- 4) Uncharacteristic prescribing or method of writing prescription by a known doctor
- 5) Dr before or after prescriber's signature

These precautions should be applied to all prescriptions for drugs liable to misuse and not only for Controlled Drugs. The dispensing of a forged prescription for a Controlled Drug or prescription-only medicine can constitute a criminal offence.

Supplementary Prescribers

A supplementary prescriber can, in accordance with the terms of a clinical management plan, prescribe prescription only medicines, or if the product is for parenteral administration, either administer it or give directions for its

administration. The clinical management plan must relate to the patient for whom the product is prescribed or is to be administered to and the plan must be in effect at the time the prescription is given or the product is administered.

A clinical management plan must state the following:

- (a) the name of the patient to whom the plan relates;
- (b) the illnesses or conditions that may be treated by the supplementary prescriber;
- (c) the date that the plan takes effect and when it is to be reviewed by the doctor or dentist who is party to the plan;
- (d) reference to the class or description of medicinal product that can be prescribed or administered under the plan;
- (e) any restrictions or limitations as to the strength or dose or period of use of any product that may be prescribed or administered under the plan;
- (f) relevant warnings about known sensitivities or difficulties of the patient with particular medicinal products;
- (g) arrangements for notifying suspected or known adverse reactions to any medicinal product prescribed or administered under the plan and any medicinal product taken at the same time as a medicinal product prescribed or administered under the plan; and
- (h) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist in the plan.

Supplementary prescribers must have access to the same health records of the patient to whom the plan relates as the doctor or dentist who is party to the clinical management plan.

For circumstances in which Controlled Drugs may be prescribed a supplementary prescriber, see Section 1.4 Controlled Drugs.

Pharmacist independent prescribers can prescribe any medicine, with the exception of Controlled Drugs, for any clinical condition but they must only prescribe within their professional and clinical competence.

Community practitioner nurse prescribers and nurse independent prescribers

Community practitioner nurse prescribers are able to prescribe medicines included in the nurse prescribers' formulary for community practitioners. Pharmacists should refer to the current Drug Tariff for the up to date list.

Nurse independent prescribers can prescribe any licensed medicine for any medical condition that the nurse prescriber is competent to treat. Nurse independent prescribers can only prescribe certain controlled drugs for certain indications.

Prescription records

Every person lawfully conducting a registered retail pharmacy business or a registered pharmacy within a hospital is required to keep a record in respect of every sale or supply of a Prescription Only Medicine, unless

- (a) it is a sale or supply in pursuance of a "health prescription" or a prescription for an oral contraceptive; or
- (b) a separate record of the sale or supply is made in the Controlled Drugs register; or
- (c) the sale is by way of wholesale dealing and the order or invoice (or copies) relating to the sale is retained for two years.

Even where exempt from the strict legal requirement to make an entry in the prescription record book (e.g. where a separate entry has been made in the CD register) it is still good practice to keep such records. Hospital pharmacies need to keep such records only if the supply of the Prescription Only Medicine required registration as a pharmacy (no records are required under the Medicines Act for medicines supplied in the course of the business of the hospital). If any concerns arise, the DHSSPS should be contacted for clarification.

The entry must be made on the day the sale or supply takes place or, if that is not reasonably practicable, on the next following day. The Prescription Only register must be preserved by the owner of the retail pharmacy business for a period of two years from the date of the last entry in the register. A prescription must be retained for two years from the date on which the Prescription Only Medicine was sold or supplied, or, for a repeat prescription, the date on which the medicine was supplied for the last time.

The particulars to be recorded in the case of a sale or supply of a Prescription Only Medicine in pursuance of a prescription are:

- (a) the date on which the medicine was sold or supplied,
- (b) the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicine,
- (c) the date on the prescription
- (d) the name and address of the practitioner giving it,
- (e) the name and address of the person for whom the medicine was prescribed.

For second and subsequent supplies made on a repeat prescription it is sufficient to record the date of supply and a reference to the entry in the record relating to the first supply.

Alternatively, pharmacists may elect to keep their records electronically, but all the particulars stated above must be recorded, adequate backups must be made and arrangements made so that inspectors can examine the records during visits with minimal disruption to the dispensing process.

Hospital pharmacies need to keep such records only if the supply of the prescription-only medicine required registration as a pharmacy (no records are required under the Medicines Act for medicines supplied in the course of the business of the hospital).

Emergency supplies of Prescription Only Medicines (outside of a pandemic or national health emergency)

In an emergency a person lawfully conducting a retail pharmacy business can sell or supply a Prescription Only Medicine if, and so long as, certain conditions are satisfied. There are two kinds of emergency supply:

(1) those made at the request of a doctor, dentist, supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber, optometrist independent prescriber, a pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist*;

and

(2) those made at the request of a patient.

Different conditions apply to each type.

*Note: An emergency supply at the request of an EEA or Swiss doctor, or EEA or Swiss dentist, or one of their patients, cannot lawfully be made for a Schedule 1, 2, 3, 4 or 5 Controlled Drug or for medicines that do not have a UK marketing authorisation.

Emergency supply made at the request of a doctor, dentist, supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber, optometrist independent prescriber, a pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist

The conditions that apply are:

- (a) that the pharmacist by or under whose supervision the prescription only medicine is to be sold or supplied is satisfied that the sale or supply has been requested by a doctor, dentist, supplementary prescriber, a community practitioner nurse prescriber, a nurse independent, optometrist independent prescriber, a pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist who by reason of some emergency is unable to furnish a prescription immediately;
- (b) that the doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist has undertaken to furnish the person lawfully conducting the retail pharmacy business with a prescription within 72 hours;

- (c) that the prescription only medicine in question is sold or supplied in accordance with the directions of the doctor, dentist, supplementary prescriber, community practitioner nurse prescriber, nurse independent prescriber, optometrist independent prescriber, pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist requesting it;
- (d) that the Prescription Only Medicine is not a Controlled Drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (an emergency sale or supply of phenobarbitone or phenobarbitone sodium is permitted, at the request of the doctor, dentist, or supplementary prescriber, provided that it is for use in the treatment of epilepsy and does not contain any of the other substances in Schedules 1, 2, or 3 to the Misuse of Drugs (Northern Ireland) Regulations 2002); where the request is made by an EEA or Swiss doctor or an EEA or Swiss dentist, the prescription-only medicine is not a Controlled Drug specified in Schedule 1,2,3,4 or 5 of the Misuse of Drugs Regulations 2001;
- (e) that an entry is made in the Prescription Only register on the day of the supply, or, if impracticable, the next day following, stating:
 - i the date on which the medicine was sold or supplied,
 - ii the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicine,
 - iii the name and address of the practitioner requesting the emergency supply,
 - iv the name and address of the person for whom the Prescription Only Medicine was prescribed,
 - v the date on the prescription, and
 - vi when the prescription is received, the entry should be amended to include the date on which the prescription is received.

Emergency supply made at the request of a patient

- (a) The conditions that apply to supplies made at the request of a patient are: that the pharmacist by or under whose supervision the Prescription Only Medicine is to be sold or supplied has interviewed the person requesting the medicine and has satisfied himself:
 - i that there is an immediate need for the Prescription Only Medicine requested to be sold or supplied and that it is impracticable in the circumstances to obtain a prescription without undue delay;
 - ii that treatment with the prescription only medicine requested has on a previous occasion been prescribed by a doctor, dentist, supplementary prescriber, a community practitioner nurse prescriber, a nurse independent prescriber optometrist independent prescriber, or a pharmacist independent prescriber, EEA or Swiss doctor, or an EEA or Swiss dentist for the person requesting it, and;
 - iii as to the dose that in the circumstances it would be appropriate for that person to take;

- (b) that no greater quantity of the Prescription Only Medicine in question than will provide 5 days' treatment in the case of a Controlled Drug (ie, phenobarbital, phenobarbitone sodium or a Schedule 4 or 5 Controlled Drug) or 30 days for other prescription-only medicines, is sold or supplied, except that there may be sold or supplied where the medicine in question is:
- i a preparation of insulin, an ointment, a cream or an aerosol for the relief of asthma, which has been made up for sale in a container elsewhere than at the place of sale or supply, the smallest pack that the pharmacist has available for sale or supply ("aerosol" means a product which is dispersed from its container by a propellant gas or liquid),
 - ii an oral contraceptive, a full cycle,
 - iii an antibiotic in liquid form for oral administration, the smallest quantity that will provide a full course of treatment;
- (c) that the pharmacist by or under whose supervision the medicine is sold or supplied makes an entry in the Prescription Only register on the day of the supply, or if impracticable, the next day following, stating:
- i the date on which the Prescription Only Medicine was sold or supplied;
 - ii the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicine;
 - iii the name and address of the patient;
 - iv the nature of the emergency (i.e. why the patient requires the Prescription Only Medicine, and the reason why a prescription cannot be obtained);
- (d) that the container or package must be labelled to show:
- i the date of supply;
 - ii the name, quantity and, where appropriate, the pharmaceutical form and strength;
 - iii the name of the patient;
 - iv the name and address of the pharmacy;
 - v the words "Emergency Supply";
 - vi the words "Keep out of the reach of children" (or similar warning).
- (e) that the Prescription Only Medicine is not a Controlled Drug specified in Schedule 1, 2 or 3 to the Misuse of Drugs Regulations (an emergency sale or supply of phenobarbitone or phenobarbitone sodium is permitted, at the request of the patient, provided that it is for use in the treatment of epilepsy and does not contain any of the other substances in Schedules 1, 2, or 3 to the Misuse of Drugs (Northern Ireland) Regulations 2002) and does not consist of, or contain, a substance in the following list:
- Ammonium bromide
 - Calcium bromide
 - Calcium bromidolactobionate
 - Embutramide
 - Fencamfamin hydrochloride

Fluanisone
Hexobarbitone (Hexobarbital)
Hexobarbitone sodium (Hexobarbital)
Hydrobromic acid
Meclofenoxate hydrochloride
Methohexitone sodium (Methohexital)
Pemoline
Phenylmethylbarbituric acid
Piracetam
Potassium bromide
Prolintane hydrochloride
Sodium bromide
Strychnine hydrochloride
Tacrine hydrochloride
Thiopentone sodium (Thiopental)

*Note: the patient of an EEA or Swiss doctor or EEA or Swiss dentist is not permitted to obtain Schedule 1-5 Controlled Drugs or medicines that do not have a UK marketing authorisation as an emergency supply.

1.4 EXEMPTIONS TO MEDICINES LEGISLATION IN THE EVENT OF A PANDEMIC

The Department for Health, Social Services and Public Safety (DHSSPS) will announce when a pandemic situation is imminent or has arisen, at which time the following provisions will apply.

Emergency Supply

In the event of a pandemic, or in anticipation of a disease being imminently pandemic which poses a serious or potentially serious risk to human health, the conditions for making an emergency supply at the request of a patient are relaxed in that the pharmacist will not need to interview the person who requests the medicine.

The pharmacist will still be required to satisfy himself/herself that the treatment had been prescribed on a previous occasion by an appropriate practitioner and that the dose is appropriate for the person to be treated to take.

Supply of POMs against a prescription during an emergency

In the event, or in anticipation, of pandemic disease, the requirement whereby prescription-only medicines are only sold or supplied (in circumstances corresponding to retail sale) in accordance with a prescription given by an appropriate practitioner, will not apply.

This change will only apply when a disease is pandemic, or anticipation of a disease being imminently pandemic, and a serious or potentially serious risk to human health. In such an event, supplies will be made from designated collection points in accordance with a specific protocol from the Department of Health and Social Services and/or Regional Health Board.

The protocol will contain criteria as to:

- (i) symptoms of, and treatment for, that disease;
- (ii) the recording of the name of the person who supplies the prescription only medicine to the person to be treated (or to a person acting on that person's behalf) and of the evidence that the medicine was supplied to the person to be treated (or to a person acting on that person's behalf).

Conditions under which the retail sale or supply of medicines can occur during an emergency

In the event, or in anticipation, of a pandemic disease, the requirement for prescription-only medicines and pharmacy medicines to be sold or supplied from registered pharmacy premises will not apply. This change will only apply while a disease is, or in anticipation of, a disease being imminently pandemic and a serious risk, or potentially serious risk, to human health and is in accordance with a specific protocol.

Labelling of certain children's medicines

The MHRA has temporarily authorised the distribution of unlicensed oseltamivir powder and an unlicensed oral liquid formulation of oseltamivir for administration to infants under one year of age in the prevention or treatment of influenza. The oral solution will be prepared in designated licensed NHS manufacturing units.

Linked to this authorisation, in the event of a disease being imminently pandemic or pandemic and a serious or potentially serious risk to human health, the labelling requirements for antiviral medicines in the form of a solution intended for the treatment of a child under the age of one year, will be simplified. Under such circumstances the container of the product only needs to be labelled with the following:

- (i) the name of the person to whom the medicine is to be administered;
- (ii) the date on which the medicine is dispensed; and
- (iii) the necessary and usual instructions for proper use.

1.5 THE RESPONSIBLE PHARMACIST REGULATIONS

Under the Responsible Pharmacist Regulations (2008) every retail pharmacy business must have a named and recorded Responsible Pharmacist who is responsible for securing the safe and effective running of the pharmacy. The regulations also require the pharmacy to maintain a series of Pharmacy Procedures on a range of issues and a conspicuously displayed notice of who the current Responsible Pharmacist is. The regulations became effective in October 2009 and replace previous "personal control" requirements.

Any qualified and registered pharmacist is eligible to be the Responsible Pharmacist. Standards and Guidance from the Pharmaceutical Society of Northern Ireland, and further information relating to the Responsible Pharmacist requirements are available from the Responsible Pharmacist section of the psni.org.uk website: <http://www.psni.org.uk/responsible-pharmacist.php>

Medicines sales protocol and Pharmacy Procedures

Since 1 January 1996, all pharmacies have been required to have a medicines sales protocol, which describes the manner in which all medicines are to be sold and specifies those transactions in which the pharmacist is required to have direct involvement. There is a requirement that all staff whose work regularly includes the sale of pharmacy medicines must be trained to know when a pharmacist should be consulted. From January 2005, pharmacists are required to have Standard Operating Procedures (SOPs) in place to cover the full range of activities undertaken in a pharmacy.

The requirement for pharmacies to have a medicines sales protocol has now been supplemented by the Responsible Pharmacist regulations (2008), effective since October 2009, that require every pharmacy to maintain procedures on a range of matters, including:

- a. the arrangements to secure that medicinal products are: ordered; stored; prepared; sold by retail; supplied in circumstances corresponding to retail sale; delivered outside the pharmacy; and disposed of, in a safe and effective manner;
- b. the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products;
- c. the identification of members of pharmacy staff who are, in the view of the responsible pharmacist, competent to perform certain tasks relating to the pharmacy business;
- d. the keeping of records about the arrangements mentioned in paragraph (a);
- e. the arrangements which are to apply during the absence of the responsible pharmacist from the premises;
- f. the steps to be taken when there is a change of responsible pharmacist at the premises;

- g. the procedure which is to be followed if a complaint is made about the pharmacy business;
- h. the procedure which is to be followed if an incident occurs which may indicate that the pharmacy business is not running in a safe and effective manner; and
- i. the manner in which changes to the pharmacy procedures are to be notified to pharmacy staff

The procedures must be available at the premises for inspection and reviewed on a regular basis.

Furthermore, all medicines sales should comply with the Pharmaceutical Society of Northern Ireland's Code of Ethics and the supporting Standards and Guidance documents. This includes the requirements that all staff whose work regularly includes the sale of pharmacy medicines must be competent, and that assistants must be trained to know when the pharmacist should be consulted.

The Pharmacy Record

A further requirement of the Responsible Pharmacist regulations (2008) is for every pharmacy to maintain a Pharmacy Record of the name of the Responsible Pharmacist during operating hours, their registration number, and the date and time at which they both became the Responsible Pharmacist for the premises, and ceased to be the Responsible Pharmacist for the premises. The Record should be kept in written or electronic format (or both), be available for inspection, and be preserved for a period of not less than 5 years.

The Responsible Pharmacist and absence from the premises

The maximum period for which the Responsible Pharmacist may be absent from the premises is two hours during the pharmacy's operating hours. If there is more than one responsible pharmacist during the pharmacy's operating hours, the maximum period relates to the total period of absence for all of them. During any period of absence, the Responsible Pharmacist must remain contactable and be able to return to the premises with reasonable promptness.

The retail sale of medicinal products on a general sale list (GSL) may continue during the period of absence of the Responsible Pharmacist, but not the sale of Pharmacy Only or Prescription Only Medicines. Further information about the Responsible Pharmacist regulations is available from the Responsible Pharmacist section of the psni.org.uk website: <http://www.psn.org.uk/responsible-pharmacist.php>

1.6 GUIDANCE ON COLLECTION AND DELIVERY SERVICES TO RURAL AREAS

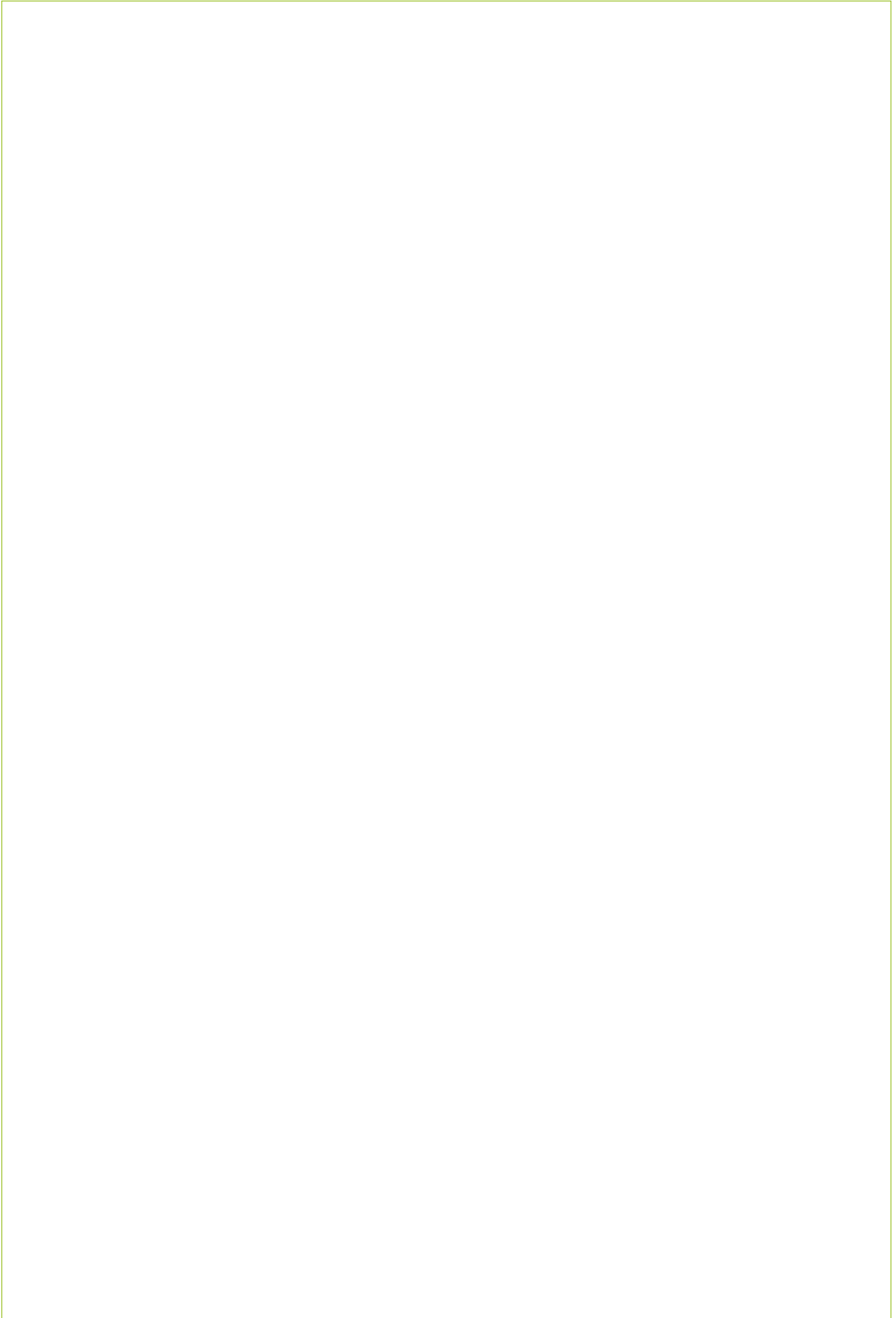
The Medicines (Collection and Delivery Arrangements) Order 1978, states that the restrictions imposed by Section 52 and 53 of the Medicines Act 1968 shall not apply to the supply of any medicinal product for human use on premises that are not a registered pharmacy, where such a supply is made in accordance with a prescription given by a doctor or dentist, and forms part of a collection and delivery arrangement used by a person who lawfully conducts a retail pharmacy business.

Essentially this enables pharmacists to make arrangements for patients to exchange a prescription issued by a doctor or dentist and collect the dispensed medicines from a general point that is not a pharmacy.

In rural areas some patients may experience difficulty in obtaining their dispensed medicines. It may not be practical in many instances to deliver the medicines to the patient's home. In circumstances where dispensed medicines are to be collected from a central point, care must be taken when making such arrangements to take into account the need for adequate security and the responsibility required when handing out medicines.

See Professional Standards on Sale and Supply of Medicines (Section 6 and 7) for more information.

Further Guidance from the Pharmaceutical Society of Northern Ireland will be published later in 2010 on the Standards and Guidance section of the psni.org.uk website: <http://www.psni.org.uk/professionals/code-of-ethics.php>





2 Medicines for Human Use: Controlled Drugs & Accountable Officer Regulations



2.1 CONTROLLED DRUGS

A number of important amendments to the Misuse of Drugs Regulations 2002 have come into force in the period 2006 -2010. Pharmacists should ensure that they are aware of all the changes as they affect current practice.

A list of relevant legislation is given at the end of this section and further information may be accessed online at www.opsi.gov.uk

In addition a number of informative Guidance Documents have been issued by both the DHSSPSNI. These are included at the end of the section.

The information provided below should be read in conjunction with the following reference documents

- Safer Management of Controlled Drugs –A guide to good practice in secondary care (Northern Ireland) August 2009 (see www.dhsspsni.gov.uk)
- Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) – due 2010

The Misuse of Drugs Act 1971 controls “dangerous or otherwise harmful drugs” which are designated as “Controlled Drugs”. The primary purpose of the Misuse of Drugs Act is to prevent the misuse of Controlled Drugs. It does that by imposing a total prohibition on the possession, supply, manufacture, import or export of Controlled Drugs except as allowed by regulations or by licence or authority from the DHSSPS. The use of Controlled Drugs in medicine is permitted by the Misuse of Drugs (Northern Ireland) Regulations 2002 and subsequent amendment regulations. Other regulations deal with the safe custody of Controlled Drugs and with the notification of and supply of drugs to addicts. The schedules to the Act are of no practical importance to pharmacists and practitioners. In the Misuse of Drugs Regulations, the drugs are classified in five schedules according to different levels of control. It is those classifications that are described in the following paragraphs. They are marked “CD Lic”, “CD No Register”, etc.

Schedule 1 Drugs (CD Lic)

Schedule 1 includes the hallucinogenic drugs (for example LSD) the ecstasy-type substances and cannabis, which have virtually no therapeutic use. Production, possession and supply of drugs in this schedule are limited, in the public interest, to purposes of research or other special purposes. A licence from the DHSSPS is needed for any of these purposes, and, apart from licence holders, the class of persons who may lawfully possess them is very limited. It does not include practitioners and pharmacists except under licence.

Some pharmacists, particularly those working within hospital, may be asked to deal with substances removed from patients on admission, which may be Schedule 1 products (for example cannabis). As a licence is required to possess Schedule 1

products, the pharmacist cannot take possession of the product other than in the two cases where exemptions are granted. The first exemption is where a person takes possession of a Controlled Drug for the purpose of destruction, and the second is for the purpose of handing over to a police officer.

The patient's confidentiality should normally be maintained, and the police should be called in on the understanding that there will be no identification of the source. If, however, the quantity is so large that the drug could not be purely for personal use, the pharmacist may decide that the greater interests of the public require identification of the source. Such a decision should not be taken without first discussing with the other health professionals involved in the patient's care, and the hospital's legal adviser, and if possible, the DHSSPS.

In theory, the patient should give authority for the removal and destruction of the drug. If the patient refuses, then the hospital may feel that it has no alternative other than to call in the police. Under no circumstances can a Schedule 1 drug be handed back to a patient at discharge, as the person doing so could be guilty of an offence of unlawful supply of a Controlled Drug. The penalties for this type of offence are high and often involve a custodial sentence.

In December 2009 the Misuse of Drugs Act 1971 was amended to include the so called "legal Highs" as Class C Controlled Drugs. The Dangerous Drugs, The Misuse of Drugs (Amendment) Regulations (Northern Ireland) inserted 1-benzylpiperazine (BZP), all but two of a group of substituted piperazines and the synthetic cannabinoid agonists into Schedule 1 of the Misuse of Drugs Regulations (Northern Ireland) 2002. Nabilone and Oripavine are inserted into Schedule 2 of the 2002 Regulations plus some other changes.

See Guidance Note 11 and SR No 389/390/397

In April 2010, Mephedrone (4-Methylmethcathinone) was included in Schedule 1 to the Misuse of Drugs Regulations (Northern Ireland) 2002.

Schedule 2 Drugs (CD)

Schedule 2 includes the opiates (such as diamorphine, morphine and methadone), the major stimulants (such as the amphetamines) and secobarbital (quinalbarbitone). In December 2009 Nabilone and Oripavine were added to this schedule.

A licence is needed to import or export drugs in this Schedule, but they may be manufactured or compounded by a licence holder, a practitioner, a pharmacist, or a person lawfully conducting a retail pharmacy business acting in his capacity as such. A pharmacist may supply them to a patient only on the authority of a

prescription in the required form (see below) issued by an appropriate practitioner. The drugs may be administered to a patient by a doctor or dentist, or by any person acting in accordance with the directions of a doctor or dentist, a nurse independent prescriber (who may currently administer certain controlled drugs), a supplementary prescriber in accordance with a clinical management plan, or any person acting in accordance with the directions of a doctor, dentist, nurse independent prescriber or a supplementary prescriber in accordance with a clinical management plan.

NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.

Requirements as to safe custody in pharmacies apply to all Schedule 2 Controlled Drugs **except secobarbital (quinalbarbitone)**. Control over destruction applies to these drugs, and the provisions relating to the marking of containers and the keeping of records must also be observed (see below).

Pharmacists should bear in mind that the requirement for safe custody of Schedule 2 drugs also applies to patient returned Schedule 2 drugs, until they are denatured for disposal.

Schedule 3 Drugs (CD No Register)

Schedule 3 includes a small number of minor stimulant drugs such as benzphetamine, and other drugs such as buprenorphine, midazolam, phenobarbitone and temazepam that are not thought so likely to be misused as the drugs in Schedule 2, nor to be so harmful if misused. Midazolam is now a Schedule 3 controlled drug but the safe custody requirements do not apply.

The controls that apply to Schedule 2 also apply to drugs in this schedule, except

- (a) there is a difference in the classes of persons who may possess and supply them;
- (b) the requirements as to destruction by an authorised witness do not apply unless the pharmacist is deemed to be "a producer" i.e. he compounds or manufactures the items;
- (c) records in the register of Controlled Drugs need not be kept in respect of these drugs unless the pharmacist is "a producer" and
- (d) safe custody requirements currently only apply to preparations of diethylpropion, buprenorphine, flunitrazepam and temazepam.

Phenobarbital (phenobarbitone) and midazolam do not require safe custody. The requirement for safe custody of these Schedule 3 controlled drugs also applies to patient returned Schedule 3 drugs, until they are denatured for disposal.

Invoices need to be retained by retail dealers.

Schedule 4 Drugs

Schedule 4 is split into two parts:

- Part I (CD Benz) contains benzodiazepines; Ketamine was added to this section in 2006 (SR No 44) and in December 2009 (SR 390/397) two substituted piperazines namely 1-(3-Chlorophenyl)-4-(3-chloropropyl) piperazine and 1-(3-Chlophenyl) piperazine were included.
- Part II (CD Anab) contains the anabolic steroids and androgenic steroids together with clenbuterol and growth hormones. Under SR 390/397 2009, 15 anabolic steroids and 2 non-steroidal agents were added to this section including:
Bolidone, Danazol, Desoxymethyltestosterone, Gestrinone, Prostanazol, Tetrahydrogestrinone, Zeranol and Zilpaterol

Part I (CD Benz)

- (a) A Home Office import or export licence is required for the importation or exportation of substances in Part 1.
- (b) No Restriction with respect to possession when contained in a medicinal product.
- (c) The prescription and labelling requirements are those laid down by the Medicines Act 1968. The validity of the prescription is limited to 28 days.
- (d) No records are required in the CD Register.
- (e) Destruction requirements apply only to importers, exporters and manufacturers but not to retail pharmacists.
- (f) Safe custody requirements do not apply.

Part II (CD Anab)

- (a) Provided the substances are formulated as medicinal products for administration to individuals, they will be exempted from the prohibition on possession of controlled drugs.
The CD safe custody requirements do not apply.
Records of receipts and supplies are not required in the CD Register.

Schedule 5 Drugs (CD Inv)

Schedule 5 contains preparations of certain Controlled Drugs, for example, codeine, pholcodine, cocaine and morphine that are exempt from full control when present in medicinal products of low strength.

- There is no restriction on the import, export, possession or administration of these preparations.
- Safe custody requirements do not apply.
- A practitioner or pharmacist acting in his capacity as such, or a person holding an appropriate licence, may manufacture or compound any of them.
- No record in the register of Controlled Drugs need be made in respect of drugs obtained or supplied by a person lawfully conducting a retail pharmacy

business, unless that person is a “producer” i.e. a manufacturer or compounder of such items.

- The invoice or a copy of it must be kept for two years.
- No authority is required to destroy these drugs.
- There are no special labelling requirements (but Medicines Act labelling requirements apply).

Possession and supply of Controlled Drugs

It is unlawful for any person to be in possession of Controlled Drugs other than those in Schedule 5 unless:

- (a) he holds an appropriate licence or authority from the DHSSPS;
- (b) he is a member of a class specified in the regulations; or
- (c) the regulations provide that possession of that drug or group of drugs is not unlawful. In any case, possession or supply is not lawful unless the person concerned is acting in his capacity as a member of his class, or in accordance with the terms of his licence or group authority.
- (d) they have been lawfully prescribed for that person or for that person’s animal.

Practitioners and pharmacists are amongst those who have a general authority to possess, supply and procure all Controlled Drugs except those in Schedule 1.

Certain other persons, including wholesalers, importers and exporters, must obtain licences or authorities from the DHSSPS. “Wholesale dealer” in this context means a person who carries on the business of selling drugs to persons who buy to sell again.

Any person who is lawfully in possession of a Controlled Drug may supply that drug to the person from whom he lawfully obtained it.

Requisitions for Schedules 1, 2 and 3 Controlled Drugs

See Guidance Note 7 and Guidance Note 13

A requisition in writing must be obtained by a supplier before he delivers any Controlled Drug (except those in Schedules 4 and 5). The requisition does not have to be in the recipient’s handwriting but must

- i be signed by the recipient
- ii state the recipient’s name and address
- iii state the recipient’s profession or occupation
- iv specify the total quantity to be supplied
- v state the purpose for which required

The supplier must be reasonably satisfied that the signature is that of the person purporting to sign the requisition and that he is engaged in the occupation stated.

A messenger sent by a purchaser ("recipient") to collect a Controlled Drug on his behalf, may only be supplied with the Controlled Drug if he produces to the supplier a statement in writing given by the recipient to the effect that the messenger is empowered to receive the drug on his behalf. The supplier must be reasonably satisfied that the document is genuine and must retain it for two years.

The requirement for the written statement does not apply to a person carrying on a business as a carrier engaged by the supplier.

On receipt of a requisition (not a veterinary requisition) for a controlled drug (except Schedule 4 and 5) the pharmacist

- should mark on the requisition in ink or otherwise to be indelible, his name and address. The pharmacy stamp may be used.
- Requisitions for controlled drugs should be submitted by community pharmacies to the Business Services Organisation (BSO) using the modified H30 form (NB: Requisitions written by veterinary practitioners must not be submitted to BSO, they should be retained at the pharmacy and drawn to the attention of the pharmacy inspector). See Guidance Note 13.

Requisitions presented on HS21S forms (Triplicate Stock Order Forms) should be submitted to the Business Services Organisation (BSO) as is current practice.

The above requirements do not apply where the supplier is either a wholesale dealer or is a person responsible for the dispensing and supply of medicines at a hospital or nursing home.

The requisition must be obtained prior to supply to any of the following:

- (a) a practitioner (a practitioner urgently requiring a drug and unable to supply a written requisition before delivery may be supplied on his giving an undertaking to furnish a requisition within the next 24 hours; failure to furnish the requisition within 24 hours is an offence on the part of the practitioner);
- (b) the person or acting person in charge of a hospital or nursing home (a requisition from the person in charge of a hospital or nursing home must be signed by a doctor or dentist employed there);
- (c) a senior registered nurse or acting senior registered nurse, for the time being in charge of any ward, theatre or other department of a hospital or nursing home, who obtains a supply of a Controlled Drug from the person responsible for dispensing and supplying medicines at that hospital or nursing home, must furnish a requisition in writing signed by her that specifies the total quantity of the drug required. She must retain a copy or note of the requisition. The person responsible for the dispensing and supply of the Controlled Drug must mark the requisition in such a manner as to show that it has been complied with and must retain the requisition in the dispensary;

- (d) a person who is in charge of a laboratory, the recognised activities of which consist in, or include, the conduct of scientific education or research and which is attached to a university, university college, hospital or institution approved for that purpose;
- (e) the owner of a ship or the master of a ship that does not carry a doctor among the seamen employed by it;
 - the installation manager of an offshore installation;
 the master of a foreign ship in a port in Northern Ireland (a requisition from the master of a foreign ship must contain a statement signed by an authorised medical officer of the Health and Social Care Board (HSCB) for the Area, within whose jurisdiction the ship is, that the quantity of the drug to be supplied is the quantity of drug necessary for the equipment of the ship).
- (f) A supplementary prescriber.
- (g) An operating department practitioner (ODP) can order S2, S3, S4 and S5 controlled drugs from a hospital pharmacy although currently a written requisition is not required. Good practice guidance in line with hospital policy and SOPs would stipulate that the supply of a controlled drug is dependant on the receipt of a requisition. (See Safer Management of Controlled Drugs - A guide to good practice in secondary care 2009).
- (h) An ODP is not permitted to obtain controlled drugs from a community pharmacy.

NB. Pharmacists who make supplies to the owners or masters of ships should make sure that they are aware of the guidelines laid down in relation to the quantities of specific Controlled Drugs that may be supplied. The legal requirements relating to the requisitions required for such supplies must be fulfilled.

Controlled Drugs in hospitals

In hospitals additional requirements relating to administration and supply, prescriptions, requisitions and registers for Controlled Drugs include:

- (1) A senior registered nurse or acting senior registered nurse, for the time being in charge of a ward, theatre, or other department, may not supply any drug otherwise than for administration to a patient in the ward, theatre or department in accordance with the directions of a doctor or dentist, supplementary prescriber under and in accordance with the terms of a clinical management plan, or of a nurse independent prescriber subject to the limited list of Controlled drugs which they may prescribe which includes a specific purpose for which the drug may be prescribed. NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.
- (2) The senior registered nurse or acting senior registered nurse, for the time being in charge of a ward, theatre or other department, is not required by

the Misuse of Drugs (Northern Ireland) Regulations 2002 to keep any register. However, DHSSPS guidance should be followed – See Section 4.7 of Safer Management of Controlled Drugs: a guide to good practice in secondary care, 2009.

- (3) The person in charge or acting person in charge of a hospital or nursing home having a pharmacist responsible for the dispensing and supply of medicines may not supply or offer to supply any drug.
- (4) A prescription issued for the treatment of a patient in a hospital or nursing home may be written on the patient's bed-card or case-sheet.
- (5) An operating department practitioner in that hospital may not supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan, or of a nurse independent prescriber. The directions given by a nurse prescriber relate only to the limited list of Controlled Drugs which they may prescribe and are subject to restrictions on the purpose for which the drug may be prescribed. NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.
- (6) (a) Private prescriptions for Schedule 2 and Schedule 3 Controlled Drugs issued within a hospital (within its legal entity) and supplied by a pharmacist in that hospital do not need to be on a standardised prescription form and do not need to specify the prescriber identification number.
(b) in the case where a private prescription for a Schedule 2 or Schedule 3 controlled drug is issued outside that hospital (i.e. outside its legal entity), the prescription would have to be issued on a standardised prescription form and would need to specify the prescriber identification number in order for the supply to be legal. This also applies where the prescription has been issued from a hospital in another legal entity. NB: In order to supply against a prescription presented from outside the legal entity of that hospital, the hospital would require to be registered with the Pharmaceutical Society)
- (7) Requisitions for Schedule 2 or 3 Controlled Drugs that are to be supplied by a pharmacist in a hospital do not need to be sent to the BSO and do not need to be marked with the name and address of the pharmacy.

Prescriptions for Controlled Drugs

No prescription is required under the Misuse of Drugs Regulations for the supply by a pharmacist of a Schedule 5 drug but, for preparations above certain strengths, a prescription is required under the Medicines Act 1968. Prescriptions are necessary for all other categories of Controlled Drugs, which are always Prescription Only Medicines. The requirements of both the Misuse of Drugs Act and the Medicines Act must be satisfied.

It is not lawful for a practitioner to issue a prescription containing a Controlled Drug other than a drug specified in Schedule 4 or 5 or temazepam, or for a pharmacist to dispense it, unless it complies with the following requirements.

The prescription must:

- (a) be written so as to be indelible, be dated and be signed by the person giving it with his usual signature;
- (b) except in the case of a health prescription, specify the address of the person issuing it. N.B. The Medicines Act requires that all prescriptions for Prescription Only Medicines contain the prescriber's address;
- (c) have written on it, if issued by a dentist, the words "for dental treatment only";
- (d) specify the name and address of the person for whose treatment it is issued;
- (e) specify the dose to be taken and
 - i in the case of preparations, the form and, where appropriate, the strength of the preparation and either the total quantity (in both words and figures) of the preparation or the number (in both words and figures) of dosage units to be supplied;
 - ii in any other case, the total quantity (in both words and figures) of the Controlled Drug to be supplied. DHSSPS/Home Office has expressed a view that a dose of "as directed" or "when required" is not acceptable but "one to be taken as directed/when required" is acceptable;
- (f) in the case of a prescription for a total quantity intended to be dispensed by instalments, contain a direction specifying the amount of the instalments that may be dispensed and the intervals to be observed when dispensing;
- (g) in the case of a private prescription for human use (including temazepam and midazolam) be on a standardised form PCD1 (in Northern Ireland) when dispensed in community pharmacy;
- (h) in the case of private prescriptions for human use (including temazepam and midazolam) contain the private prescriber's identification number on the prescription.

For the purposes of prescription writing temazepam can be written up as for any other Prescription Only Medicine. (See section on Prescriptions for Prescription Only Medicines).

A practitioner shall not issue a private prescription for temazepam for human use, unless it is written on a prescription form provided by the BSO or equivalent body for the purposes of private prescribing and it specifies the prescriber identification number and the address of the person issuing it. (This requirement does not apply to veterinary prescriptions.)

However under current legislation, private prescriptions for controlled drugs must be retained for 2 years.

A Controlled Drug (except Schedule 4 and Schedule 5) must not be supplied by any person on a prescription:

- (a) unless the prescription complies with the provisions set out above (except temazepam);
- (b) unless the prescriber's address on the prescription is within the United Kingdom;
- (c) unless the supplier is either acquainted with the prescriber's signature and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine;
- (d) before the appropriate date specified on the prescription;
- (e) later than 28 days after the appropriate date on the prescription. This requirement applies to temazepam, midazolam and Schedule 4 drugs. (The appropriate date is defined as "the later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it shall not be supplied". Where a prescriber wishes the 28 day period to start on a date other than the date of signing, he may specify a start date from which the period will begin);
- (f) in the case of an instalment prescription, unless the first instalment is dispensed within 28 days of the appropriate date with the remaining instalments dispensed in accordance with the instructions.

Owings of dispensed prescriptions for Schedule 2, 3 and 4 controlled Drugs cannot be supplied more than 28 days after the appropriate date.

The date must be marked on the prescription at the time of supply.

Instalment prescriptions for Controlled Drugs, Schedule 2, 3 and 4

- (a) the first instalment must be dispensed within 28 days of the appropriate date, and the remainder of instalments dispensed in accordance with the instructions given.
- (b) The 28 day period of validity starts from the appropriate date on the prescription, which may be the date of signing the prescription or the start date as indicated by the prescriber
- (c) Where a start date is given, it must be complied with and the instalment directions shall run from that date
- (d) In every other case, the instalment direction will run from the date of first dispensing of the prescription
- (e) The prescription must be marked with the date of each dispensing
- (f) Prescriptions that contain a direction that specified instalments of the total amount may be dispensed at stated intervals must not normally be dispensed otherwise than in accordance with the directions.

The Home Office has provided guidance on approved wording that may be used on prescriptions to cover situations where an instalment to be collected has been missed.

(For Home Office Wording – access www.nta.nhs.uk/publications/documents/clinical_guidelines_2007.pdf)

Private prescriptions for Controlled Drugs

All Private prescriptions for Schedule 2 and 3 controlled drugs including temazepam) must be

- written on dedicated private controlled drug prescription forms PCD1 issued by the BSO in Northern Ireland.
- the private prescription must contain the prescriber's identification number.

The above requirements do not apply to veterinary prescriptions for controlled drugs.

In line with current prescribing patterns, it is envisaged that the usage in practice of these forms will be low.

Equivalent forms have been issued by the relevant bodies in England, Scotland and Wales. (FP10PCD in England, PPCD (1) in Scotland and WP10PCD in Wales).

These prescriptions will be valid for dispensing in Northern Ireland and pharmacists must continue to verify the authenticity of the prescription before a supply is made.

For private prescriptions in a hospital situation see page 49

Private prescription forms PCD1 should be treated in the same way as for other private prescription

- enter in the prescription book
- endorse appropriately
- submit to the BSO

From April 1st 2010 PCD1 forms should be submitted by community pharmacies to the BSO using the modified HS 30 form.

See Guidance Note 4 and Guidance Note 13.

Sativex is an oromucosal spray containing derivatives of cannabis and has been available as an unlicensed medicine on a named patient basis for the treatment of spasticity associated with multiple sclerosis. In June 2010 it was granted a licence as a prescription only medicine. It is anticipated that the product will be classified as a Schedule 4 controlled drug in the future.

Technical errors on prescriptions for Controlled Drugs.

Pharmacists may supply Schedule 2 or 3 controlled drugs (excluding temazepam) if the prescription contains minor typographical errors or spelling mistakes or if it does not comply with the provisions of regulation 15(1) f (Words and Figures requirements) provided that

- (i) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that the prescription is genuine;
- (ii) having exercised all due diligence, the pharmacist is satisfied on reasonable grounds that he is supplying the drug in accordance with the intention of the person issuing the prescription;
- (iii) the pharmacist amends the prescription in ink or otherwise indelibly to correct the minor typographical errors or spelling mistakes so that the prescription complies with the requirements of regulation 15 as the case may be; and,
- (iv) the pharmacist marks the prescription so that the amendment he has made (under (c) above) is attributable to him/her.

No other amendments can be made or added to the prescription including the date, the dose or the form as currently these are not regarded as minor typographical errors.

Prescribing for up to 30 days treatment

Although not a legal requirement, it is recommended practice that quantities prescribed should not exceed 30 days supply except in exceptional circumstances. For further information see Guidance Note 8 and Pharmacy Inspectors' Newsletter Issue 3 November 2007 DHSSPS.

Collection of Schedule 2 Controlled Drugs

HS21 prescription forms have been amended to have a space on the reverse of the form to permit the recording of the signature of the person collecting a Schedule 2 or 3 controlled drug. At present obtaining the signature is not a legal requirement (this may change in the future) but it is considered good practice to do so. See Guidance Note M150 18/09/06 DHSSPS.

Pharmacists are required to ascertain the role of any person collecting a Schedule 2 Controlled Drug to determine whether that person is (a) the patient, (b) the patient's representative or (c) a healthcare professional acting within their professional capacity on behalf of the patient.

If the person collecting the Schedule 2 drug is the patient or the patient's representative, the pharmacist may request evidence of that person's identity and may refuse to supply the CD if they are not satisfied as to the identity of the person.

In order not to deny patient access to the drugs that they require, it will not be a criminal offence to supply the CD without proof of identity, even if that person is not known to the pharmacist.

Circumstances where ID may not be required are when the person collecting the CD is known to the pharmacist (e.g. the patient, close relative or a local healthcare professional) or when the pharmacist considers that asking for ID may compromise patient confidentiality.

If the person collecting the Schedule 2 CD is a healthcare professional, the pharmacist must obtain the name and address of the healthcare professional and unless they are already acquainted with that person, they must request evidence of that person's identity. However, even if the pharmacist is not satisfied as to the identity of the person, they may still supply the CD.

Types of ID that may be considered suitable include:

Driving licence (with photo card section), passport, credit card, cheque book etc

For other examples of appropriate documentation that may be used as ID –See Appendix B of Guidance Note 3, issued 26/06/06

The requirement for record keeping with regard to proof of identity came into force on February 1st 2008.

In circumstances where a controlled drug is conveyed by messenger such as a porter or delivery driver the appropriate guidance should be consulted

- Safer Management of Controlled Drugs – A guide to good practice in secondary care (Northern Ireland) August 2009
- Safer Management of Controlled Drugs – A guide to good practice in primary care (Northern Ireland) due 2010.

Controlled Drug registers

See Guidance Note 7.

Records must be kept, by the above persons authorised to possess Controlled Drugs, of all Schedule 1 and 2 drugs obtained or supplied. Entries in the controlled drugs register must be recorded under the following headings:-

- (a) In respect of entries made for drugs obtained
 - i Date supply received
 - ii Name and address from whom received
 - iii Quantity received
- (b) In respect of entries for drugs supplied
 - i Date supplied

- ii Name and address of person or firm supplied
- iii Details of authority to possess – prescriber or licence holder’s details
- iv Quantity supplied
- v Person collecting Schedule 2 controlled drugs (patient/patient’s representative, healthcare professional). If a healthcare professional collecting the Schedule 2 controlled drug, their name and address. If the healthcare professional is unknown to the pharmacist, proof of identification must be seen and recorded.
- vi Was proof of identity requested of the patient/patient’s representative? (Yes/No)
- vii Was proof of identity of the person collecting the drug provided? (Yes/No)

The above requirements represent the minimum fields of information to be recorded. The regulations allow for additional information to be recorded as appropriate.

The following points are important in relation to the keeping of Controlled Drug registers:

- (a) Entries must be in chronological sequence.
- (b) A separate register or a separate part of the register must be used for each class of drugs. Separate sections are required for amphetamines (which includes dexamphetamine) and methylamphetamine.
- (c) A separate page shall be used in respect of each strength and form of that drug.
- (d) The head of each such page shall specify the class of drug, its form and its strength.
- (e) Entries must be made on the day of the transaction or on the next day following.
- (f) No cancellation, obliteration or alteration may be made; correction must be by dated marginal note or footnote.
- (g) Every such entry and every correction of such an entry shall be made in ink or otherwise so as to be indelible or shall be in a computerised form in which every such entry is attributable and capable of being audited and which is in accordance with best practice guidance endorsed by the Secretary of State under Section 2 of the National Health Services Act 1977.
- (h) The register must not be used for other purposes.
- (i) The register must be kept at the premises to which it is related and a separate register must be kept for each premises of the business,
- (j) where the register is in computerised form, it must be accessible from these premises.
- (k) With DHSSPS approval, separate registers may be kept for each department of a business.
- (l) Particulars of stock receipts and supplies must be furnished to any authorised person on request (this includes the inspectors for the DHSSPS and any

person authorised in writing by DHSSPS). Other documents and stocks of drugs must also be produced if required. The Department or other person authorised in writing by the Department in that behalf may request that a register which is kept in computerised form be produced by sending a copy of it in computerised or other form, to the appropriate person.

- (m) Registers must be kept for two years from the last date of entry.
- (n) The information to be contained in these records to be preserved in the original paper form, or as a copy on computer

Good practice points

- It is good practice that the controlled drug register maintains a running balance
- Where an entry has been made in the controlled drugs register, no entry is required in the prescription only register, but it is good practice to make such entries

Pharmacists are advised that CD registers may only be held in computerised form if safeguards are incorporated into the software to ensure that all of the following requirements are met:

- The author of each entry is identifiable
- Entries cannot be altered at a later date
- A log of all data entered is kept and can be recalled for audit purposes
- Access control systems should be in place to minimise risk of unauthorised or unnecessary access to the data
- Adequate backups must be made.
- Pharmacists are advised that provisions must be in place to enable inspectors to examine computerised records during a visit with minimum disruption to the dispensing process.

Computerised registers for controlled drugs should not be maintained unless the pharmacist can be satisfied that the above requirements and any future guidance issued can be met.

Supply of Controlled Drugs under Patient Group Directions

There are currently only three circumstances in which certain Controlled Drugs may be administered or supplied under a PGD. These are outlined below:

- (i) A registered nurse may, when acting in her capacity as such, supply or administer diamorphine under a PGD for the treatment of cardiac pain to a person admitted as a patient to a coronary care unit or accident and emergency department of a hospital.
- (ii) A registered nurse, pharmacist or any of the other named healthcare professionals listed in Schedule 8 of the Misuse of Drugs Regulations, as amended, may, when acting in their capacity as such, supply or administer any schedule 5 CD in accordance with a valid PGD.

- (iii) A registered nurse, pharmacist or any of the other named healthcare professionals listed in Schedule 8 of the Misuse of Drugs Regulations, as amended, may, when acting in their capacity as such, supply or administer any Part 1 Schedule 4 CD or midazolam in accordance with a valid PGD provided that it is not a drug in parenteral form for the treatment of addiction.

Midazolam is a Schedule 3 controlled drug and can be included in a PGD under certain circumstances.

Under no other circumstances can a controlled drug be considered for inclusion in a PGD. (The list of Controlled Drugs that may be included in a PGD and the circumstances in which they can be supplied or administered is being reviewed. Changes to legislation may occur in the future.)

Examples of named healthcare professionals include paramedics, health visitors, midwives, ophthalmic opticians, chiropodists, orthoptists, physiotherapists and radiographers.

Controlled Drugs and Supplementary Prescribing

A supplementary prescriber is permitted, when acting under and in accordance with the terms of a clinical management plan (CMP) to administer and/or supply CDs in Schedules 2, 3, 4 and 5.

Supply of Controlled Drugs by Nurse Independent Prescribers

NB: Legislation will change with respect to the prescribing of CDs by nurse independent prescribers and pharmacist independent prescribers.

Nurse independent prescribers are currently permitted to prescribe, supply, administer or direct any other person to administer, the following Controlled Drugs, solely for the medical conditions indicated:

- (i) diamorphine hydrochloride (orally or parenterally), morphine hydrochloride (rectally), morphine sulphate (orally, parenterally or rectally) or oxycodone hydrochloride (orally, or parenterally) for use in palliative care;
- (ii) buprenorphine (transdermal) and fentanyl (transdermal) in palliative care
- (iii) diamorphine hydrochloride (orally or parenterally), or morphine hydrochloride (rectally), morphine sulphate (orally, parenterally or rectally) for pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma, including in either case post operative pain relief
- (iv) chlordiazepoxide hydrochloride (orally) and diazepam (orally, parenterally or rectally) for treatment of initial or acute alcohol withdrawal symptoms;

- (v) codeine phosphate (orally), dihydrocodeine tartrate (orally) and co-phenotrope (orally) (no restrictions on medical conditions)
- (vi) diazepam (orally, parenterally or rectally), lorazepam (orally, or parenterally) or midazolam (parenterally or via the buccal route) for use in palliative care or treatment of tonic-clonic seizures.

Controlled drugs and pharmacist independent prescribers

Pharmacist independent prescribers are not currently permitted to prescribe, administer in their own right or direct the administration of Controlled Drugs.

This situation is under review and legislation may change in the future and guidance would then be issued in this regard. Initial changes to legislation came into force on 1st April 2008, (SI No. 464) but further amendments to the Misuse of Drugs Regulations (NI) 2002 and the Pharmaceutical Services Regulations are required to implement the changes.

Midwives and Controlled Drugs

A registered midwife may possess pethidine, diamorphine and morphine (S2) and pentazocine (S3), so far as is necessary for the practice of her profession. Supplies of pethidine, diamorphine, morphine and pentazocine may only be made to her on the authority of a Midwife's Supply Order signed by the "appropriate medical officer" who is authorised in writing by the local supervising authority, or the person appointed by the local supervising authority to exercise supervision over midwives. The midwife's supply order means an order in writing specifying the name and occupation of the midwife obtaining the drug, the purpose for which the controlled drug is required, and the total quantity to be obtained.

A midwife is required to keep a record of supplies of pethidine, diamorphine and morphine received and administered in a book used solely for that purpose. She must not destroy surplus stock but may surrender it to the "appropriate medical officer". (For destruction provision, see below.)

The pharmacist must retain the Midwife's Supply Order for two years. As pethidine, diamorphine and morphine are Schedule 2 Controlled Drugs, an appropriate entry is required in the CD register.

Pentazocine is a Schedule 3 Controlled Drug and therefore no entry is required in the CD register although an entry should be made in the prescription only register.

Under a Patient Group Direction, midwives are also permitted to supply all Part 1 Schedule 4 Controlled Drugs and all Schedule 5 CDs provided that it is not a drug in parenteral form for the treatment of addiction.

Controlled drugs and operating department practitioners

An operating department practitioner may, when acting in their capacity as such possess and supply or offer to supply any Controlled Drug specified in Schedule 2, 3 or 5 or any drug specified in Schedule 4 which is contained in a medicinal product, for the purposes of administration to a patient in a ward, theatre or department, in accordance with the directions of a doctor, dentist, supplementary prescriber acting under a clinical management plan.

The directions given by a nurse prescriber relate only to the limited list of Controlled Drugs that they may prescribe and the restrictions on the purpose for which the drug may be prescribed.

See also additional information on the ordering of CDs by an ODP under Requisitions.

2.2 THE ACCOUNTABLE OFFICER REGULATIONS

The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 (SR No 225) (made under the Health Act 2006) came into operation on 1 October 2009. The legislation requires Designated Bodies to nominate an Accountable Officer who is responsible for the management and use of CDs to minimise risk to patients. This will include the identification of poor systems and / or poor clinical practice that may exist.

The Regulations contain three key elements

- Accountable Officers and their duties
- Powers of entry and periodic inspections
- Co-operation between health bodies and other appropriate organisations

The legislation addresses the following matters

- Identification of Designated Bodies
- Appointment and removal of an Accountable Officer
- Establishment of arrangements to secure the safe management and use of CDs including destruction and disposal.
- Monitoring Systems
- Investigations and concerns
- Duty of collaboration

The Designated Bodies include

- The Health and Social Care Board (the Board)
- The Health and Social Care Trusts (5)
- Northern Ireland Ambulance Service Trust
- Independent Hospitals (including Hospices)

An Accountable Officer (AO) must be nominated by each Designated Body, and an up-to-date list including contact details for each AO can be found on the DHSSPS website www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm.

The AO is responsible for ensuring the safe and effective management and use of controlled drugs within their own organisation and by any body or person acting on behalf of or providing services to their organisation. This will include establishing and operating safe systems for the management and use of CDs, monitoring and auditing of the management and use of CDs and, where necessary, investigating concerns and incidents related to controlled drugs.

The Accountable Officer appointed by the Designated Body must be

- A senior person within their organisation.
- The AO must not routinely supply, administer or dispose of controlled drugs as part of his duties.
- The AO must submit a quarterly Occurrence Report to the Chair of the Local Intelligence Network (LIN).

The legislation gives power to require periodic declarations and self-assessments and these will be issued to all community and HSC Trust pharmacies annually and monitored by the Departmental Inspectors in conjunction with their established inspection arrangements. The Departmental Inspectors will, through their reporting arrangements, provide assurances to the Board Accountable Officer relating to the management and use of controlled drugs in contracted community pharmacies.

The completed form must be retained in the front of the Controlled Drug register and will become part of the routine record-keeping which will be examined by the Pharmacy Inspectors during their visits.

Forms should be retained, in accordance with the Pharmacy Inspectors advice, as part of the audit process. (Additional copies of the Declaration and Self Assessment Forms may be accessed from www.dhsspsni.gov.uk/index/pas/pas-accountable-officer/pas-forms.htm).

A range of guidance documents and training resources on the "Accountable Officer" legislation may be downloaded from the website www.dhsspsni.gov.uk/index/pas/pas-accountable-officer.htm

These include

- Safer Management of Controlled Drugs – A Guide to Strengthened Governance Arrangements in Northern Ireland October 2009
- Safer Management of Controlled Drugs – Guidance on Standard Operating Procedures for Northern Ireland October 2009
- Safer Management of Controlled Drugs Guidance-A Guide to Good Practice in Secondary Care 2009
- Safer Management of Controlled Drugs Guidance-A Guide to Good Practice in Primary Care 2010

- Contact List of Accountable Officers
- Contact List of Responsible Bodies

2.3 STANDARD OPERATING PROCEDURES FOR CONTROLLED DRUGS

For full details consult the following document:

“Safer Management of Controlled Drugs – Guidance on Standard Operating Procedures for Northern Ireland” October 2009

Pharmacists are required to have adequate and up-to-date standard operating procedures in place to cover the following matters as stated in Regulation 9 (SR 2009/225):

- who has access to the controlled drugs
- where the controlled drugs are stored
- security in relation to the storage and transportation of controlled drugs as required by the Misuse of Drugs legislation
- disposal and destruction of controlled drugs
- who is to be alerted if complications arise; and
- record keeping including:
 - (i) maintaining relevant controlled drugs registers under misuse of drugs legislation, and
 - (ii) maintaining a record of the controlled drugs specified in Schedule 2 to the Misuse of Drugs Regulations (Northern Ireland) 2002(17) (specified controlled drugs to which certain provisions of the Regulations apply) that have been returned by patients.

SOPs are needed for every stage of the controlled drug’s journey from procurement (ordering, receipt, and transport), safe storage, supply, administration, destruction and guidance for dealing with an incident.

The SOPs need to be accessible to staff at all times.

National Health prescriptions for the treatment of addicts (misusers)

Substitute Prescribing in Northern Ireland

For details of the process, check guidance from the BSO.

The system allows the prescribing of Methadone and Buprenorphine in certain circumstances. The prescription forms used in Northern Ireland are SP1 and SP2 available from the BSO. Prescribing of the drugs may be made in instalments for up to 14 days.

The system allows the prescribing of Methadone and Subutex in certain circumstances.

Details of the prescription format and the details to be completed by pharmacists are available from the BSO. For additional information, consult – Safer Management of Controlled Drugs - A guide to good practice in primary care (Northern Ireland) due 2010.

For systems in force in England, Scotland and Wales check the Department of Health website.

In England prescription form FP10 (MDA) is used for instalment prescribing by both drug treatment centres and GPs. A maximum of 14 days' supply of any Schedule 2 Controlled Drug, buprenorphine and diazepam can be prescribed for the treatment of addiction using this form. Computer based prescription forms FP10SS are also in use in England.

In Scotland form HBP (A) issued from drug addiction clinics can be used for instalment prescribing for drug addicts (misusers). General practitioners may prescribe by instalment for the treatment of addiction on a GP10 form.

In Wales two types of prescription form are used for the treatment of addicts (misusers) by instalment: WP10 (MDA), issued by general practitioners and WP10 (HP) Ad used by drug treatment centres. The prescription may be for up to 14 days supply.

NB. Cocaine, diamorphine and dipipanone can only be prescribed for the treatment of addiction by doctors who hold the required Home Office licence.

DHSSPS prohibitions

Prohibitions under Sec 13 of the Misuse of Drugs Act are enforced under the Misuse of Drugs (Northern Ireland) Rules 1974 and power is exercised by the DHSSPS. This enables them to make a direction against a practitioner prohibiting him from having in his possession, prescribing, administering, manufacturing, compounding and supplying, and from authorising the administration and supply of those Controlled Drugs specified in the direction.

In order to confirm whether or not a practitioner has had a direction made against him under the Misuse of Drugs Act 1971, prohibiting him from dealing with Controlled Drugs as indicated above, pharmacists are advised to contact the DHSSPS 02890 523348. (The Home Office Tel No is 020 7035 4848).

Marking of containers for Controlled Drugs

A container in which a Controlled Drug other than a preparation is supplied must be plainly marked with the amount of drug contained in it. If the drug is a preparation made up into tablets, capsules or other dosage units, the container

must be marked with the amount of Controlled Drug(s) in each dosage unit and the number of dosage units in it.

For any other kind of preparation, the container must be marked with the total amount of the preparation in it and the percentage of Controlled Drug(s) in the preparation.

These requirements do not apply to Schedule 4 or 5 drugs, or to drugs supplied on prescription, or to poppy straw. Also exempt are Schedule 3 drugs comprising a preparation that is required for use as a buffering agent in chemical analysis and is premixed in a kit. Also exempt is the supply of a CD for administration in a clinical trial or a medicinal test on animals.

Safe Custody of Controlled Drugs

The regulations relating to safe custody apply to all Controlled Drugs included in Schedules 1 and 2 (except secobarbital (quinalbarbitone), plus buprenorphine, diethylpropion, flunitrazepam and temazepam which are Schedule 3 drugs.

Although secobarbital (quinalbarbitone) is not subject to the safe custody requirements, pharmacists may wish to keep the drug in the Controlled Drug cupboard to serve as a reminder that an entry is required in the Controlled Drug register.

Retail dealers, nursing homes and private hospitals must ensure that all Controlled Drugs to which safe custody applies are, so far as circumstances permit, kept in a locked safe, cabinet or room that is so constructed and maintained as to prevent unauthorised access to the drugs. This requirement does not apply in respect of any Controlled Drug that is for the time being constantly under the direct personal supervision of a pharmacist, for example, when dispensing a prescription.

The specifications with which safes, cabinets and rooms must comply are given in great detail in the regulations. The owner of a pharmacy may, however, elect to apply, as an alternative, to the DHSSPS for a certificate that his safes, cabinets or rooms provide an adequate degree of security. Applications must be made in writing. The certificate may specify conditions to be observed.

All community pharmacies in Northern Ireland have installed a Time Delay Safe for the storage of Controlled Drugs. Any exemptions to this requirement must have the approval of the Misuse of Drugs Inspector.

Supply of Controlled Drugs to addicts (misusers)

A person is regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent on a drug that he has an

overpowering desire for the administration of it to be continued. Under the Regulations, any doctor who attends a person whom he considers is addicted to any drug in the prescribed list must within seven days furnish certain particulars to the Chief Medical Officer of the DHSSPS.

No doctor may administer or authorise the supply of cocaine, diamorphine or dipipanone, or their salts, to an addicted person, except for the purpose of treating organic disease or injury, unless he is licensed to do so by the DHSSPS.

There is provision for addicts (misusers) to receive daily supplies of cocaine, diamorphine, methadone, and other Schedule 2 drugs on special prescriptions. (See earlier Page 43).

Legislation permits practitioners, pharmacists, persons employed or engaged in the lawful provision of drug treatment services and supplementary prescribers acting in accordance with a clinical management plan to supply specified drug paraphernalia to drug users.

The exempted articles are: swabs, utensils for the preparation of controlled drugs, ascorbic acid, citric acid, filters and ampoules of water for injection.

Ampoules of sterile water for injection containing not more than 2ml of sterile water can be supplied by persons employed or engaged in the lawful provision of drug treatment services only in the course of those services.

A pharmacist who is not engaged or employed in such services can only supply water for injection against a prescription or under a PGD.

(NB - Crushing of buprenorphine tablets prior to administration. Pharmacists should follow the guidance laid down in the NPA protocol and ensure that they have the appropriate Indemnity Insurance cover.)

Destruction of Controlled Drugs

Any person required by the regulations to keep records of Controlled Drugs, that is Schedule 1 and 2 drugs, may only destroy them in the presence of a person authorised by the DHSSPS either personally or as a member of a class; this includes pharmaceutical inspectors of the DHSSPS. Particulars of the date of destruction and the quantity destroyed must be entered in the register of Controlled Drugs and signed by the authorised person in whose presence the drug is destroyed. The authorised person may take a sample of the drug that is to be destroyed.

Date expired or unusable stocks of Schedule 2 Controlled Drugs should be segregated in the safe until destruction is witnessed by an authorised person. Appropriate records of the destruction must be made.

The master of a ship or the installation manager of an offshore installation may not destroy any surplus drugs but may dispose of them (for destruction) to a constable or a person who may lawfully supply them (that is, to any pharmacist or licensed dealer who could have supplied them to him).

A pharmacist or a practitioner may destroy prescribed Controlled Drugs returned to him by a patient or a patient's representative without the presence of an authorised person. Such Controlled Drugs should not be returned to stock. The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 require a range of SOPs to be in place including a SOP for maintaining a record of Schedule 2 CDs that have been returned by patients. The record of the destruction for patient returned drugs must not be made in the CD Register but recorded either at the back of the Private Prescription Register or in a separate book designated as the "Destruction Book" (a number of such books are available commercially for this purpose.) It is advisable to have the destruction witnessed by an appropriate member of staff (e.g. another pharmacist or a pharmacy technician).

Details to be recorded in the destruction book should include:

- date of return of the Controlled Drug
- details of the Controlled Drug(s) - name, strength and form, plus the quantity
- role of the person who returned the Controlled Drugs (if this is known)
- name and signature of the person who received the Controlled Drugs
- the patient's name and address (if known)
- the name, position and signature of the person destroying the Controlled Drugs and the same details for the witness
- date of destruction

If such drugs are stored prior to destruction they should be segregated carefully in the CD safe to minimise the risk of inadvertent supply.

As the quantity of controlled drugs being returned by patients can often pose a storage problem, as well as an increased security risk, pharmacists are encouraged to destroy patient returned Controlled Drugs as soon as possible.

Out of date controlled drugs, which must be destroyed only in the presence of an authorised witness, should be destroyed by arrangement with the DHSSPS inspector.

Guidance on Destruction of CDs

Pharmacists are recommended to use commercially available CD denaturing kits wherever possible to denature Controlled Drugs. Pharmacists should ensure that where such alternative methods are used to denature CD's that they should protect the environment and workers who might be affected by this activity.

Currently, the destruction (denaturing) of controlled drugs can be undertaken in a pharmacy without obtaining a waste management licence as the Environment Agency regards this as low risk activity.

The situation will be kept under review and enforcement may be considered in any circumstance where an activity is likely to cause pollution or harm to health.

Information on disposal of controlled drugs can be accessed at www.dhsspsni.gov.uk/pharmaceutical-waste-guidance.pdf or www.rpsgb.org.uk

Liquid Dose Formulations should be added to, and absorbed by, an appropriate amount of cat litter, or similar product.

Capsule and tablet formulations. The outer packaging material should be removed and then the preparations removed from the blister packaging (if necessary) and placed in a CD denaturing kit. It is recommended that commercially available CD denaturing kits are used to ensure that whole tablets or capsules may not be recovered. Alternatively the solid dose formulation should be crushed and placed in a small amount of hot, soapy water ensuring that the drug has been dissolved or dispersed. The resultant mixture should be placed in an appropriate waste disposal bin.

Parenteral Formulations (such as ampoules). These should be opened and the liquid poured into the Controlled Drug denaturing kit. The ampoule itself may be added to the sharps bin. An ampoule that contains powder can have water added to it to dissolve the powder and the resulting mixture can be poured into the Controlled Drug denaturing kit.

Aerosols. The contents of the aerosol should be expelled into water to prevent droplets of drug entering the air. The resultant liquid should then be disposed of as a liquid preparation.

Fentanyl and buprenorphine Patches. The active ingredient in the patches can be rendered irretrievable by removing the backing and folding the patch over upon itself. The patch may then be placed in the waste disposal bin or preferably a Controlled Drug denaturation kit.

Personnel involved in the destruction of Controlled Drugs should wear suitable gloves and in addition suitable face masks for protection (in some circumstances) and work in an area that is well ventilated.

The table below summarises the legal requirements of the Regulations for Schedules 2 to 5 for the possession and supply of Controlled Drugs by pharmacists.

Summary of legal requirements for Controlled Drugs as they apply to pharmacists

	Schedule 2	Schedule 3	Schedule 4, Part I	Schedule 4, Part II	Schedule 5
Designation of legal category for a controlled drug	CD	CD No Reg	CD Benz	CD Anab	CD Inv
Safe custody	Yes, except *Secobarbital/ quinalbarbitone	No, except temazepam, diethylpropion, flunitrazepam and buprenorphine	No	No	No
Prescription requirements (see Note 1)	Yes	Yes, except temazepam	No	No	No
Requisitions necessary (see Note 2)	Yes	Yes	No	No	No
Records to be kept in CD Register	Yes	No	No	No	No
Emergency supplies allowed	No	No, except phenobarbital for epilepsy	Yes	Yes	Yes
Repeats allowed on prescription	No	No	Yes	Yes	Yes
Invoices to be retained for two years	No	Yes	No	No	Yes
Address of prescriber must be in the UK	Yes	Yes	No	No	No
Licences required for import and export	Yes	Yes	Yes	Yes, unless the substance is in the form of a medicine and for administration by a person to himself	No
Validity of prescription (see Note 3)	28 days	28 days	28 days	28 days (if POM)	6 months
Private CD prescriptions to be written only on standardised form [see Note 4]	Yes	Yes	No	No	No
Private prescriber identification number required on private prescription [see Note 5]	Yes	Yes	No	No	No
Pharmacist must ascertain the identity of the person collecting the CD [see Note 6]	Yes	No	No	No	No
Private CD prescription forms to be sent to the appropriate NHS agency [See note 7]	Check guidance by BSO	Check guidance by BSO	No	No	No

*Note: A number of barbiturates have been discontinued in the BNF. Amobarbital sodium, butobarbital and secobarbital sodium are available only on a named patient basis

Notes

1. Prescription requirements: This refers to the particulars that must be present for a prescription to be valid as a prescription for a Controlled Drug, i.e., it must include dose, form strength (where appropriate) and a total quantity of the preparation in both words and figures. These requirements do not apply to temazepam prescriptions, which need only comply with the requirements for POM medicines.

Private prescriptions for temazepam must be on the standardised form and must also contain the private prescriber's identification number.

2. Requisitions: i.e., whether a requisition is necessary before supply may be made to practitioners, persons in charge of hospitals, masters of ships. etc. From January 1st 2008, for requisitions (other than veterinary requisitions) for Schedule 2 and Schedule 3 controlled drugs, the pharmacist must mark on the requisition his name and address in ink or otherwise so as to be indelible. Requisitions should be submitted by community pharmacies to the BSO using the modified HS30 form.

3. Validity of repeatable prescriptions: Where a drug in Schedule 4 is prescribed on a repeatable prescription, the first supply must be made within 28 days of the date of issue or the date specified by the doctor as the valid period for that drug. Where a drug in Schedule 5 is prescribed on a repeatable prescription, the first supply must be made within six months of the date of issue of the prescription.

4. Private prescription standardised forms: Private prescriptions issued for human use must be on PCD1 in N. Ireland, (FP10PCD in England, PPCD (1) in Scotland and WP 10PCD in Wales.

5. Private prescriber identification number: This number is required on private prescriptions for human use issued in N. Ireland, England, Scotland and Wales.

6. Identity of person collecting CD: The pharmacist must ascertain the role of the person collecting a Schedule 2 CD supplied against a prescription. It must be ascertained whether the person is the patient, the patient's representative or a healthcare professional acting within their professional capacity. If a healthcare professional is collecting the CD, their name and address must be obtained and if they are not known to the pharmacist, ID must be requested. Details are recorded in CD register.

7. Submission of private CD prescriptions to the appropriate agency: Private prescription forms PCD1 should be submitted by community pharmacies to the BSO using the modified HS 30 form.

Guidance on all the above Notes can be accessed from the references in Section 1.4 Controlled Drugs.

Useful References

Recent legislation:

- The Misuse of Drugs and the Misuse of Drugs (Notification and supply to Addicts) Regulations SR No. 564 2005 (16/01/06).
- The Misuse of Drugs (Amendment)(No.2) Regulations (Northern Ireland) 2006 SR No. 214 (1/06/06)
- The Misuse of Drugs (Amendment) (No.3) Regulations (Northern Ireland) 2006 SR No. 264 (14/06/06) – See below guidance from DHSSPS on Partial Revocation
- Misuse of Drugs (Amendment) (No 4) Regulations (Northern Ireland) 2006 SR No334, 1/09/06
- Misuse of Drugs Act 1971 (Amendment Order) 2006 SI No 3331 – Reclassification of Methylamphetamine, 18/01/07
- The Misuse of Drugs and Misuse of Drugs (Safe Custody)(Amendment) Regulations (Northern Ireland) 2007 SR No 348 – Midazolam becomes a Schedule 3 Controlled Drug,
- The Misuse of Drugs Act 1971 (Amendment) Order 2008, SI No 3130, 25/01/09 – reclassification of cannabis and cannabinol derivatives from Class C to Class B drugs
- The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009 SR No 225, 1/10/09
- The Misuse of Drugs (Designation)(Amendment) Order (Northern Ireland) 2009 SR No 389, 23/12/09
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2009 SR No 390, 23/12/09
- The Misuse of Drugs (Amendment)(No 2) Regulations(Northern Ireland) 2009 SR No 397, 23/12/09
- The Misuse of Drugs (Amendment) Regulations (Northern Ireland) 2010 SR No 148, 16/04/10

Full details may be accessed on the www.opsi.gov.uk website.

Guidance Notes

The DHSSPS has also circulated a series of Guidance Notes for pharmacists and these should be used as an additional reference source e.g.

1. Amendments to the Misuse of Drugs Regulations (Northern Ireland) 2002 3/01/06
2. Prescriptions for Schedule 2, 3 and 4 Controlled Drugs 16/05/06.
3. Amendments to the Misuse of Drugs Regulations (Northern Ireland)2002 26/06/06
4. Prescription Form PCDI (Private Prescription) 29/06/06 See Amendment Guidance Note 13 below.

5. Partial revocation of Statutory Instrument 2006/264 11/08/06 –delay with regard to implementation of the recording details in the controlled drugs register until January 1st 2008.
6. Prescribing of Schedule 2 and 3 Controlled Drugs in the Repeat Dispensing Scheme, 6/07/07
7. Amendments to the Misuse of Drugs Regulations(Northern Ireland) 2002 17/08/07 Delete(M77), ODPs Nursing Homes, Requisitions, Midazolam, CD Registers See amendment on requisitions Guidance Note 13 below.
8. Prescribing of Schedule 2, 3 and 4 Controlled Drugs, 22/02/08
9. Prescribing of Controlled Drugs by Nurse Independent Prescribers, 22/05/08
10. Controlled Drugs: Licensing of Paramedics, 07/09. (See list of substances with exemption for paramedics Section 1.5 Page X (formerly Page 60)
11. Changes to the legal control over substances formerly known as “legal highs” – BZP and others, 25/01/10
12. Controlled Drugs: Private Prescriptions (PCD1 Forms) and Private Prescriptions, 01/03/10
13. The Controlled Drugs (Supervision of Management and Use)
 - Regulations (Northern Ireland) 2009 – Guidance on SOPS for CDs, Declaration and Self Assessment Form 2010, issued 28th January 2010
14. Pharmacy Inspectors’ Newsletters – information relevant to Controlled Drugs
 - Issue 1 June 2006,
 - Issue 2 April 2007,
 - Issue 3 November 2007,
 - Issue 4 November 2008,
 - Issue 5 December 2009.

Further details and information can be accessed at www.dhsspsni.gov.uk/index/pas

Reference Documents:

- Safer Management of Controlled Drugs - A guide to good practice in secondary care (Northern Ireland) August 2009.
- Safer Management of Controlled Drugs - A guide to good practice in primary care (Northern Ireland) due in 2010.



3 Medicines for Human Use: Exemptions from the Controls on Retail Sale



3.1 EXEMPTIONS FROM THE CONTROLS ON RETAIL SALE

There are certain exemptions from the restrictions that apply to General Sale List medicines, Pharmacy medicines and Prescription Only Medicines. The main classes of persons and the bodies exempted, the medicinal products to which the exemptions apply, and the conditions (if any) which attach to the sale, supply or administration by these exempted persons are described below. Other persons or bodies to which an exemption applies are listed at the end of this section. Any pharmacist who is asked for advice, or who wishes to check on the legality of supplying to such persons, should contact the DHSSPS for advice.

In order to sell, supply or administer these medicines the people and/or organisations must first be able to obtain them. These medicines can be obtained from a registered pharmacy. When a registered pharmacy supplies these medicines to the individual or organisation this is a wholesale transaction. Pharmacists must keep a record in the prescription-only register of the wholesale supply of any prescription-only medicines, or keep a copy of the order for prescription-only medicines provided by the individual or organisation requesting the medicines for two years. It is good practice to make a record in the prescription-only register and keep the order for two years. Pharmacists can only supply original and complete packs when making a wholesale supply and must not label the product in any way.

Hospitals and health centres

The restrictions on sale or supply of Prescription Only Medicines do not apply to the sale or supply of any such medicine in the course of the business of a hospital where the medicine is sold or supplied for the purpose of being administered (whether in the hospital or elsewhere) to a particular person in accordance with the written directions of a person (other than a veterinary surgeon or veterinary practitioner) who is an appropriate practitioner in relation to that medicine.

The restrictions on the sale, offer for sale, or supply of any other medicinal product (not being a Prescription Only Medicine) do not apply when the sale, offer for sale, or supply is in the course of the business of a hospital or health centre for the purpose of being administered (whether in the hospital or health centre or elsewhere). All written directions need not satisfy the requirements for a prescription given in the Prescription Only Order but must relate to the particular person to whom the medicine is being administered.

Practitioners

The restrictions do not apply to the sale, offer for sale or supply of any medicinal product by a doctor or dentist to a patient of his, or to a person under whose care such a patient is.

Midwives: sale or supply

The restrictions do not apply to the supply or sale (but not offer for sale) of certain medicinal products by a registered midwife in the course of her professional practice.

The medicinal products to which this exemption applies are:

- all medicinal products on a General Sale List;
- all Pharmacy medicines; and,
- Prescription Only Medicines containing any of the following substances (but no other Prescription Only Medicine):
 - Diclofenac
 - Ergometrine maleate (only when contained in a medicinal product which is not for parenteral administration)
 - Hydrocortizone Acetate
 - Lidocaine
 - Lidocaine Hydrochloride
 - Miconazole
 - Nystatin
 - Phytomenadione

A midwife can only sell or supply these medicinal products, under certain conditions. These conditions are:

- (i) the sale or supply shall be only in the course of their professional practice;
- (ii) in the case of ergometrine maleate they can only sell or supply a medicinal product that is not for parenteral administration

A supply made by a registered pharmacy to a midwife under this exemption is a wholesale transaction.

Midwives: administration

Registered midwives may also administer parenterally in the course of their professional practice Prescription Only Medicines containing any of the following substances:

- Adrenaline
- Anti-D immunoglobulin
- Carboprost
- Cyclizine hydrochloride
- Diamorphine
- Ergometrine maleate
- Gelofusine
- Haemaccel
- Hartmann's solution
- Hepatitis B vaccine

- Hepatitis immunoglobulin
- Lidocaine
- Lidocaine hydrochloride
- Morphine
- Naloxone hydrochloride
- Oxytocins, natural and synthetic
- Pethidine hydrochloride
- Phytomenadione
- Prochlorperazine
- Sodium Chloride 0.9%

Therefore, midwives can obtain these medicines by wholesale from a registered pharmacy.

A midwife can only administer the above parenteral medicines under certain conditions. These conditions are:

- (i) the administration is in the course of their professional practice.
- (ii) in the case of promazine hydrochloride, lignocaine and lignocaine hydrochloride it shall only be administered while attending on a woman in childbirth.

A supply made by a registered pharmacy to a midwife under this exemption is a wholesale transaction.

Under Patient Group Directions, Schedule 4 Controlled Drugs (except Anabolic Steroids) and all Schedule 5 CD's are also available for use by midwives.

Chiropodists/Podiatrists: sale or supply

Chiropodists are referred to as podiatrists, although the Medicines Act 1968 legislation still refers to "state registered chiropodists". Pharmacists must ensure that any person presenting himself as a podiatrist does in fact comply with the definition for "state registered chiropodist" and is registered as such by the Health Professions Council.

Registered chiropodists can obtain these medicines by wholesale from a registered pharmacy:

- medicinal products for external use that are on a General Sale List; and
- any of the following Pharmacy medicines for external use:
 - i potassium permanganate crystals or solution;
 - ii ointment of heparinoid and hyaluronidase;
 - iii products containing as their only active ingredients any of the following substances, not exceeding the strength specified in each case:

Borotannic complex 9.0%
Buclosamide 10.0%
Chlorquinaldol 3.0%
Clotrimazole 1.0%
Crotamiton 10.0%
Diamthazole hydrochloride 5.0%
Econazole nitrate 1.0%
Fenticlor 1.0%
Glutaraldehyde 10.0%
Griseofulvin 1.0%
Hydrargaphen 0.4%
Mepyramine maleate 2.0%
Miconazole nitrate 2.0%
Phenoxypropan-2-ol 2.0%
Podophyllum resin 20%
Polynoxylin 10.0%
Pyrogallol 70.0%
Salicylic acid 70.0%
Terbinafine 1.0%
Thiomersal 0.1 %

The registered chiropodist can only sell or supply these medicinal products under the conditions that:

- the sale or supply is made in the course of their professional practice,
- the product has been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied.

Annotated chiropodists

Registered chiropodists who have the relevant annotation in the Health Professions Council register signifying that they are qualified to use the medicines specified below, can obtain these medicines by wholesale from a registered pharmacy:

Co-dydramol 10/500 tablets where the quantity sold or supplied to a person at any one time does not exceed the amount sufficient for three days treatment to a maximum of 24 tablets;

Amorolfine hydrochloride cream where the maximum strength of the amorolfine in the cream does not exceed 0.25 per cent by weight in weight.

Amorolfine hydrochloride lacquer where the maximum strength of the amorolfine in the lacquer does not exceed 5 per cent by weight in volume.

Topical hydrocortisone where the maximum strength of the hydrocortisone in the medicinal product does not exceed 1 per cent by weight in weight.

Ibuprofen, other than preparations of ibuprofen that are prescription-only medicines. In the case of ibuprofen an amount sufficient for three days treatment where the maximum dose is 400 mg, the maximum daily dose 1,200 mg and the maximum pack size is 3,600 mg

Amoxicillin

Erythromycin

Flucloxacillin

Tioconazole

Silver Sulfadiazine

As before, an annotated chiropodist can only sell or supply these medicinal products under the conditions that:

- (a) the sale or supply is made in the course of their professional practice,
- (b) the product has been made up for sale or supply in a container elsewhere than at the place at which it is sold or supplied.

Supplies made by a registered pharmacy to registered and annotated chiropodists for the above medicines are a wholesale transaction. Therefore pharmacists can only supply original and complete packs to chiropodists. Consideration should thus be given to the pack size wholesaled to chiropodists especially in the case of co-dydramol and ibuprofen as chiropodists are limited to the quantity they can supply to their patients and are unable to alter the pack size once it has been supplied to them from the pharmacy.

Chiropodists/Podiatrists: administration

Registered chiropodists, who have the relevant annotation in the Health Professions Council register signifying that they are qualified to use the medicines specified below, can obtain these medicines by wholesale from a registered pharmacy:

- Adrenaline
- Bupivacaine hydrochloride
- Bupivacaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of bupivacaine hydrochloride
- Levobupivacaine hydrochloride
- Lidocaine hydrochloride
- Lidocaine hydrochloride with adrenaline where the maximum strength of the adrenaline does not exceed 1 mg in 200 ml of lidocaine hydrochloride
- Mepivacaine hydrochloride
- Methylprednisolone
- Prilocaine hydrochloride
- Ropivacaine

A chiropodist can only administer the above parenteral prescription only medicines if the administration is in the course of their professional practice.

A supply made by a registered pharmacy to a registered chiropodist under these exemptions is a wholesale transaction.

Chiropodists may also supply or administer specified Controlled Drugs (Schedule 4 CD's **except Anabolic Steroids**) under a Patient Group Direction.

Ophthalmic opticians/Optometrists: sale or supply

Registered optometrists may sell or supply the following medicines. Therefore, they can obtain these medicines by wholesale from a registered pharmacy:

- (a) all medicinal products on a general sale list;
- (b) all pharmacy medicines.

However, if a registered optometrist has premises which can be closed so as to exclude the public, general sale list medicines can be sold by retail in a similar manner to that in other retail premises.

Registered optometrists may also sell or supply certain medicinal products which are not for parenteral administration, provided it is in the course of their professional practice, and in an emergency. These medicinal products can also be sold or supplied by persons lawfully conducting a retail pharmacy business on the presentation of an order signed by a registered ophthalmic optician. The medicinal products to which this applies are:

- (a) eye drops or eye ointments that are prescription-only medicines by reason only that they contain
 - i mafenide propionate, or
 - ii not more than 30% sulphacetamide sodium, or
 - iii sulphafurazole diethanolamine equivalent to not more than 4% sulphafurazole or
 - iv eye drops containing not more than 0.5% chloramphenicol, or eye ointments containing not more than 1% chloramphenicol.
- (b) prescription-only medicines containing any of the following substances:
 - Cyclopentolate hydrochloride
 - Fusidic acid
 - Tropicamide

A registered optometrist can only sell or supply these medicinal products, under certain conditions. These conditions are:

- (i) in the case of general sale list medicines and pharmacy medicines the sale or supply must be in the course of their professional practice

- (ii) in the case of prescription-only medicines the sale or supply must be in the course of their professional practice and in an emergency.

A supply made by a registered pharmacy to a registered optometrist under this exemption is a wholesale transaction.

The sale or supply of the above prescription only medicines requires the pharmacist to be presented with an order signed by the registered optometrist. The signed order allows the pharmacist to make a supply directly to a patient under the care of an optometrist. It is not, however, a prescription, as a prescription is an authority to supply prescription-only medicines issued by an appropriate practitioner, and an optometrist does not come under this definition.

In making such a supply, pharmacists must ensure that the product supplied is labelled accordingly, a patient information leaflet must be provided and the sale or supply must be recorded in the prescription-only register. The pharmacist must also be satisfied that the optometrist has provided sufficient information and advice to enable safe and effective use of the medicine and has made a follow-up appointment where necessary.

Registered optometrists may also purchase for use in their practice (but not for sale or supply) prescription-only medicines containing any of the following substances:

- Amethocaine hydrochloride
- Lignocaine hydrochloride
- Oxybuprocaine hydrochloride
- Proxymetacaine hydrochloride

As before, a supply made by a registered pharmacy to a registered optometrist under this exemption is a wholesale transaction.

Additional supply optometrists

Registered additional supply optometrists may sell or supply certain prescription only medicines provided it is in the course of their professional practice and in an emergency. This applies to medicinal products which are not for parenteral administration and which are prescription only medicines by reason only that they contain any of the following substances:

- Acetylcysteine
- Atropine sulphate
- Azelastine hydrochloride
- Diclofenac sodium
- Emedastine
- Homatropine hydrobromide
- Ketotifen
- Levocabastine

- Lodoxamide
- Nedocromil sodium
- Olopatadine
- Pilocarpine hydrochloride
- Pilocarpine nitrate
- Polymyxin B/ bacitracin
- Polymyxin B/ trimethoprim (Discontinued)
- Sodium cromoglycate

These non-parenteral medicinal products can also be sold or supplied by persons lawfully conducting a retail pharmacy business on the presentation of an order signed by an additional supply optometrist. The signed order is not, however, a prescription, as a prescription is an authority to supply prescription-only medicines issued by an appropriate practitioner, and an additional supply optometrist does not come under this definition.

In making such a supply, pharmacists must ensure that the product supplied is labelled accordingly, a patient information leaflet must be provided and the sale or supply must be recorded in the prescription-only register. The pharmacist must also be satisfied that the additional supply optometrist has provided sufficient information and advice to enable safe and effective use of the medicine and has made a follow-up appointment where necessary.

Registered additional supply optometrists can also obtain the following medicines by wholesale from a registered pharmacy:

- (i) thymoxamine hydrochloride

A supply made by a registered pharmacy to a registered additional supply optometrist under this exemption is a wholesale transaction.

Drug treatment services

A person employed or engaged in the provision of lawful drug treatment service may supply the following medicinal product. Therefore, they can obtain this medicinal product by wholesale from a registered pharmacy:

- (i) Ampoules of sterile water for injection containing not more than 2ml of sterile water.

A person employed or engaged in the provision of lawful drug treatment service can only supply these medicinal products, under certain conditions. The condition is that:

- (i) the supply shall be only in the course of provision of lawful drug treatment services.

A supply made by a registered pharmacy to a person employed or engaged in the provision of a lawful drug treatment service under this exemption is a wholesale transaction.

Owners and masters of ships (including masters of foreign ships)

Owners and masters of ships that do not carry a doctor on board as part of their complement may supply (but not sell) all medicines, provided such supply is necessary for the treatment of persons on the ship. Such owners and masters may also administer Prescription Only Medicines that are for parenteral administration for the treatment of persons on the ship.

A supply made by a registered pharmacy to an owner or master of a ship under this exemption is a wholesale transaction. Pharmacists who receive a request for a supply of medicines from the owner or master of a ship would then need to establish the identity of the owner or the master of the ship and ensure that the request is genuine. The company owning the ship could be contacted for confirmation or the Lloyds Register of Shipping could be checked. The pharmacist should also check that the prescription only medicines which have been requested are appropriate for the category of ship by contacting the Maritime and Coastguard Agency (MCA) on 0870 600 6505.

Factories Act (NI) 1965 requirements

Persons requiring medicinal products for the purpose of enabling them, in the course of any business carried on by them, to comply with any requirements made by, or in pursuance of, any enactment with respect to the medical treatment of employees may supply medicinal products for such a purpose and subject to such conditions and in such circumstances as may be specified in the relevant enactments.

Royal National Lifeboat Institution

The Royal National Lifeboat Institution or certificated first aiders of the Institution may supply any medicinal product only so far as it is necessary for the treatment of sick and injured persons, and in the case of prescription-only medicines, the supply is necessary for the treatment of sick or injured persons in the exercise of the functions of the Institution.

A supply made by a registered pharmacy to Royal National Lifeboat Institution and certified first aiders of the Institution under this exemption is a wholesale transaction.

British Red Cross Society, and other bodies

The restrictions on the supply of Pharmacy medicines and all medicinal products on a General Sale List (but not Prescription Only Medicines) do not apply to the

bodies specified below and their certificated first-aid and certificated nursing members. In all cases the supply shall be only so far as is necessary for the treatment of sick and injured persons.

The bodies concerned are:

- British Red Cross Society
- St John Ambulance Association and Brigade
- St Andrew's Ambulance Association
- Order of Malta Ambulance Corps.

A supply made by a registered pharmacy to these first aid organisations under this exemption is a wholesale transaction.

Occupational health schemes

A person operating an "occupational health scheme" (OHS), that is, a scheme in which a person, in the course of a business carried on by him, provides facilities for his employees for the treatment or prevention of disease, may supply all medicinal products.

However, the supply must be made in the course of the scheme. In the case of Prescription Only Medicines, these may only be supplied to the person operating the scheme in response to an order in writing signed by a doctor or a registered nurse.

The individual supplying or administering the medicines in the course of the scheme, if not a doctor, must be a registered nurse, and where the medicinal product in question is a Prescription Only Medicine, acting in accordance with the written instructions of a doctor.

A supply made by a registered pharmacy to an OHS under this exemption is a wholesale transaction.

First aid personnel on offshore installations

Persons employed as qualified first aid personnel on offshore installations may:

- supply all GSL, pharmacy and Prescription Only Medicines;
- administer all parenteral Prescription Only Medicines provided the supply or administration is only so far as is necessary for the treatment of persons on the installation.

A supply made by a registered pharmacy to a person employed as the qualified first aider on offshore installations under this exemption is a wholesale transaction.

Ambulance paramedics: administration

Persons who hold a certificate of proficiency in ambulance paramedic skills issued by, or with the approval of, the Secretary of State or persons who are state registered paramedics may administer certain parenteral Prescription only medicines:

- diazepam 5 mg per ml emulsion for injection;
- succinylated modified fluid gelatin 4% intravenous infusion;
- medicines containing the substances ergometrine maleate 500 mcg per ml with oxytocin 5 iu per ml, but no other active ingredient;
- prescription only medicines for parenteral administration containing one or more of the following substances* but no other active ingredients:

Adrenaline acid tartrate

Amiodarone in certain circumstances

Anhydrous glucose

Benzylpenicillin

Bretylium tosylate

Compound sodium lactate intravenous infusion (Hartmann's solution)

Ergometrine maleate

Furosemide (Frusemide)

Glucose

Heparin sodium

Lidocaine hydrochloride

Metoclopramide

Morphine sulphate

Nalbuphine hydrochloride

Naloxone hydrochloride

Polygeline

Retepase

Sodium bicarbonate

Sodium chloride

Streptokinase

Tenecteplase

*At the time of going to print, the MHRA was undertaking a consultation to permit ambulance paramedics to add adrenaline hydrochloride to the list of parenteral medicines which can be administered by registered paramedics on their own initiative. Check Standards and Guidance updates, and other communications, of the Pharmaceutical Society of Northern Ireland for more details.

The administration shall be only for the immediate, necessary treatment of sick or injured persons and, in the case of a prescription only medicine containing heparin sodium, shall be only for the purpose of cannula flushing.

Certain specified Controlled Drugs are available for use by paramedics under Patient Group Directions (Schedule 4 CD's (except Anabolic Steroids) and all Schedule 5 CD's).

A supply made by a registered pharmacy to a registered paramedic under this exemption is a wholesale transaction.

*To note, at the time of going to print, the Department of Health (London) were in the process of consulting on the principles of extending independent prescribing responsibilities to paramedics.

Other exempted persons and organisations

The following persons or organisations can be sold or supplied medicinal products for certain specified purposes. Because they do not buy them for the purpose of selling or supplying them, or administering them in the course of their business, the sale to them does not fall within the definition of a wholesale transaction and therefore is a retail transaction:

- Dental schemes
- The operator or commander of an aircraft
- Unorthodox practitioners
- Marketing authorisation holders and holders of manufacturers' licences
- Group authorities and licences
- Universities and other institutions
- Public analysts / sampling officers / NHS drug testing / British
- Standards Institution
- Prison officers
- Health authorities or Primary Care Trusts
- Persons holding a certificate in first aid from the Mountain Rescue Council of England and Wales, or from the Northern Ireland Mountain Rescue Co-ordinating Committee.

A pharmacist who is approached to make a sale or supply to any of the above can check with the DHSSPS if any doubts exist as to the extent of the purchaser's authority.

3.2 WHOLESALE DEALING

The Medicines Act 1968 requires most persons who engage in wholesale dealing to possess a licence. Persons lawfully conducting a retail pharmacy business may sell by wholesale provided the sale constitutes no more than an inconsiderable part of the business. Although the term inconsiderable has not been the subject of judicial interpretation, it is likely that a pharmacy that wholesales no more than 5% of its total medicines trade will fall within this exemption. In any cases of doubt, the DHSSPS should be consulted.

Sales of Pharmacy or Prescription Only Medicines by way of wholesale dealing may only take place if the purchaser is authorised to sell or supply the goods, or to administer to human beings in the course of their business.

A sale can therefore take place to:

- practitioners (in other words, a doctor, dentist or veterinary practitioner entitled to practice in this country);
- any person lawfully conducting a retail pharmacy business (i.e. another registered retail pharmacy);
- authorities or persons carrying on the business of:
 - i an independent hospital, independent clinic or independent medical agency, or
 - ii a hospital or health centre that is not an independent hospital or independent clinic;
- any person who may sell by retail or supply in circumstances corresponding to retail sale by virtue of an exemption (see "Exemptions from control on retail sale" above) but only in respect of the medicinal products covered by the exemption;
- a Health and Social Services Trust established under Article 10 of the Health and Personal Social Services (Northern Ireland) Order 1991;
- a National Health Service Trust established under Section 5 of the National Health Service and Community Care Act 1990 or Section 12A of the National Health Service (Scotland) Act 1978;
- the Common Services Agency for the Scottish Health Service established under Section 10 of the National Health Service (Scotland) Act 1978;
- a Health Authority or Special Health Authority;
- a Hospital Trust;
- a person, other than an excepted person, who carries on a business consisting (wholly or partly) of supplying medicinal products in circumstances corresponding to retail sale, or if administering such products, pursuant to an arrangement made with :
 - i the Common Services Agency, as referred to above;
 - ii a Health Authority or Special Health Authority;
 - iii a Health and Social Services Trust or a National Health Service trust, as referred to above; or
 - iv a Primary Care Trust;
- a person, other than an excepted person, who carries on a business consisting (wholly or partly) of the supply or administration of medicinal products for the purpose of assisting the provision of healthcare by, or on behalf of, or under arrangements made by:
 - i a police force in England, Wales or Scotland
 - ii the Police Service of Northern Ireland
 - iii a prison service
 - iv Her Majesty's Forces;
 - v Ministers of the Crown and Government departments and officers thereof.

Pharmacists must not wholesale medicines to holders of wholesale dealer's licences. The holder of a wholesale dealer's licence may only obtain supplies of medicine from either:

- (i) a manufacturer's licence holder or a wholesale dealer's licence holder; or
- (ii) a person authorised by another EEA State to manufacture or distribute medicines by way of wholesale dealing.

This prevents a wholesale dealer buying medicines, by way of wholesale, from a registered pharmacy.

Where a wholesale transaction occurs, only whole packs can be supplied and there would not be a requirement on the pharmacy to label the medicines.

Pharmacists will be aware that non-pharmacy outlets cannot sell Pharmacy medicines. Pharmacists should therefore be alert to any requests for multiple packs of Pharmacy medicines, which could be being purchased for onward sale.

Records of sales or supplies of Prescription Only Medicines

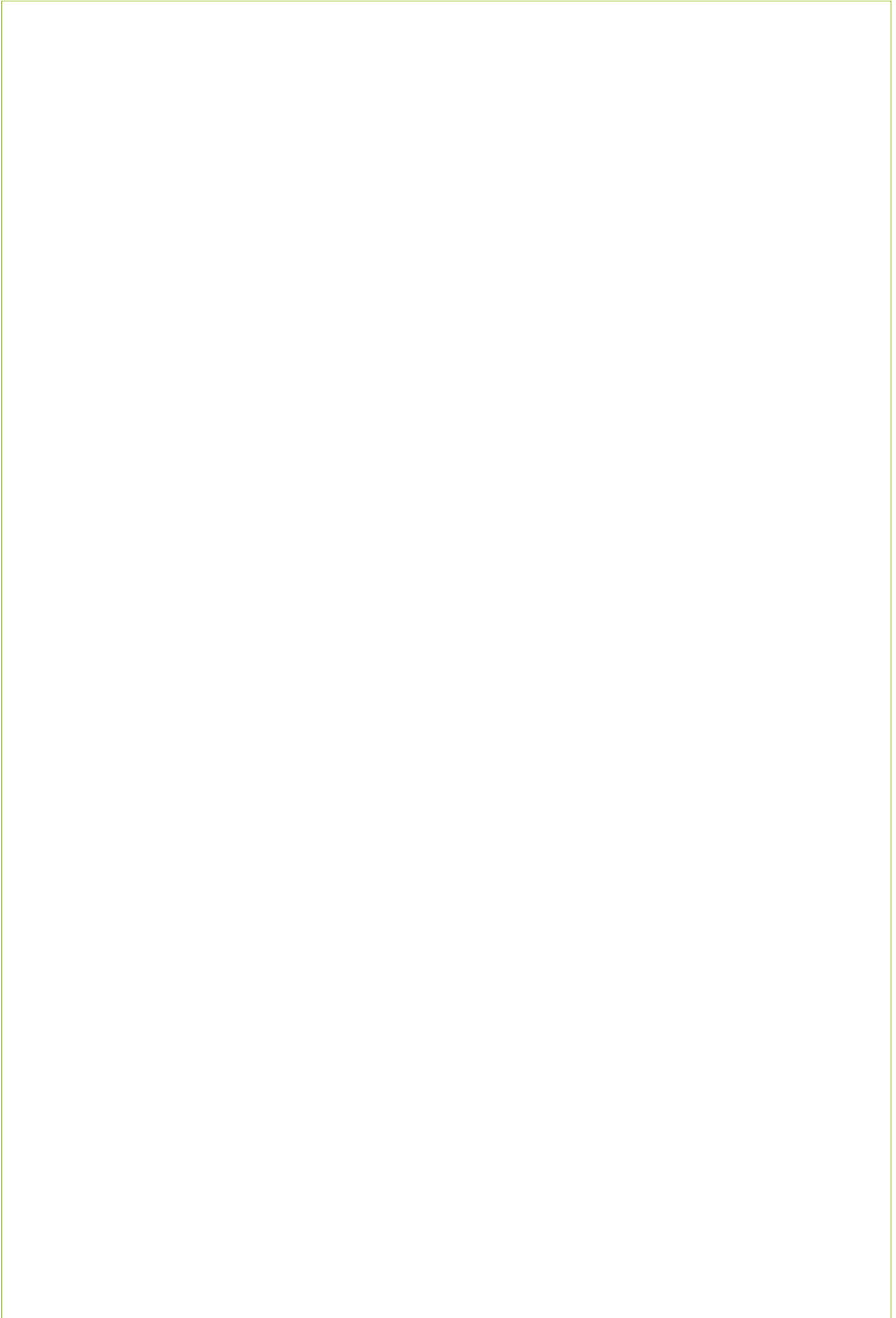
An entry must be made in the Prescription Only register in respect of every sale or supply of a Prescription Only Medicine made from a registered retail pharmacy business. The form of the register and the particulars to be recorded for private prescriptions and emergency supplies to patients have been described earlier. For sales or supplies of Prescription Only Medicines made otherwise than in pursuance of a practitioner's prescription (for example the sale to one of the exempted persons above) the particulars to be recorded are:

- the date on which the Prescription Only Medicine was sold or supplied;
- the name, quantity and, except where it is apparent from the name, the pharmaceutical form and strength of the medicine;
- the name and address, trade, business or profession of the person to whom the medicine is sold or supplied;
- the purpose for which it is sold or supplied.

There is no legal requirement for an entry to be made in the Prescription Only register where:

- a separate record of the sale or supply is made in accordance with the Misuse of Drugs (Northern Ireland) Regulations 2002, or
- a sale is by way of wholesale dealing if, and so long as, a copy of the order or invoice relating thereto is retained by the owner of the retail pharmacy business.

It is good practice to maintain records of all Prescription Only Medicines sold or supplied (except where supplied against a health prescription). The pharmacist is then able to account for all stocks that have left the pharmacy, without the dangers associated with the loss of the copy of an invoice or order. All orders or invoices must be kept for two years from the date of the sale or supply.





4 Medicines for Human Use: Labelling, Advertising and Devices



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 rINN

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.

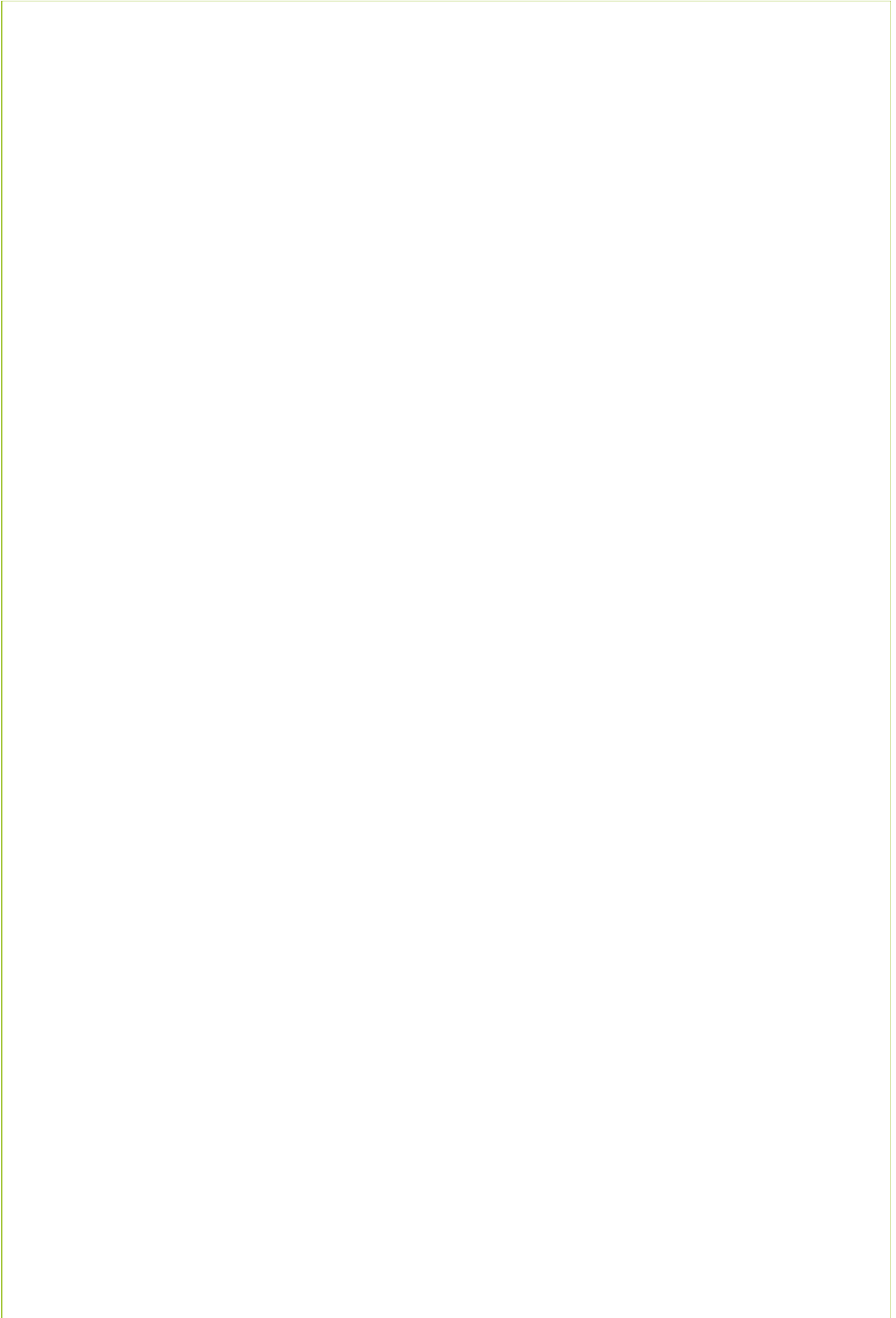
4.6 CHLOROFORM: SALE AND SUPPLY

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.





5

Medicines for Veterinary Use



5 MEDICINES FOR VETERINARY USE

The Veterinary Medicines Regulations SI No. 2297 came into force on October 1st 2009. The regulations are revoked and replaced each year, as necessary.

Full details of the legislation are available on www.opsi.gov.uk and guidance can be found at Veterinary Medicines Directorate (www.vmd.gov.uk)

The Medicines Act 1968 no longer applies to veterinary medicines.

“Veterinary medicinal product” means:

- (a) any substance or combination of substances presented as having properties for treating or preventing disease in animals or
- (b) any substance or combination of substances that may be used in, or administered to animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action or to making a medical diagnosis.

“animal” means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees.

The following guidance on legal requirements in relation to Medicines for Veterinary Use is presented in the following sections:

- 5.1 Classification and supply of Veterinary Medicinal Products
- 5.2 Prescriptions for Veterinary Medicinal Products
- 5.3 Form of prescription – Schedule 3 Part 1 (6)
- 5.4 Supply of Controlled Drugs 1-3 on Veterinary Prescriptions
- 5.5 Feedingstuffs and Breaking of Bulk
- 5.6 Supply of Veterinary Medicinal Products for use under the Cascade Schedule 3 Part 1(13) and Schedule 4 (1)
- 5.7 Withdrawal Periods – Schedule 4 (2)
- 5.8 Labelling Requirements at the time of retail sale - Schedule 3 (12) and (13)
- 5.9 Record Keeping - Regulation 17 - 24
- 5.10 Annual Audit - Schedule 3 (15)
- 5.11 Supply of a Sheep Dip –Schedule 3 Part 3 (22)
- 5.12 Inspections
- 5.13 Further information

5.1 CLASSIFICATION & SUPPLY OF VETERINARY MEDICINAL PRODUCTS

In accordance with The Veterinary Medicines Regulations 2009 SI No. 2297, the classes of Veterinary Medicinal Products (VMPs) are:

- (a) Prescription Only Medicine - Veterinarian (POM-V)

- (b) Prescription Only Medicine - Veterinarian, Pharmacist, Suitably Qualified Person* (POM-VPS)
- (c) Non-Food Animal - Veterinarian, Pharmacist, Suitably Qualified Person (NFA-VPS)
- (d) Authorised Veterinary Medicine -General Sale List (AVM -GSL)

A pharmacist who supplies a veterinary medicine classified as POM-V in accordance with a prescription, supplies an NFA-VPS or prescribes a POM-VPS must provide advice on how to administer the medicine safely and when appropriate to advise on any warnings or contraindications on the label or package leaflet. The pharmacist must also be satisfied that the person using the product is competent to use it safely and intends to use it for the purpose for which the product is authorised.

- A veterinary medicinal product classified as POM-V may only be supplied by a veterinary surgeon or a pharmacist and must be supplied in accordance with a prescription from a veterinary surgeon.
- A veterinary medicinal product classified as POM-VPS may only be supplied by a veterinary surgeon, a pharmacist or a suitably qualified person and must be in accordance with a prescription from one of those persons.
- A veterinary medicinal product classified as NFA-VPS may be supplied without a prescription, but may only be supplied by
 - (a) a veterinary surgeon
 - (b) a pharmacist or
 - (c) a suitably qualified person.

“Suitably qualified persons” (SQPs) may prescribe and supply veterinary medicinal products classified as POM-VPS and NFA-VPS. Such persons must undertake a training programme and pass the necessary examinations of the training body and be registered with such a body. The supply of permitted products by a SQP must take place from premises approved by the Secretary of State as being suitable for storage and supply by a SQP. An SQP can also prescribe and supply products classified as POM-VPS and NFA-VPS from a retail pharmacy (in accordance with the paragraph that follows).

A SQP who supplies a product classified as POM-VPS or NFA-VPS must either-

- (a) hand over or dispatch the product himself;
- (b) ensure that, when the product is handed over or dispatched, he is in a position to intervene if necessary; or
- (c) check the product after it has been allocated for supply to a customer, and satisfy himself that the person handing over or dispatching it is competent to do so.

The Secretary of State shall publish a list of persons registered; the premises approved and issue a Code of Practice for suitably qualified persons.

5.2 PRESCRIPTIONS FOR VETERINARY MEDICINAL PRODUCTS

- (a) A veterinary surgeon who prescribes a POM-V medicine must first carry out a clinical assessment of the animal and the animal must be under his care, and failure to do so is an offence.
- (b) It is an offence to prescribe (or, in the case of a NFA - VPS product, supply) more than the minimum amount of veterinary medicinal product required for treatment.

5.3 FORM OF PRESCRIPTION – SCHEDULE 3 PART 1(6)

A prescription may be ORAL or WRITTEN, but must be written, if the veterinary medicinal product is not supplied by the person who has prescribed it.

No person may alter a written prescription unless authorised to do so by the person who signed it.

A prescription, where written, must include:

- (a) the name, address and telephone number of the person prescribing the product;
- (b) the qualifications enabling the person to prescribe the product;
- (c) the name and address of the owner or keeper;
- (d) the species of animal, identification and number of the animals;
- (e) the premises at which animals are kept (if different from address of the owner or keeper);
- (f) the date of the prescription;
- (g) the signature, or other authentication, of the person prescribing the product;
- (h) the name and amount of product prescribed;
- (i) the dosage and administration instructions;
- (j) any necessary warnings;
- (k) the withdrawal period if relevant;
- (l) if it is prescribed under cascade, a statement to that effect;

A written prescription for a controlled drug under the Misuse of Drugs Regulations is valid for 28 days. A written prescription for any other drug is valid for 6 months or such shorter period as may be specified in the prescription. If the prescription is repeatable, but does not specify the number of times the product may be supplied, the prescription may only be repeated once.

5.4 SUPPLY OF CONTROLLED DRUGS 1-3 ON VETERINARY PRESCRIPTIONS

Veterinary prescriptions are excluded from the requirements that all non-NHS Schedule 1, 2 and 3 controlled drugs prescriptions must be issued on a standard form (PCD1) which includes the prescriber's unique identification number.

The Veterinary Medicines Regulations 2009 require all documents and records pertaining to prescription-only medicines for veterinary use (including a copy of the prescription) to be retained for at least five years.

5.5 FEEDINGSTUFFS AND BREAKING OF BULK

A pharmacist may only supply a Veterinary Medicinal Product which is intended to be incorporated into a premixture or feedingstuff, to an approved premixture manufacturer or an approved feedingstuffs manufacturer. Note: An approved feedingstuffs manufacturer may be a farmer. It is advisable to seek expert advice from a source such as the Veterinary Medicines Directorate (www.vmd.gov.uk) before making a supply.

In relation to any specialised activity, such as breaking bulk, which, for example, might include the mixing of a VMP with feeding stuff, or mixing VMPs with liquid feed supplements or trace elements, depending on the nature of the business, advice should be obtained from the Veterinary Medicines Directorate.

The VMD advises that VMPs should not be mixed with other supplements unless in accordance with a prescription from a veterinary surgeon.

Contact details for the Veterinary Medicines Directorate are below:

Veterinary Medicines Directorate,

Woodham Lane, New Haw,

Addlestone, Surrey KT15 3LS.

Tel: 01932 336911

E-mail: enquiries@vmd.defra.gsi.gov.uk

5.6 SUPPLY OF VETERINARY MEDICINAL PRODUCTS UNDER THE CASCADE SCHEDULE 3 PART 1(6) AND SCHEDULE 4(1)

A veterinary medicine for use under the cascade must be prescribed by a veterinary surgeon and may only be supplied by a veterinary surgeon or pharmacist. The written prescription must state that the medicinal product is for administration under the cascade.

If there is no authorised veterinary medicinal product in the UK for a condition, the veterinary surgeon responsible for the animal may treat the animal with the following "cascade". This is to avoid unacceptable suffering to the animal concerned.

The vet may:

- (a) use a veterinary medicinal product authorised in the UK for use in another animal species, or for another condition in the same species; or

- (b) if no such product is suitable, either:
- i a medicinal product authorised (licensed) in the UK for human use;
 - ii a veterinary medicinal product not authorised in the UK but authorised in another member State(of EU) for use with any animal species (in the case of a food producing animal, it must be a product licensed for use in a food-producing species);
 - iii if there is no product suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation allowing the manufacture of that type of product.

Pharmacists may not supply licensed human GSL or P medicines OTC for animal administration, unless prescribed by a veterinary surgeon for use under the cascade.

5.7 WITHDRAWAL PERIODS - SCHEDULE 4(2)

A veterinary surgeon administering a veterinary medicinal product to a food-producing animal under the cascade must specify an appropriate withdrawal period.

The withdrawal period must not be less than:

- (a) 7 days for eggs
- (b) 7 days for milk
- (c) 28 days for meat from poultry and mammals including fat and offal
- (d) 500 degree days for fish meat (this is calculated by dividing 500 by the mean temperature of the water in degrees Celsius).

A pharmacist may only supply a VMP which is intended to be incorporated into a premixture or feeding stuff, to an approved premixture manufacturer or an approved feeding stuffs manufacturer.

In the case of the approved manufacturer being the livestock keeper (i.e. an on-farm manufacturer) the supply of the VMP must also be in accordance with a medicated feedingstuffs prescription.

5.8 LABELLING REQUIREMENTS

If a veterinary medicinal product is supplied in a container specified in the marketing authorisation, it is an offence to supply it if any information on the outer packaging (or, if there is no outer packaging, the immediate packaging) is not clearly visible at the time of supply or has been changed in any way.

However, the above does not apply to a veterinary surgeon who amends a label, or a pharmacist who amends it in accordance with a prescription from a veterinary surgeon, provided that the unamended information remains clearly visible.

If a veterinary medicinal product is supplied in a container other than that specified in the marketing authorisation, the person supplying the veterinary medicinal product must ensure that the container is suitably labelled and must supply sufficient written information (which may include a copy of the summary of product characteristics or the package leaflet) to enable the product to be used safely, and failure to do so is an offence.

In relation to supply of veterinary medicinal products for use under the cascade, unless the veterinary surgeon who prescribed the veterinary medicinal product both supplies the product and administers it to the animal in person, the person supplying it must label it (or ensure that it is labelled) with at least the following information:

- (a) the name and address of the pharmacy, veterinary surgery or approved premises supplying the veterinary medicinal product;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification (including the species) of the animal or group of animals;
- (e) the date of supply;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product, which should include at least the name and quantity of active ingredients;
- (h) dosage and administration instructions;
- (i) any special storage precautions;
- (j) any necessary warnings for the user, target species, administration or disposal of the product;
- (k) the withdrawal period, if relevant; and
- (l) the words "Keep out of reach of children" and "For animal treatment only".

The keeper of a food-producing animal must keep proof of purchase of all veterinary medicinal products (or, if he did not buy them, documentary evidence of how he acquired them) acquired for the animal. This can be in the form of a till receipt from the pharmacy.

5.9 RECORD KEEPING - PART 3(23)

When any person permitted to supply a veterinary medicinal product classified as POM-V or POM-VPS receives or supplies any such veterinary medicinal product he must keep all documents relating to the transaction including:

- (a) the date;
- (b) the name of the veterinary medicinal product;
- (c) the quantity;
- (d) the name and address of the supplier or the recipient;
- (e) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription;
- (f) the batch number.

However, where the VMP is for a non-food-producing animal, the batch number need only be recorded either on the date he receives the batch or the date he starts to use it.

If all the information is not included in the documents, the missing information must be recorded as soon as reasonably possible. The batch number and the date must be recorded at the time of supply.

The documentation and records must be kept for at least 5 years.

5.10 ANNUAL AUDIT – SCHEDULE 3 PART 1 (10)

At least once a year, every person entitled to supply a veterinary medicinal product on prescription must carry out a detailed audit, and incoming and outgoing veterinary medicinal products must be reconciled with the products held in stock. Discrepancies must be recorded. It is an offence to fail to comply with this requirement. It would be good practice to audit stocks of NFA-VPS medicines although this is not mandatory. There is no requirement to audit stocks of AVM-GSL medicines.

5.11 SUPPLY OF A SHEEP DIP – SCHEDULE 3 PART 1 (11)

The supply of a sheep dip must either be to a person who holds a Certificate of Competence in the Safe Use of Sheep Dips (The certificate shows that Parts 1 and 2 of the assessment have been completed satisfactorily), or NPTC Level 2 Award in the Safe Use of Sheep Dip (QCF) issued by the National Proficiency Tests Council and the Department of Agriculture Northern Ireland or to a person acting on behalf of such a person. The certificate shows that Parts 1 and 2 of the assessment have been completed satisfactorily. The supplier must make a record of the Certificate number as soon as reasonably practical and keep it for at least 3 years.

If the active ingredient of the veterinary medicinal product is an organophosphorus compound the supplier must give the buyer:

- (a) a double sided laminated notice providing the relevant safety advice;
- (b) two pairs of gloves to provide protection.

For full details see the Regulations.

5.12 INSPECTIONS

Pharmacies supplying veterinary medicines will be subject to inspection by the DHSSPS.

5.13 FURTHER INFORMATION

The Veterinary Medicines Inspectorate publish a series of useful Veterinary Medicines Guidance Notes (VMGNs) at the following URL:

<http://www.vmd.gov.uk/General/VMR/vmgn.htm>



6

Non-Medicinal Poisons



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6 NON-MEDICINAL POISONS

A “non-medicinal poison”, or simply a “poison”, is a substance that is included in the Poisons List Confirmation Order made under the Poisons (NI) Order 1976. A reference to a poison includes substances containing that poison. Other substances, no matter how toxic, are not poisons under this Order.

The Royal Pharmaceutical Society of Great Britain has produced a useful fact sheet on poisons (www.rpsgb.org – Legal & Ethical Advisory Service)

A committee called the Poisons Board advises the DHSSPS about which substances should be included in the Poisons List Confirmation Order, and about the content of the Poisons Regulations that contain the detail of the legislation.

Some substances in the Poisons List also have medicinal uses. When sold as medicines, such substances are controlled by the Medicines Act 1968, but when sold for non-medicinal purposes they are subject to the Poisons (NI) Order 1976.

The Poisons List Confirmation Order 1983 is divided into two parts. In general, substances included in Part I of the List (i.e. Part I poisons) may be sold only by persons lawfully conducting retail pharmacy businesses. Such sales must be conducted at a registered pharmacy under the supervision of a pharmacist.

Part II poisons may be sold both by such persons and by Registered Sellers of Part II poisons, that is by persons whose names appear in a register of sellers maintained by a district council. A Registered Seller may nominate one or two deputies who also may effect the sale of Schedule I poisons.

Registered Sellers may only sell Part II poisons in pre-packed containers and sales must be made on the registered premises.

Certain Part II poisons may be sold only by Registered Sellers if the poison is in a specified form, and some of these poisons may be sold only to persons engaged in the trade or business of agriculture, horticulture or forestry and for the purpose of that trade or business. Apart from these matters, the requirements for the sale of Part II poisons are substantially the same for Registered Sellers as for persons lawfully conducting retail pharmacy businesses.

6.1 POISONS SCHEDULES

The Poisons Regulations (NI) apply or relax the restrictions imposed by the Order in particular circumstances.

There are 8 schedules to the Regulations and they are described briefly (more detailed reference is made to some of them later):

Schedule 1: A list of poisons to which apply special restrictions relating to storage, conditions of sale and keeping of records of sales. The restrictions do not apply to articles that contain barium carbonate, or to, alpha-chloralose or zinc phosphide and are prepared for the destruction of rats and mice.

Schedule 4: A list of articles exempted from control as poisons. There are two groups. Group 1 comprises classes of articles that contain poisons but are totally exempt, e.g., builders' materials. Group 2 lists exemptions for certain poisons when in specified articles or substances, e.g., sulphuric acid in accumulators.

Schedule 5: Some Part II poisons may be sold by Registered Sellers only in certain forms. The details are given in this schedule, which also specifies certain poisons that may be sold by Registered Sellers only to persons engaged in the trade or business of agriculture, horticulture or forestry and for the purpose of that trade or business. In any other circumstances the sale of Schedule 5 poisons is restricted to pharmacies.

Schedule 8: Form of application for inclusion in District Council's Register of Sellers of Part II poisons.

Schedule 9: Form of the register of Registered Sellers of Part II poisons kept by a District Council.

Schedule 10: Form of certificate for the purchase of a poison (see Figure 1).

Schedule 11: Form of entry to be made in poisons book on sale of Schedule 1 poison.

Schedule 12: Restriction of sale and supply of strychnine and other substances. Forms of authority required for certain of these poisons.

Schedules 2, 3, 6 and 7 were deleted by the Poisons (Amendment) Regulations (NI) 1985.

6.2 SALES OF POISONS

Containers for poisons

Substances in the poisons list are subject to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (SR 2009 No 238) and must be supplied in an appropriate container.

The container of any poison must be impervious to the poison and sufficiently stout to prevent leakage arising from the ordinary risks of handling and transport. The outer surface of a bottle, if of no greater capacity than 1.14 litres, used for the sale or supply of a liquid poison must be fluted vertically with ribs or grooves recognisable by touch. This requirement applies to bottles made of any material. It does not apply to the sale or supply of poisons to be exported to purchasers outside the United Kingdom, or the sale or supply to a person or institution concerned with scientific education or research or chemical analysis, for the purpose of that education or research or analysis.

Pharmacists should refer to the requirements of the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (SR 2009 No 238) with respect to containers for poisons.

Labelling of poisons

Substances in the Poisons List Confirmation Order are subject to the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 and must be labelled accordingly.

The particulars for labelling must be in English and indelibly marked on the container or on a label securely fixed to the container. No substance may be supplied unless it is in a container that is clearly labelled with the following particulars:

- (a) the name of the substance or the trade name if it is a preparation;
- (b) the name and address, including telephone number, of the supplier;
- (c) the indication of a general nature of risk and the symbol(s) specified for the general indications of risk;
 - (a) the risk phrases; and
 - (b) the safety phrases.

Each substance is classified in the approved list as to its general nature of risk, its particular risk and the indication of safety precautions with which the container must be labelled. The approved list is voluminous and anyone seeking to supply such substances should seek advice from the Pharmaceutical Branch of the DHSSPS.

Label: Requirements are set out in Regulations 14 to 19 of the Poisons Regulations (NI) 1983. See also CHIP Requirements.

Container: Requirements are set out in Regulations 10(1)(a) and 20 of the above Regulations. See also CHIP requirements.

Sales of Schedule 1 poisons

For requirements concerning containers and labelling see above.

Knowledge of the purchaser

The purchaser of a Schedule 1 poison must be either:

- (a) certified in writing in the prescribed manner by a householder to be a person to whom the poison may properly be sold (see Figure 1). If the householder is not known to the seller to be a responsible person of good character, the certificate must be endorsed by a police officer in charge of a police station. It must be retained by the seller; or,
- (b) known by the seller, or by a pharmacist employed by him at the premises where the sale is effected, to be a person to whom the poison may properly be sold.

If the purchaser is known by the person in charge of the premises on which the poison is sold, or of the department of the business in which the sale is effected, then the requirement as to knowledge of the purchaser by the seller is deemed to be satisfied in the case of (a) sales made by Registered Sellers of Part II poisons, and (b) sales exempted by Section 6 of the Order.

The requirements as to knowledge of the purchaser, entry in the Poisons Book and signature (or signed order) by the purchaser do not apply to:

- (a) the sale of poisons to be exported to purchasers outside the United Kingdom;
- (b) the sale of any article by its manufacturer or by a person carrying on a business in the course of which poisons are regularly sold by way of wholesale dealing, if
 - i the article is sold to a person carrying on a business in the course of which poisons are sold or regularly used in the manufacture of other articles; and
 - ii the seller is reasonably satisfied that the purchaser requires the article for the purpose of that business.

The requirements that apply to the sale of Schedule 1 poisons apply also to the supply of such poisons in the form of commercial samples. The requirement that the person supplied must be known to the seller must be satisfied for the supply of commercial samples, if the person to be supplied is known by the person in charge of the department of the business through which the sale is made.

Records

The seller must not deliver a Schedule 1 poison until he has made the required entry in the Poison Book and the purchaser has signed it. The particulars to be recorded are:

- (a) the date of the sale;
- (b) the name and address of the purchaser;
- (c) the name and address of the householder, if any, by whom certificate was given; and the date of the certificate
- (d) name and quantity of poison;
- (e) the purpose for which it is stated by the purchaser to be required;
- (f) the business, trade or occupation of the purchaser.

Entries in the Poisons Book must be made in the manner prescribed in the Poisons Regulations. The book must be retained for two years from the date on which the last entry was made.

A signed order may be accepted in lieu of the purchaser's signature in the circumstances described below.

The Regulations require that any authority or certificate, relating to the supply of a specific poison, must be retained by the seller. The authority or certificate must be retained for at least two years.

Signed orders

A signed order in writing may be accepted from a person who requires a Schedule 1 poison for the purpose of his trade, business or profession. The seller must be reasonably satisfied that the purchaser carries on the trade, business or profession stated, and that the signature is genuine. In addition to the signature of the purchaser the order must state:

- (a) his name and address;
- (b) his trade, business or profession;
- (c) total quantity to be purchased;
- (d) the purpose for which the poison is required.

A signed order is required to be dated. The entry made in the Poisons Book before delivery of the poison must be dated. The date of the signed order and the words "signed order" must be recorded in place of the signature. The entry in the register, must be identified by a reference number. In an emergency the seller may deliver the poison on receiving an undertaking that a signed order will be furnished within the next 72 hours. Failure to comply with an undertaking, or the making of false statements to obtain a Schedule 1 poison without a signed order, are contraventions of the Poisons Regulations.

Schedule 1 Poisons subject to special restrictions

Some Schedule 1 poisons are subject to special restrictions on sale or supply. They may only be sold

- (a) by way of wholesale dealing,
- (b) for export to purchasers outside the United Kingdom, or
- (c) to persons or institutions concerned with scientific education or research or chemical analysis for the purpose of that education, research or analysis.

Sale or supply of these poisons is also permitted in the circumstances indicated below:

- (1) Strychnine may be sold or supplied: in Northern Ireland in accordance with articles 5 and 6 of the Poisons (NI) Order 1976 as extended by Regulation 6 of the Poison Regulations (NI) 1983.

NB. Since July 1992, the sale or supply of strychnine in Northern Ireland to a person for the purpose of killing foxes has been banned. Strychnine can now only be supplied in special circumstances to an officer of DOE for the purpose of killing foxes in an infected area as laid down in the Rabies (Control) Order.

Strychnine was previously available in England and Wales for the purpose of killing moles. Since 1st September 2006 strychnine no longer has approval for purchase or use for mole control from the Pesticides Safety Directorate (PSD).

- (2) Fluoroacetic Acid, its salts or fluoroacetamide may be sold to a person producing a certificate, in form "A" or form "B" as provided in Schedule 12, which has been issued within Regulations.
- (3) Restrictions on the sale and supply of:
 - a. Thallium and its salts
 - b. Zinc phosphide
 - c. Sodium arsenites or potassium arsenitesare laid down in the relevant sections of the Poisons Regulations (Northern Ireland) Order 1983 SR No. 201, article 12 and Schedule 12.

Storage of Schedule 1 poisons

Schedule 1 poisons in any retail shop, or premises used in connection with such a shop, must be stored in one of the following ways:

- (a) in a cupboard or drawer reserved solely for the storage of poisons; or
- (b) in a part of the premises that is partitioned off or otherwise separate from the remainder of the premises and to which customers are not permitted to have access; or
- (c) on a shelf reserved solely for the storage of poisons, and no food is kept directly under the shelf.

If the poison is to be used in agriculture, horticulture or forestry then:

- (a) it must not be stored on any shelf or any part of the premises where food is kept; and
- (b) it may only be stored in a cupboard or drawer that is reserved for poisons used in agriculture, horticulture or forestry.

Sales exempted by Section 6

Section 6 of the Poisons (NI) Order 1976 exempts certain categories of sales of poisons from the provisions of the Order, except as provided by the Poisons Regulations. The principal effect is that exempted transactions in any Part I poison may be made without the supervision of a pharmacist, provided the sales are not made by a shopkeeper on premises connected with his retail business. The requirements as to signed orders and Poisons Book records in respect of Schedule 1 poisons also apply. The exempted categories are:

- (1) Sales of poisons by way of wholesale dealing, that is, sales made to a person who buys for the purpose of selling again.
- (2) Sales of poisons to be exported to persons outside Northern Ireland.
- (3) The sale of an article to a duly qualified medical practitioner, registered dentist, registered veterinary surgeon or registered veterinary practitioner for the purpose of his profession.
- (4) The sale of an article for use in connection with any hospital infirmary or dispensary or similar institution maintained by any public authority or out of any public funds or by a charity or by voluntary subscriptions.
- (5) The sale of an article by a person carrying on a business in the course of which poisons are regularly sold either by way of wholesale dealing or for use by purchasers in their trade or business to:
 - (a) a government department or an officer of the Crown requiring the article for the public service, or any local authority requiring the article in connection with the exercise of its statutory powers;
 - (b) a person or institution concerned with scientific education or research, if the article is required for the purposes of that education or research;
 - (c) a person who requires the article for the purpose of enabling him to comply with any requirements made by, or in pursuance of, any enactment with respect to the medical treatment of persons employed by that person in any trade or business carried on by him;
 - (d) a person who requires the article for the purpose of his trade or business. A person can be said to be carrying on a business if he engages in full-time or part-time commercial activity with a view to profit. Eg A sale of cyanide to a commercial fruit grower for killing wasps would be a "trade or business" sale, but a sale for the same purpose to a householder for garden use would not. Sales exempted by Section 6 are the only sales of cyanides that are lawful, so that a sale to a householder would be unlawful.

Wholesale dealing to a shopkeeper

A person who sells a Part I poison to a shopkeeper by way of wholesale dealing must have reasonable grounds for believing that the purchaser is a person lawfully conducting a retail pharmacy business. If not, then the wholesaler must obtain a statement signed by the purchaser, or person authorised by him, to the effect that the purchaser does not intend to sell the poison on any premises used for or in connection with his retail business. "Sale by way of wholesale dealing" means sale to a person who buys for the purpose of selling again.

SCHEDULE 10

Regulation 26

Certificate for the purchase of a non-medicinal poison

For the purpose of Article 5(2)(a)(i) of the Poisons (Northern Ireland) Order 1976.

I, the undersigned, a householder occupying (a).....
hereby certify from my knowledge of (b).....
of (a).....
that he is a person to whom (c).....may properly be supplied.

I further certify that (d)
is the signature of the said (b)

.....
Signature of householder giving certificate

Date.....

- (a) Insert full postal address.
- (b) Insert full name of intending purchaser.
- (c) Insert name of poison.
- (d) Intending purchaser to sign his name here.

Endorsement required by regulation 26 of the Poisons Regulations (Northern Ireland) 1983 to be made by a police officer in charge of a police station when, but only when, the householder giving the certificate is not known to the seller of the poison to be a responsible person of good character.

I hereby certify that in so far as is known to the police of the district in which
*.....resides he is a responsible person of good character.

Signature of Police Officer
Rank

In charge of Police Station at
Date

Office Stamp of
Police Station

*Insert full name of householder giving the certificate.

Figure 1 Certificate for the purchase of a non-medicinal poison





7

Denatured Alcohol



7 DENATURED ALCOHOL

Law affecting denatured alcohol

Section 77 of the Alcoholic Liquor Duties Act 1979 gives HM Revenue and Customs the power to make regulations laying down requirements for the manufacture, supply and use of denatured alcohol. Section 78 of the Act prescribes penalties for offences in connection with denatured alcohol. The requirements are set out in the Denatured Alcohol Regulations 2005 (SI No. 1524) which revoked the Methylated Spirits Regulations 1987 and The Iso-Propyl Alcohol Regulations 1927 and further implements Articles 27 (l)(a) and (b) of Council Directive 92/83/EEC.

The Denatured Alcohol Regulations 2005 cover the whole of the United Kingdom.

Further information on denatured alcohol can be found in HM Revenue and Customs Reference Notice 473 (November 2009) Production, Distribution and Use of Denatured Alcohol. This is available at <http://customs.hmrc.gov.uk> This notice cancels and replaces Notice 473 (July 2005). Update 1 (June 2006) and Update 2 (August 2008) have now been incorporated within this notice.

7.1 TYPE OF DENATURED ALCOHOL

There are three types of denatured alcohol: completely denatured alcohol; industrial denatured alcohol; and trade specific denatured alcohol, although most pharmacists will deal only with the first two.

(a) Completely denatured alcohol (CDA) (Formerly known as Mineralised Methylated Spirits - MMS)

Completely denatured alcohol is a mixture of 90 parts by volume of alcohol, 9.5 parts by volume of wood naphtha or a substitute for wood naphtha and 0.5 parts by volume of crude pyridine, to each 1000 litres of the mixture of which is added 3.75 litres mineral naphtha (petroleum oil) and 1.5g of synthetic organic dyestuff (methyl violet). CDA is suitable for heating, lighting, cleaning and general domestic use. Pharmacists can obtain CDA from wholesalers in any quantity. A full list of formulations of CDA used in EU Member States can be found in HMRC Reference Notice 473 (Nov 2009), which is available from the HM Revenue and Customs Helpline on 0845 010 9000.

**(b) Industrial denatured alcohol (IDA)
(Formerly known as Industrial Methylated Spirits - IMS)**

IDA consists of 95 parts by volume of alcohol and 5 parts by volume of wood naphtha, or a substitute for wood naphtha. Where a substitute for wood naphtha is used, the volume mixed with every 95 parts of alcohol may be less than 5 parts depending on: (a) the proportion of the marker in the resulting mixture, and (b) the resulting mixture contains the other substances that the Commissioners approved when they approved the substitute for wood naphtha in the proportions that they specify.

IDA is usually approved for use in industrial, scientific and external medical applications. A full list of authorised uses can be found in HMRC Reference Notice 473 (Nov 2009), which is available from the HMRC Helpline on 0845 010 9000. To use IDA in a way not on the approved list, the National Registration Unit should be contacted with the details of the proposed use. They may approve its use as an alternative.

**(c) Trade specific denatured alcohol (TSDA)
(Formerly known as Denatured Ethanol B - DEB)**

There is a list of formulations of, and uses for, TSDA, which have been approved by the Commissioners of HM Revenue and Customs. The current list can be found in Section 18 of Reference Notice 473.

7.2 APPLICATION FOR AUTHORITY TO RECEIVE IDA OR TSDA

An application has to be made to HM Revenue and Customs National Registration Unit (NRU) to obtain authority to receive IDA or TSDA. The form can be found at the back of HM Revenue and Customs Reference Notice 473 (November 2009)

IDA and TSDA may be obtained only by persons specifically authorised by HM Revenue and Customs to receive it. Users must furnish the pharmacist (supplier) with a copy of the authorisation before they may receive IDA or TSDA. These statements are valid indefinitely, but the supplier must notify HM Revenue and Customs of any changes to its use or formulation.

However, medical and veterinary practitioners can obtain IDA from any pharmacist, authorised by HM Revenue and Customs to receive, against a written order or prescription without being authorised.

7.3 SUPPLY OF DENATURED ALCOHOL BY AUTHORISED USERS

Authorised users may supply denatured alcohol or articles containing denatured alcohol as follows:

CDA

England, Wales and Northern Ireland There are no restrictions on the quantity of CDA that can be supplied. There are also no conditions on its use.

CDA may be received free of duty if the denatured alcohol made in a Member State is in accordance with a formulation of that Member State, or it is made nearly as possible in accordance with the UK CDA formulation or a CDA formulation of another Member State. The acceptability of the formulation should be checked with the HMRC Helpline (See Reference Notice 473 (Nov 2009)). CDA may be imported directly to your premises from a Member State if the CDA is denatured in accordance with a CDA formulation of a Member State, otherwise it has to be consigned to an excise warehouse with the relevant approval to hold such goods.

IDA and TSDA

IDA and TSDA can only be supplied to other producers or distributors who are authorised by HM Revenue and Customs as users. The pharmacist must hold a copy of that user's authorisation to receive and use IDA/TSDA and must not supply it for any other use. The authorisation may cover any number of consignments of IDA or TSDA supplied. Supply of IDA or TSDA must not be made without holding a copy of the user's authorisation or for a use that is not included in the user's authorisation. Any authorised pharmacist may supply IDA to a medical or veterinary practitioner against a written order or prescription without being authorised.

An authorised user may supply IDA/TSDA in quantities of less than 20 litres at any one time to another authorised user provided the supplier's authority does not specifically restrict this.

Only licensed, or authorised producers or distributors are permitted to supply denatured alcohol in quantities of greater than 20 litres (wholesale quantities).

Supply of IDA by a pharmacist

Users must furnish the pharmacist (supplier) with a copy of the authorisation before they may receive IDA.

A copy of the person's authorisation to receive and use denatured alcohol is not needed, however, when a pharmacist supplies IDA for medical use on a

prescription or order of a medical or veterinary practitioner. There is no limit to the amount of denatured alcohol that can be supplied on an order. An "order" is a request to be supplied with a specific quantity of denatured alcohol. There is no set format for an order, but should include the quantity and class of denatured alcohol required.

The definitions for the above section are:

- "Pharmacist" has the meaning given in section 132(1) of the Medicines Act 1968;
- "Medical or veterinary practitioner" means a person entitled by law to provide medical or veterinary services in the United Kingdom (HM Revenue and Customs have confirmed that this does include a dentist, nurse and chiropodist);
- "Medical use" means any medical, veterinary, surgical or dental purpose other than administration internally.

Do I need to "make entry" of premises?

If stocks of denatured alcohol are held by the pharmacist, an entry of the premises will need to be made before beginning to hold denatured alcohol (unless the premises are approved as an excise warehouse). To do this, Form EX 103 for a sole trader or partnership, or Form EX 103A for an incorporated company, should be completed. Each continuation sheet to the EX 103(A) must be signed and dated. To obtain copies of these forms or help in completing them, the HM Revenue and Customs Helpline should be contacted. Forms are also available at www.hmrc.gov.uk.

7.4 CONDITIONS OF USE OF IDA AND TSDA

The authority to receive denatured alcohol states what is authorised to be received, what it can be used for and the conditions that must be observed. The authority will be reviewed from time to time and the conditions may be varied or the authorisation revoked. The user must notify the National Registration Unit of any changes and may not receive any further supplies of IDA or TSDA until the National Registration Unit has been notified.

The main conditions are:

- (a) Storage All stocks of IDA and TSDA must be kept under lock and key and under the pharmacist's control or that of a responsible person appointed by him.
- (b) Use IDA and TSDA can be used only as set out in the letter of authority and all conditions must be complied with.
- (c) Supply Suppliers can only distribute the formulations of denatured alcohol that are approved in the UK. For supply, the following must be kept for inspection by the local HM Revenue and Customs officer:

- i. written statements from authorised users;
 - ii. written signed orders from medical practitioners. These records are required for a supply made against a prescription.
- (d) Closing or transfer of business If the business is discontinued while holding stocks of denatured alcohol, the authority to hold stocks of denatured alcohol is revoked and the HMRC Helpline should be contacted to arrange how the stocks must be disposed of and within what time period. Once all stocks are disposed of, the National Registration Unit must be contacted to cancel the authorisation. If the discontinuation of the business is caused by the death of a producer or distributor or other person, their personal representative must contact the Helpline.

Records

Authorised persons must keep and preserve records relating to their use of denatured alcohol as specified by the Commissioners, and must also comply with any conditions or restrictions imposed by them.

On receipt of IDA or TSDA the following must be kept:

a record of the amount of denatured alcohol received; and one copy of the supplier's dispatch document signed as a receipt and returned to the supplier, and the other copy retained on the premises for records. These will need to be shown to the HM Revenue and Customs officer when the premises are visited.

Distribution

For a pharmacist to be considered a distributor, the following criteria would need to be met:

- (a) holds an excise licence for the purpose of Section 75 of the Act;
- (b) does not denature alcohol at any premises on which denatured alcohol is kept;
- (c) deals or intends to deal wholesale in denatured alcohol.

Only the denatured alcohols which are detailed on the licence may be distributed.

Further details can be found in Reference Notice 473.

Specific record keeping requirements for producers/ distributors

Under the Denatured Alcohol Regulations 2005, there is a requirement to keep records which show the following information:

- (i) purchases of any alcohol, denaturants and other materials used in the production of denatured alcohol;
- (ii) imports of denatured alcohol, including details of the country of origin;
- (iii) the class of denatured alcohol held in containers, that is whether it is CDA, IDA or TSDA;

- (iv) quantities of alcohols, denaturants, markers, dyes and denatured alcohol held and used on your premises;
- (v) the results of stocktakes and action taken to investigate deficiencies and surpluses identified by those stocktakes;
- (vi) exports and sales of denatured alcohol;
- (vii) copy authorisations received in support of orders for denatured alcohols.

Specific record keeping requirements for users

Under the Denatured Alcohol Regulations 2005, there is a requirement to keep records which show the following information:

- (i) purchases of IDA or TSDA;
- (ii) imports of IDA or TSDA, including details of the country of origin;
- (iii) the class of denatured alcohol held in containers, whether it is IDA or TSDA;
- (iv) quantities of IDA or TSDA held and used on the premises;
- (v) the results of stocktakes and action taken to investigate deficiencies and surpluses identified by those stocktakes;
- (vi) sales of IDA or TSDA to other authorised users;
- (vii) copy authorisations received in support of supplies of IDA or TSDA.

HM Revenue and Customs will visit from time to time to inspect the premises and examine any denatured alcohol on the premises.

Penalties are liable and the authorisation may be withdrawn if there are unexplained losses of denatured alcohol if:

- (a) as a distributor supplies have been made to users without receiving a copy of the authorisations, or
- (b) supplies have been made to persons who are not authorised users, or
- (c) as a user the denatured alcohol has not been used in accordance with its authorised use.

Some EU countries may require a certificate of denaturing for cosmetics or toiletries which are exported to them. The HMRC Helpline should be contacted for more details.

Surplus/deficiency in stocks of denatured alcohol as a distributor

Any surplus or deficiency would have to be investigated and the reasons recorded for the deficiency/surplus in the business records and the Helpline notified immediately. A demand may be issued to pay the duty on the alcohol in the missing amount.

Surplus/deficiency in stocks of denatured alcohol as a user

Any surplus or deficiency would have to be investigated and the reasons recorded for the deficiency/surplus in the business records and the Helpline notified immediately. If the denatured alcohol cannot be accounted for and has been supplied to an unauthorised user, or for an unauthorised purpose, a demand may be issued to pay the duty on the alcohol in the missing amount.

Review and Appeal Procedures

When HMRC make a decision that can be appealed, that information will be conveyed and a review offered. The decision will be explained and information given as to action to be taken if there is disagreement. Examples include; (a) the amount of an assessment, (b) the issue of a civil penalty, (c) a decision specifically connected to the relevant duty.

There will usually be 3 options. Within 30 days:

- (i) new information or arguments can be sent to the officer concerned
- (ii) the case can be reviewed by a different officer
- (iii) the case can be heard by an independent tribunal after a written request to the Tribunals Service.

Further information is available in Reference Notice 473

Contacts

HM Revenue and Customs
Helpline
0845 010 9000
8am to 8pm Monday to Friday

HM Revenue and Customs
National Registration Unit
Portcullis House
21 India Street
Glasgow
G2 4PZ

Tribunals Service
0845 223 8080

e-mail enquiries
intenquiries@hmrc.gov.uk

website
www.hmrc.gov.uk

7.5 ISOPROPYL ALCOHOL

Isopropyl alcohol 70% (which is isopropyl alcohol diluted down with water) is not a denatured alcohol and is not covered by the Denatured Alcohol Regulations 2005. Therefore, there is no requirement to be authorised by HM Revenue and Customs to receive or supply isopropyl alcohol 70%.

7.6 ETHER (ETHYL ETHER)

Ether does not come under the Denatured Alcohol Regulations.

7.7 DUTY FREE SPIRITS (DFS)

Duty free spirits cannot be used for general cleaning and other purposes. Duty free spirits are not permitted to be used for making for sale any product which contains spirits (other than, subject to special conditions, ethyl esters and ethyl ethers); or use any beverage, food-stuff, flavouring, essence or cosmetic preparation.

There is no definitive list of allowable medicinal uses of DFS. HM Revenue and Customs would consider each case on its own merits, however the general medical applications and uses for which DFS will be allowed include:

- (i) for the production of recognised medical products, drugs and pharmaceuticals (whether or not the final product contains spirits) including veterinary products including DFS to be used in the manufacture of any product (including herbal or homeopathic) which has a Medicines and Healthcare Regulatory Agency (MHRA) product licence;
- (ii) herbal or homeopathic remedies which do not have an MHRA licence. They must be recognised by HMRC as having medicinal properties;
- (iii) the manufacture of intermediate products used exclusively for the production of medical products (as above);
- (iv) for use in hospitals, and, where applicable, dental and veterinary surgeries for specific uses.

DFS can be used in the manufacture of any product prescribed by a doctor to be made by a pharmacist. This includes 'specials' which may be made up on behalf of a pharmacist and which may not have an MHRA licence.

A pharmacist would have to apply for authorisation to obtain and use duty free spirits. Further details can be obtained from HMRC Reference Notice 47 (November 2009) "Duty Free Spirits: Use in Manufacture or for Medical or Scientific Purposes"

The application for authority to receive duty free spirits (Form EX 240) is available from HMRC Helpline or at www.hmrc.gov.uk.





8

Chemicals



8 CHEMICALS

Chemicals are controlled under CHIP, which is the short name for the Chemicals (Hazard Information and Packaging for Supply) Regulations. CHIP has been in place for a number of years and has been changed several times to keep up to date with developing science and technology.

The most recent version of CHIP is known as CHIP 4. This is the name for the Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 SR No.230, which came into operation on the 27th July 2009. CHIP implements the Dangerous Substances Directive (No 67/548/EEC) and Dangerous Preparations Directive (No 1999/45/EC) that are due to be replaced by the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation (Regulation (EC) No. 1272/2008) over a transitional period which adopts the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) system in the EU.

CHIP 4 does not introduce any new duties but consolidates previous amendments and ensures that UK law is consistent with the new EU Regulation during the transitional period. Suppliers can use either the CHIP or the CLP classification and labelling of chemicals during the transitional period.

Globally Harmonised System of Classification and Labelling of Chemicals (GHS)

The United Nations (UN) created the Globally Harmonised System of Classification and labelling of Chemicals (GHS) which aims to have the same criteria for classifying chemicals worldwide according to their health, environmental, physical hazards and hazard communication requirements for labelling and safety data sheets. The GHS is not legally binding and each country has to introduce separate legislation to adopt it.

Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulations

The EU has introduced the Classification, Labelling and Packaging of Substances and Mixtures (CLP) Regulation ((EC) No 1272/2008) to adopt the GHS system in the EU. The CLP Regulation came into effect on 20 January 2009, subject to a transitional period and is directly-acting in all Member States. This will replace, gradually, the Dangerous Substances Directive, the Dangerous Preparations Directive and CHIP over a transitional period until 1 June 2015 when the CLP Regulation will be fully in force.

The transitional arrangements are:

Substances

20 January 2009 to 1 December 2010

Suppliers must classify substances according to CHIP and may continue to label and package them according to regulations 6 to 11 of CHIP. However, they may, as an alternative, choose to classify, label and package according to CLP. In this case, they must, in addition, continue to classify under regulation 4 of CHIP, but the requirements on labelling and packaging in regulations 6 to 11 of CHIP no longer apply.

1 December 2010 to 1 June 2015

Suppliers must classify substances according to both CHIP and CLP. They must label and package according to CLP.

1 June 2015 onwards

Suppliers must classify, label and package according to CLP.

Preparations (Mixtures)

20 January 2009 to 1 June 2015

Suppliers must classify preparations according to CHIP and may continue to label and package them according to regulations 6 to 11 of CHIP. However, they may, as an alternative, choose to classify, label and package according to CLP. In this case they must, in addition, continue to classify under regulation 4 of CHIP, but the requirements on labelling and packaging in regulations 6 to 11 of CHIP no longer apply.

1 June 2015 onwards

Suppliers must classify, label and package according to CLP.

Chemicals (Hazard Information and Packaging for Supply) Regulations (Northern Ireland) 2009 (CHIP)

CHIP does not apply to certain chemicals, including those intended for use as medicinal / veterinary products, investigative medicinal products, controlled drugs, waste substances or preparations, to which the Pollution Prevention and Control Regulations 2003 consolidated version produced December 2009 apply, medicinal devices, food, animal feedingstuffs or radioactive substances or preparations. Neither does CHIP apply to any sample taken by an enforcement authority.

Due to the complexities of CHIP, totally comprehensive information cannot be provided. Those pharmacists involved in the supply, labelling or packaging of chemicals are advised to contact the HSENI. Published guidance on HSENI website www.hseni.gov.uk. Additional information can be obtained from HSENI Tel 02890243249

The main objectives of CHIP are:-

- (a) the identification of harmful properties of chemicals (hazards) and the communication of this information to users by means of labels; and
- (b) to cover hazards to health, safety and the environment and use of chemicals both in the home and at work.

CHIP requires suppliers of dangerous substances and dangerous preparations to:-

- (a) identify the hazards (or dangers) of dangerous substances and dangerous preparations they supply (this process is called classification)
- (b) give information about those hazards to the persons they supply - both on the label and methods of marking; certain preparations have particular labelling requirements
- (c) package the substances safely, including appropriate child resistant closures, tactile warning devices and other consumer protection measures and
- (d) retain data pertaining to any dangerous preparation (this will not apply on or after June 2018)

These requirements are known as the supply requirements.

The transportation of chemicals is not the same as the supply. However, persons transporting chemicals by road or rail have similar duties placed on them.

These are known as the carriage requirements and are specified in The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations (Northern Ireland) 2010 SR No. 160. There are exemptions within these Regulations and they also permit the application of derogations and transitional provisions. See the publication "Carriage of Dangerous Goods – Approved Derogations and Transitional Provisions" available as a free download from HSENI website. (http://www.hseni.gov.uk/cdg_approved_derogations_and_transitional_provisions_leaflet.pdf). Further advice should be sought from HSENI.

8.1 SUPPLY REQUIREMENTS

Classification of dangerous substances and dangerous preparations

The fundamental requirement of CHIP is to assess whether the particular chemical is hazardous (dangerous) or not. If it is, then it must be classified by precise identification of the hazard by assigning a category of danger (e.g., Toxic) and a description of the hazard by allocation of a risk phrase (e.g., Harmful in contact with skin).

The main categories of danger (these are further sub-divided as follows):-

- Substances and preparations dangerous because of their physico-chemical properties - explosive, oxidising, extremely flammable, highly flammable, flammable;
- Substances and preparations dangerous because of their health effects - very toxic, toxic, harmful, corrosive, irritant, sensitising, carcinogenic, mutagenic, toxic for reproduction;
- Substances and preparations dangerous to the environment

CHIP makes it an offence to supply a dangerous chemical before it is classified and it is important that this process is carried out correctly as failure to do so could lead to errors being made in the other requirements of CHIP (i.e., labelling, safety data sheet (SDS) preparation and packaging).

When chemicals are supplied to a pharmacy, they should already have been classified properly by your supplier. If this is the case, then the pharmacist could use this classification of supplies provided he is satisfied that it is correct and the competence of the supplier is known to him.

From 1 June 2015 all dangerous substances and preparations must be classified in accordance with the requirements of CLP Regulations. CHIP makes suppliers of chemicals responsible for the classification of a chemical right throughout its supply chain. Remember, a pharmacist will be the final supplier.

CHIP requires a supplier to exercise "all due diligence" in complying with its legal requirements. This means that if a pharmacist uses the classification assigned by the manufacturer or supplier higher up the supply chain, then he may wish to make appropriate enquiries about the classification to ensure accuracy. If suppliers are known to the pharmacist and there is confidence in their ability, then only simple checks may be necessary. Examples are: a common sense check, for an acid commonly known to cause burns not being classified corrosive and making enquiries with a supplier or from any people the pharmacist knows to be competent in this area.

Labels/Safety Data Sheets

CHIP sets down requirements for the detail of information on the label of products to be provided to persons supplied with dangerous substances and preparations.

Safety Data Sheet (SDS) requirements are no longer part of CHIP. CHIP 4 refers to Annexe 31 of REACH (European Regulation (EC) No 1907 / 2006 on the Regulation, Evaluation, Authorisation and Restriction of Chemicals, which signposts the provisions for SDS. See "REACH and Safety Data Sheets" Leaflet January 2009

Labelling

Details of information required to be on the label of products to be provided to persons supplied with dangerous substances and preparations are set out in CHIP. For domestic users, the CHIP label will contain all the information required to be given under CHIP.

Pharmacists are advised to supply dangerous substances and preparations in original packs, which should be labelled up to comply with the CHIP regulations. However, as the supplier of the product, you will still be responsible for the labelling and it is advisable to make "due diligence" checks. As a guide pharmacists are advised to check that the requirements of CHIP in relation to the labelling are present (see below) and a common sense check would also be beneficial. In cases where pharmacists are packing down preparations, these must be labelled to comply with CHIP.

Pharmacists regularly preparing their own label products may be interested in a database available from the Health and Safety Executive that can be used to generate labels.

CHIP specifies exactly what must appear on the label of a dangerous substance or preparation. This is potentially dependent on whether it is a substance (usually a single chemical) or preparation (in general terms, a mixture of substances) being labelled. It is also dependent on how it has been classified under CHIP.

The particulars required for labelling a dangerous substance supplied in a package are:

- (a) the name, full address and telephone number of a person in an EEA State who is responsible for supplying the substance, including the pharmacist, whether that person is its manufacturer, importer or distributor;
- (b) the name of the substance being:
 - (i) where the substance appears in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the name or one of the names listed therein for that substance;
 - (ii) where the substance does not appear in Table 3.2 of part 3 of Annex VI of the CLP Regulation, an internationally recognised name; and
- (c) the following particulars ascertained in accordance with Part 1 of Schedule 4, namely
 - (i) any indication of danger together with corresponding symbols;
 - (ii) the risk phrases, set out in full; and
 - (iii) the safety phrases, set out in full; and
 - (iv) any EC number and, in the case of a substance which is listed in Table 3.2 of part 3 of Annex VI of the CLP Regulation, the words " "EC label".

The particulars required for labelling a dangerous preparation supplied in a package are:

- (a) the name, full address and telephone number of a person in an EEA State who is responsible for supplying the substance, including the pharmacist, whether he be its manufacturer, importer or distributor;
- (b) the trade name or other designation of the preparation; and
- (c) the following particulars ascertained in accordance with Part 1 of Schedule 4, namely
 - (i) indication of the constituents of the preparation which result in its being classified as a dangerous preparation,
 - (ii) any indication of danger, together with corresponding symbols,
 - (iii) the risk phrases, set out in full; and
 - (iv) the safety phrases, set out in full; and
 - (v) in the case of a preparation intended for sale to the general public, the nominal quantity (nominal mass or nominal volume).

Indications such as "non-toxic", "non-harmful", "non-polluting", "ecological", or any other statement indicating that the dangerous substance or preparation is not dangerous or that it is likely to lead to underestimation of the danger of the dangerous substance or preparation must not appear on the package.

Where the package contains such small quantities of that substance or preparation that there is no foreseeable risk, under conditions of supply, use and disposal, arising from that hazardous property to persons handling that substance or preparation or to other persons, the packaging of a dangerous substance or preparation classified in one or more of the categories of danger, harmful, extremely flammable, highly flammable, flammable, irritant or oxidising are not required to be labelled in respect of that hazardous property.

Where the package in which a dangerous substance is supplied does not contain more than 125 millilitres of that substance the risk phrases and safety phrases do not have to be shown if the dangerous substance is classified only in one or more of these categories of danger:

- (i) highly flammable, flammable, oxidising, irritant; or
- (ii) harmful, provided the dangerous substance is not sold to the general public.

Where the package in which a dangerous preparation is supplied does not contain more than 125 millilitres of that substance the risk phrases and safety phrases do not have to be shown if the dangerous preparation is classified only in one or more of these categories of danger:


- (i) irritant (except those assigned the risk phrase R41);
- (ii) dangerous for the environment and assigned the N symbol;
- (iii) oxidising; or
- (iv) highly flammable.

The safety phrases do not have to be shown if the dangerous preparation is classified only in one or more of these categories of danger:


- (i) flammable; or
- (ii) dangerous for the environment and not assigned the N symbol.

Safety data sheets

European symbols



New International symbols



Products you use may be 'dangerous for supply'. If so, they will have a label that has one or more hazard symbols. S

These products include common substances in everyday use such as paint, bleach, solvent or fillers. When a product is 'dangerous for supply', by law, the supplier must provide you with a safety data sheet. Note: medicines, pesticides and cosmetic products have different legislation and don't have a safety data sheet. Ask the supplier how the product can be used safely.

Safety data sheets can be hard to understand, with little information on measures for control. However, to find out about health risks and emergency situations, concentrate on:

- Part 15 of the sheet, which tells you what the dangers are;
- Parts 4 to 8, which tell you about emergencies, storage and handling.

International symbols will replace the European symbols in 2009. Some of them are similar to the European symbols but there is no single word describing the hazard. Read the hazard statement on the packaging and the safety data sheet from the supplier.

Examples of symbols taken from HSE Guidance Note: Working with substances hazardous to health.

Dangerous preparations to be supplied to the general public

The label on the packaging of dangerous preparations intended to be supplied to the general public must, in addition to the relevant safety advice, bear the relevant safety phrase S1 (Keep locked up), S2 (Keep out of reach of children), S45 (In case of accident or if you feel unwell seek medical advice immediately (show the label where possible) or S46 (If swallowed, seek medical advice immediately and show the container or label), in accordance with the approved classification and labelling guide.

When the dangerous preparations are classified as very toxic, toxic or corrosive and where it is physically impossible to give the information on the package itself, packages containing such preparations must be accompanied by precise and easily understandable instructions for use including, where appropriate, instructions for the destruction of the empty package.

Pharmacists involved in preparing labels for dangerous substances and dangerous preparations should refer to CHIP and HSE guidance and also Table 3.2 in Annex VI of the CLP Regulation.

Packaging

It is an offence to supply a dangerous chemical unless it is in a suitable package. The packaging and fastenings should be strong and solid throughout to ensure they will not loosen when subjected to the stresses and strains of normal handling. The container must not be adversely affected by the chemical or react with the chemical to form other dangerous chemicals. Where the package is fitted with a replaceable closure, its integrity must remain with repeated use. Except where a special safety device has been fitted to make the receptacle closable, the package should be designed and constructed so that its contents cannot escape.

In addition, there is a requirement for packaging with a child resistant fastening (CRF) for certain chemicals that are sold to the public containing either:-

- (i) products classified as "toxic, very toxic or corrosive";
- (ii) methanol (3% or more by weight);
- (iii) dichloromethane (1% or more by weight); or
- (iv) substances which have been assigned the risk phrase (R65) in Table 3.2 of part 3 of Annex VI of the CLP Regulation, which states "Harmful: may cause lung damage if swallowed" (except where the chemical is supplied in an aerosol dispenser or a container fitted with a sealed spray attachment);
- (v) substances and preparations which are assigned the risk phrase (R65) and are classified and labelled according to the approved classification and labelling guide, except where such a substance or preparation is supplied in an aerosol dispenser or a container fitted with a sealed spray attachment.

CRFs are not required if it can be shown that a child cannot gain access to the chemical without the help of a tool.

Chemicals sold to the public that are labelled "very toxic, toxic, corrosive, harmful, extremely flammable or highly flammable" must also have a tactile danger warning (normally a small raised triangle) to alert the blind and partially sighted that they are handling a dangerous product. This does not apply to an aerosol dispenser which is classified and labelled only with the indication of danger "extremely flammable" or "highly flammable".

Pharmacists are advised to check that packaging complies with the above before supplying chemicals to the public.

The majority of sales of hazardous chemicals from pharmacies will probably require very little extra work by the pharmacist. It is important, however, to remember the need for due diligence and, when there is a legal obligation, to supply a safety data sheet (SDS).

When a substance or preparation has been classified, labelled and packaged in accordance with the CLP Regulation, the packaging of dangerous substances,

dangerous preparations and certain other preparations, labelling and child resistant fastening, tactile warning devices and other consumer protection measures as detailed above do not apply to that substance from 1 December 2010, or preparation from 1 June 2015.

Advertising

The provisions for advertisements have been removed from CHIP and it is now the CLP Regulation which applies. The CLP Regulation requires all advertisements for a substance classified as hazardous to mention the hazard classes and hazard categories concerned. Any advertisement for a mixture classified as hazardous or covered by Article 25(6) which allows a member of the public to conclude a contract to purchase a dangerous chemical before they have seen the label relating to that chemical (eg via mail order or the internet) must mention the type or types of hazard indicated on the label. The term "advertisement" does not include a price list and therefore this is unlikely to affect the majority of pharmacists.

Regulation, Evaluation, Authorisation and restriction of Chemicals (REACH)

REACH is the European regulation on the Registration, Evaluation, Authorisation and restriction of Chemicals (REACH) Regulation ((EC) No 1907/2006) which came into effect on 1 June 2007. The regulations run in parallel to the European CLP regulations. They have direct legal impact within the EU, however, the enforcement is up to the individual Member State. The REACH Enforcement Regulations 2008 apply to the UK and provide for the enforcement of REACH.

REACH covers the registration, pre-registration, evaluation, authorisation, restrictions, classification and labelling and information provision of chemicals.

For further guidance pharmacists are advised to contact www.hse.gov.uk/reach or ukreachca@hse.gsi.gov.uk

Substances of Very High Concern (SVHC)

REACH contains a list of substances of very high concern, the registration and use of which is subject to further restrictions including authorisation and the provision of information.

SVHCs are substances which are classified as

- carcinogenic, mutagenic or toxic for reproduction (CMR) category 1 or 2;
- persistent, bio-accumulative and toxic (PBT);
- very persistent and very bio-accumulative (vPvB);

- substances not classified as above but where there is scientific evidence of probable serious effects to human health or the environment.

Substances meeting the above criteria may be placed on the Candidate List (published by ECHA) and the Annex XIV List. It is possible that some substances that meet the criteria will not appear on either list.

Pharmacists supplying any substance should check with the HSE whether it is a SVHC and for further guidance refer to www.hse.gov.uk/reach/svhc.pdf

Safety Data Sheets for substances and preparations (SDS)

The rules relating to Safety Data Sheets (SDS) are now to be found in the REACH regulations. They were previously covered in the CHIP regulations.

The supplier of a substance or a preparation must provide the recipient with a SDS compiled in accordance with Annex 2 where the substance or preparation is:

- classified
- a PBT or a vPvB
- a SVHC or on the Candidate List; or
- hazardous as it contains at least one substance in an individual concentration less than or equal to: 1% by weight for non-gaseous preparations; 0.2% by volume for gaseous preparations; or less than or equal to: 0.1% by weight for non-gaseous preparations which is a PBT or vPvB in accordance with specified criteria; or
- there are workplace exposure criteria.

A SDS does not need to be provided where dangerous substances or preparations are sold to the general public where sufficient information is given to enable the user to take measures which are necessary for the protection of health and safety and the environment, unless requested by a downstream user or distributor.

The headings under which information must be provided are listed below together with a general description of the information which may be found under each heading. These descriptions are not all encompassing. For further information please contact the HSE.

(1) Identification of the substance/preparation and company/undertaking

The name of the substance/preparation should be identical to the name used on the label. It should indicate the intended or recommended use of the substance/preparation. The name, full address and telephone number and e-mail address of the competent person responsible for the SDS. Where this person is not in the Member State where the substance or preparation is placed on the market, the full address and telephone number for the person

responsible in that Member State. An emergency telephone of the company and/or relevant advisory body should be added if access to advice in the event of an emergency is not available on the number already given and specify if the phone number is available only during office hours.

(2) Hazards identification

The classification of the substance or preparation under the classification rules should be given here. The most important hazards of the substance or preparation to man and the environment should be stated.

(3) Composition/information on ingredients

Sufficient information must be given to enable the recipient to readily identify the hazards of the components of the preparation. The hazards of the preparation itself are listed in (2) above.

(4) First aid measures

The information should state whether immediate medical attention or professional assistance by a doctor is needed or advisable. The information should be brief and easy to understand by the victim, bystanders and first aiders. Sub-headings should be given for different routes of exposure, e.g. skin and eye contact, inhalation or ingestion. If immediate medical attention or if a specific form of treatment is required, that should be stated.

(5) Fire fighting measures

Suitable extinguishing media should be stated, together with details of extinguishing media which are not safe to be used and details of special protective equipment for fire fighters. Exposure hazards arising from the substance or preparation, combustion products and resulting gases should be stated.

(6) Accidental release measures

Information should be provided on personal precautions, e.g., "removal of ignition sources", "provision for sufficient ventilation/respiratory protection", environmental precautions, e.g., "keep away from drains, surface and ground water and soil", and methods of clearing up, e.g., "use of absorbent material" "sand". Consideration should also be given to using statements such as "Never use with..." or "Neutralise with...".

(7) Handling and storage

This information relates to the protection of human health, safety and the environment and assist the employer in implementing suitable working procedures and organisational measures. Precautions necessary for safe handling, such as measures to prevent dust generation, fire etc. and conditions for storage, e.g., ventilation, temperature, light and humidity, should also be stated. For end products designed for specific use(s) recommendations must refer to the identified use, with reference to industry/sector specific guidance.

(8) Exposure controls and personnel protection

This should include the full range of precautionary measures to be taken during use to minimise worker and environmental exposure. It should specify

where necessary the type of equipment to afford suitable protection e.g., respiratory, eye, skin and hand protection.

(9) Physical and chemical properties

The following information should be provided:

- Appearance, e.g., white solid;
- odour, if perceptible, a brief description;
- pH; boiling point/melting range;
- flash point;
- flammability (solid, gas);
- explosive properties;
- oxidising properties;
- vapour pressure;
- relative density;
- solubility (water or fat);
- partition coefficient;
- viscosity;
- vapour density;
- evaporation rate;
- other important safety parameters of the product.

(10) Stability and reactivity

State the stability of the substance or preparation and the possibility of hazardous reactions occurring under certain conditions of use and also if released into the environment, i.e., conditions to avoid (temperature, pressure, shock, etc.); materials to avoid (water, air, etc.); hazardous materials produced in dangerous amounts on decomposition, addressing specifically the need for and the presence of stabilisers; possibility of a hazardous exothermic reaction; safety significance, if any, of a change in physical appearance of the substance or preparation, hazardous decomposition products, if any, formed upon contact with water and the possibility of degradation to unstable products.

(11) Toxicological information

Provide a concise but complete and comprehensive description of the toxicological effects resulting from contact with the substance or preparation. Known delayed and immediate and chronic effects from short and long term exposure should be stated. Information on different routes of exposure and a description of the symptoms related to the physical, chemical and toxicological characteristics should be given.

(12) Ecological information

An assessment should be given of the possible effects on the environment in relation to such factors as ecotoxicity, mobility, persistence and degradability, bioaccumulative potential, results of a persistent, bioaccumulative and toxic assessment (BPT) and any other adverse effects.

(13) Disposal consideration

Information should be provided on the dangers associated with disposal. Safety and appropriate methods of disposal should be given together with references to appropriate legislation.

(14) Transport Information

Details of special precautions relating to transport or conveyance, either within or outside premises.

(15) Regulatory information

The health, safety and environmental information on the label as required by Regulation 9 of CHIP should be given. Reference to the Health and Safety at Work (Northern Ireland) Order 1978 and Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34, Amendment SR No. 288 (COSHH) might also be made.

(16) Other information

Advice on other information which "may be of importance for health and safety of the user and for protection of the environment, e.g., training advice, recommended restrictions on use, further information, i.e., written references and/ or technical contact point, sources of key data used to compile the safety data sheet. A list of the relevant R-phrases referred to under headings (2) and (3) above, the full text of which must be written out in full, must appear under this heading on the SDS. A revised SDS should clearly indicate the information which has been added, deleted or revised (unless this has been indicated elsewhere).

Pharmacists must be able to use the SDS provided by their supplier, who is responsible for the accuracy of the SDS. The pharmacist may wish to make the following 'due diligence' checks: that

- (i) all the safety headings (as detailed above) are present;
- (ii) the SDS is comparable with those for similar products;
- (iii) the sections dealing with safe use/storage, etc, are adequate for the intended application of the pharmacy's customers; and
- (iv) the SDS covers foreseeable eventualities.

Substances restricted to professional users

Certain substances specified in Annex XVII of REACH, in addition to the classification packaging and labelling requirements of dangerous substances and preparations must contain the safety labelling phrase, legible and indelibly marked 'Restricted to professional users'.

The substances to which this restriction applies are those classified as 'carcinogenic', 'mutagenic' or 'toxic to reproduction' and are listed as category 1 or 2. These products are not usually sold through pharmacies and pharmacists should therefore not supply such products for use by the general public.

A SDS and any updated version should be provided free of charge on paper or electronically and be dated, in an official language of the Member State where the substance or preparation is placed on the market. The suppliers must update the SDS as soon as new information on risks and hazards becomes available or there are changes to the authorisation or restrictions imposed. The new, dated version of the information, identified as "Revision: (date)", including the registration number, must be supplied to all persons who have received the substance or preparation within the preceding 12 months. For this reason it would be wise to keep a record of sales of such products.

Chloroform and certain other halogenated hydrocarbons

Chloroform and certain other halogenated hydrocarbons (including carbon tetrachloride) are listed in Annex XVII of REACH, with specific restrictions on their use (and also in Schedule 2 COSHH). Chloroform and carbon tetrachloride must not be used in concentrations equal to or greater than 0.1% by weight, in substances and preparations placed on the market, for sale to the general public and / or in diffusive applications such as in surface cleaning and cleaning of fabrics. In addition to the classification, packaging and labelling requirements of dangerous substances and preparations containing them in concentrations equal to or greater than 0.1% must be legible and indelibly marked with: "For use in industrial installations only". This does not, however, apply to medicinal, veterinary products or cosmetic products as defined in the Directives.

Some Relevant References

- 1 Comprehensive information is available on the websites www.opsi.gov.uk and www.hse.gov.uk This includes:-
 - The Chemicals (Hazard Information and Packaging for Supply Regulations (Northern Ireland) 2009 SR No. 238
www.opsi.gov.uk/sr/sr2009/nisr_20090238_en_1
 - CHIP Approved Classification & Labelling Guide. Guidance on Regulations L131 (6th Edition) (Approved for use in NI with SR No. 238)
www.hse.gov.uk/pubns/books/l131.htm
 - CHIP The Compilation of Safety Data Sheets. Approved Code of Practice L130 (3rd Edition)
www.hse.gov.uk/pubns/books/l130.htm
 - "The Idiots Guide to CHIP (2002)" INDG350
www.hse.gov.uk/pubns/indg350.pdf
 - "Read the Label" INDG352
www.hse.gov.uk/pubns/indg362.pdf
- 2 Guidance on REACH is available on the following:-
www.hse.gov.uk/reach
ukreachca@hse.gsi.gov.uk

8.2 CONTROL OF SUBSTANCES HAZARDOUS TO HEALTH (COSHH)

The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34 (made under The Health and Safety (NI) Order 1978) and as amended, including the Control of Substances Hazardous to Health (Amendment) Regulations (Northern Ireland) 2003 SR No 288 and 2005 SR No 165, "COSHH(NI)", imposes duties on employers to protect employees and other persons who may be exposed to substances hazardous to health. They also impose certain duties on employees concerning their own protection in the workplace.

REACH (the Registration, Evaluation, Authorisation and restriction of Chemicals) will operate alongside COSHH to enable better information on hazards and safe use of chemicals to be passed down the supply chain by chemical manufacturers and importers through improved safety data sheets (SDS).

The COSHH Regulations apply to any place of work including:

- Hospital or community pharmacies
- Pharmaceutical laboratories
- Administrative offices

They cover virtually any substance but are particularly relevant to chemicals, harmful micro-organisms, pesticides and some medicines. The medicines dispensed in a pharmacy are potent chemicals but generally are not harmful to the people in the workplace unless hazards arise in handling (e.g. skin reactions), or in the extemporaneous preparation of products.

'Substances hazardous to health' are those defined in the CHIP Regulations 2009 SR No. 238.

The Regulations require employers to:

- Assess the risk to health from the way a particular substance is used in their own individual workplace and decide on the precautions needed.
- Introduce measures to control the risk to health and to protect people exposed to hazardous substances.
- Ensure that control measures are used, that equipment provided is used correctly and is properly maintained and that procedures are followed.
- Monitor, if necessary, the exposure of workers to hazardous substances and to carry out appropriate health surveillance.
- Inform, instruct and train employees about the risks and precautions that must be taken and prepare plans to deal with accidents, incidents and emergencies. Employees must be aware of labels, data sheets on safety, and instruction manuals available regarding the precautions to be taken when handling the substance.

Risk can be reduced by:

- avoiding use of the substance completely;
- using a safer substance;
- enclosing a particular process;
- extracting by-products;
- improving ventilation or hygiene facilities;
- the use of safer handling procedures;
- use of personal protective equipment (PPE) e.g. gloves, masks, and respirators.

Some COSHH References

- 1 The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003 SR No. 34 www.hseni.gov.uk
- 2 Advice on specific procedures can be obtained from the Health and Safety Executive Northern Ireland, 83, Ladas Drive, Belfast BT6 9FR, Tel: 02890 243249, Fax: 02890 235383 and Helpline: 0800 032 0121. Useful information includes:
 - 'Legal Framework of Health and Safety at work in Northern Ireland' www.hseni.gov.uk/legal_framework.pdf
 - COSHH (NI): A brief guide to the Regulations www.hseni.gov.uk/coshh_booklet.pdf
 - Working with Substances Hazardous to Health - "What you need to know about COSHH" www.hse.gov.uk/pbns/indg136.pdf
 - COSHH Essential Website (www.coshh-essentials.org.uk)
- 3 Additional information and guidance on COSHH is available on www.hse.gov.uk and www.hseni.gov.uk

8.3 BIOCIDES - CITRONELLA OIL AND EUCALYPTUS OIL

Biocidal products are used to control unwanted organisms, such as animals, insects, bacteria, viruses and fungi. They are intended to kill or otherwise exert a controlling effect by chemical or biological means.

Biocidal products are regulated across Europe under the Biocidal Products Directive (BPD)(98/8/EC). In Northern Ireland control of these products is by the Biocidal Products Regulations (Northern Ireland) 2001 SR No 422, as amended by the Biocidal Products (Amendment) Regulations (Northern Ireland) 2010 which came into operation on 19 May 2010 SR No 163.

Citronella oil and Eucalyptus oil (among other active ingredients) have been "identified" under the EU Biocidal Products Directive above, which means that any biocidal products containing these two substances cannot be stored for any purpose (other than export and disposal) within the EU market effective from 1st September 2006.

The HSE website provides further information including a list of biocidal products currently approved under the Control of Pesticides Regulations which are affected by the Biocidal Products Directive 1st September 2006 deadline. Pharmacists are advised to check the list and remove any biocidal products containing citronella oil or eucalyptus oil from sale (<http://www.hse.gov.uk/biocides/liveissues/listbpappcopr.pdf>). Pharmacists should contact the supplier of biocidal products for further advice on affected products.

8.4 WASTE MANAGEMENT

There is considerable legislation and guidance in relation to waste management. The Hazardous Waste Regulations (Northern Ireland) 2005 (SR No 300) and the List of Waste Regulations (Northern Ireland) 2005 (SR No 289) came into force in July 2005 and replaced the Special Waste Regulations (Northern Ireland) 1998 (SR No 289).

The legislation in relation to management of waste is very broad and applies to many different kinds of waste products. The purpose of the legislation is to provide a more effective system of control over special waste from the time of its production to the time of its final destination for disposal or recovery. Waste holders have a duty of care in relation to waste.

Under previous legislation all waste prescription only medicines were classified as special waste but under new regulations only cytotoxic and cytostatic medications will be classified as hazardous waste.

The information in the legislation is both specific and complex and further information in respect of pharmaceuticals should be sought from the Department of the Environment for Northern Ireland and the NI Department of Health, Social Services and Public Safety.

Some sources of information:

www.dhsspsni.gov.uk - including Health Technical Memorandum 07-01 The Safe Management of Healthcare Waste (Northern Ireland)

www.ni-environment.gov.uk

www.rpsgb.org - Guidance on Waste

www.psn.org.uk - PSNC Contract Workbook 2009-10 Appendix 7

Guidance on Pharmaceutical Waste