

# GENERAL LEGAL REQUIREMENTS



**A Guide for Pharmacists  
in Northern Ireland**

**2010 Edition**



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## CONTENTS

### GENERAL LEGAL REQUIREMENTS

Introduction	4
Definitions	5

### **1 MEDICINES FOR HUMAN USE: POM, P, GSL & GENERAL PHARMACY REGULATIONS**

1.1	General Sale List Medicines (GSL)	16
1.2	Pharmacy Medicines (P)	18
1.3	Prescription Only Medicines (POM)	20
1.4	Exemptions to Medicines legislation in the event of a pandemic	35
1.5	Responsible Pharmacist Regulations	37
1.6	Guidance on Collection and Delivery to Rural Areas	39

### **2 MEDICINES FOR HUMAN USE: CONTROLLED DRUGS AND ACCOUNTABLE OFFICER REGULATIONS**

2.1	Controlled Drugs	42
2.2	The Accountable Officer Regulations	59
2.3	SOPs for Controlled Drugs	61

### **3 MEDICINES FOR HUMAN USE: EXEMPTIONS FROM THE CONTROL ON RETAIL SALE**

3.1	Exemptions from the control on Retail Sale	72
3.2	Wholesale Dealing	83

### **4 MEDICINES FOR HUMAN USE: LABELLING, ADVERTISING AND DEVICES**

4.1	Labelling of Medicinal Products	88
4.2	Advertising and Promotion of Medicines	95
4.3	Medical Devices	95
4.4	Clinical Trials	96

4.5	Use of Fluted Bottles	96
4.6	Chloroform - Sale and Supply	98
<b>5</b>	<b>MEDICINES FOR VETERINARY USE</b>	
5.1	Classification of Veterinary Medicinal Products	102
5.2	Prescriptions for Veterinary Medicinal Products	104
5.3	Form of Prescription	104
5.4	Supply of Controlled Drugs 1-3 on Veterinary Prescriptions	104
5.5	Feeding stuffs and Breaking of Bulk	105
5.6	Supply of Veterinary Medicinal Products under the Cascade	105
5.7	Withdrawal Periods	106
5.8	Labelling Requirements	106
5.9	Record Keeping	107
5.10	Annual Audit	108
5.11	Supply of a Sheep Dip	108
5.12	Inspection	108
5.13	Further Information	108
<b>6</b>	<b>NON-MEDICINAL POISONS</b>	
6.1	Poisons schedules	110
6.2	Sales of poisons	111
<b>7</b>	<b>DENATURED ALCOHOL</b>	
7.1	Type of Denatured Alcohol	120
7.2	Application for authority to receive IDA or TSDA	121
7.3	Supply of Denatured Alcohol by authorised users	122
7.4	Conditions of use of IDA and TSDA	123
7.5	Isopropyl Alcohol	127
7.6	Ether (Ethyl ether)	127
7.7	Duty Free Spirits (DFS)	127
<b>8</b>	<b>CHEMICALS</b>	
8.1	Supply requirements	132
8.2	Control of Substances Hazardous to Health	144
8.3	Biocides - Citronella oil and Eucalyptus Oil	145
8.4	Waste Management	146

# 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-medical uses. Several of these substances are included (together with other non-medical 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.

