



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



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

[E417E6037974/58174/ContactdetailsforcompetentauthoritiesineachMemberS.doc](http://www.gdc-uk.org/NR/rdonlyres/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.psn.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>

