



Advicesheet

Prescribing in general practice

B9



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Rules and regulations

- ✓ As a registered dentist, you may supply medicines to your patients provided you comply with the provisions of the Medicines Act 1968. If you provide treatment under the NHS you are also required to follow the requirements of The National Health Service regulations for your NHS patients.

The Medicines Act 1968

The Medicines Act 1968 governs all aspects of medicinal products including the sale or supply of medicines, the exemptions affecting dentists and the labelling requirements for containers and packaging of medicines.

The Act requires medicines that are not on a general sales list to be sold or supplied only from a registered pharmacy under the supervision of a pharmacist. This restriction does not apply to dentists who wish to sell or supply medicines to their patients, but they must comply with rules governing record keeping, labelling and container safety.

A medicinal product is defined as any substance that is manufactured, sold, supplied, imported or exported for various specific purposes including the diagnosis, treatment or prevention of disease and anaesthesia induction. Dental materials, such as cavity liners and filling materials, are not included in the definition.

The NHS regulations

If you provide treatment under the NHS, you may only prescribe medicines for NHS patients using NHS prescription forms (FP10D in England and Wales, GP14 in Scotland and HS47 in Northern Ireland). The medicines that can be prescribed are restricted to those appearing on the Dental Practitioners' Formulary's Secretary of State's List, which appears at the back of the British National Formulary (see below). If the medicine to be prescribed is not included on the Secretary of State's list, the GDS Regulations allow you to provide a private prescription.

Under the GDS terms of service, you should provide your NHS patients, at no extra charge, with all the medicines they require for immediate use before a supply can be otherwise obtained. For any medicines that are required after the appointment, you should provide an NHS prescription form (or a private prescription if the required medicine does not appear on the Secretary of State's List - see below). You should only prescribe the appropriate amounts of drugs necessary for the proper treatment of the patient and avoid 'excessive prescribing'. A registered pharmacist must dispense the medicines requested on the NHS or private prescription; you cannot sell medicines to patients receiving care under the NHS.

Issuing an NHS prescription, will allow you to claim 0.75 units of dental activities (UDAs). You cannot claim UDAs for issuing a private prescription, even to an NHS patient.

'Over-the-counter' medicines

Now that prescription charges are so high, it can sometimes be cheaper for patients to buy medicines over-the-counter rather than to pay the prescription charge (provided that the medicine is not a prescription-only medicine). You should advise the patient to ask the retail price of the medicine before presenting the prescription and to buy it without a prescription if the charge is less than the NHS prescription charge. This does not apply where the medicines are prescription-only (PoM).

Private patients

Where a private patient requires medicines as part of their treatment, you should provide a private prescription, not an NHS prescription. The Medicines Act also allows you to sell or supply medicines to your private patients but you should be aware of the requirements for container safety and labelling, patient information and product liability. There are also specific requirements for prescribing controlled drugs to private patients (see page 9).

'The Medicines Act 1968 governs all aspects of medicinal products.'

GDS requirements

There are no limitations on the number or type of medicines that you can administer or prescribe to a private patient under your care although you have an ethical responsibility to restrict your prescribing to areas in which you are competent. This means that generally dentists should prescribe only medicines that have uses in dentistry. Dentists should not self-prescribe.

There is no statutory requirement for dentists to communicate with a patient's medical practitioner when prescribing in relation to dental treatment. There are, however, occasions when it would be in the patient's interest for you to do so and it is therefore encouraged.

Faxed prescriptions and emergency supplies of prescription-only medicines

A fax of a prescription does not fall within the definition of a legally valid prescription because it is not written in indelible ink and has not been signed by a dentist. A fax can, however, confirm that at the time of receipt a valid prescription is in existence. A pharmacist is not obliged to dispense against a faxed prescription, but where the decision is taken to do so, the pharmacist must be sure of the integrity of the original prescription and that it will be in their possession within a short time.

In an emergency, a pharmacist can dispense medicines without a prescription at the request of a medical practitioner so long as certain conditions are satisfied. This exemption does not apply to dentists, however, and it is likely that a dentist who contacts a pharmacist to request the supply of medicines to a patient without a prescription, will have the request refused (even if the prescription is to be sent to the pharmacist at the earliest opportunity).

Dental Practitioners' Formulary and Secretary of State's List

The Dental Practitioners' Formulary (DPF) is incorporated in the British National Formulary (BNF) and consists of a list of drugs which dental practitioners can prescribe on the NHS. The BNF is sent to all dentists with an NHS contract. It provides useful guidance on prescribing in general, explains the side effects and contraindications of medicines and the procedures for reporting adverse incidents. It also contains a useful section on the management of the more common medical emergencies that may occur in a dental practice, with a suggested list of emergency drugs that you might hold in the practice.

The Secretary of State's List is found at the back of the BNF and specifies the general medicines that you can prescribe, not branded medicines. Prescribing a general medicine allows any suitable product to be dispensed and may prevent delay to the patient and expense to the health service. The Prescription Pricing Division of the NHS Business Services Authority will allow branded medicines to be prescribed in England and Wales (but not Scotland) if they have a generic equivalent on the List.

Supplying /dispensing medicines

Product liability (Consumer Protection Act 1987)

An individual who suffers damage as a result of a defective product is no longer required to prove negligence; it is adequate to demonstrate that the product was defective and that the damage was the result of the defective product. Liability for damage will generally fall upon the producer or importer of the finished product. However, in order to give the claimant a clear route of action, strict liability will attach to any supplier of a product who cannot identify a supplier or producer further up the supply chain.

If you are supplying medicines to your patients, you must ensure that the patient retains a clear route to the manufacturer, importer or supplier as intended by the legislation so that you do not inadvertently find yourself liable for any damage resulting from a defective medicine. You should therefore keep records of suppliers for eleven years; a claim under the Consumer Protection Act can be brought up to ten years after the event.

Liability for damage can also be attributed to the prescribing dentist if the medicine has been prescribed for a condition not listed in the product marketing authorisation or in a

dosage higher than specified in the authorisation. Information on the indications for prescribing medicines and the associated cautions, contraindication and side effects are stated in the individual drug entries in the BNF.

✓ To minimise the risk of liability, you should:

- keep accurate records of the source of supply of all medicines, including dates of supply, batch numbers and expiry dates
- keep accurate records of the supply of all medicines to patients
- retain all records of supply for a period of eleven years
- avoid the unnecessary breaking of manufacturers' original packs
- dilute medicines only in accordance with manufacturers' instructions and avoid diluting medicines wherever possible
- ensure that the manufacturer's name or any cautionary advice is not removed from or obscured by the label
- store all medicines according to the manufacturers' recommendations
- above all, make sure you are adequately insured against professional negligence and product liability claims.

Patient packs and containers

Many medicines are available in the manufacturer's original packs complete with patient information leaflets. Where patient packs are available, the BNF shows the number of dose units in the packs. In particular clinical circumstances, where patient packs need to be split or medicines are provided in bulk dispensing packs, manufacturers will provide additional supplies of patient information leaflets on request.

If you receive your supplies of medicines in bulk and dispense to patients in containers, the containers should be the opaque or dark tinted, child-resistant and re-closable type for solid dose forms. You are allowed to exercise professional judgement in the type of container used - it may be more appropriate to not use child-resistant containers if your patient has limited manual dexterity, for example - but you may then be liable for any injury or harm which might result from not using child-resistant containers.

Containers

Labelling

✓ All medicines have approved labelling and patient information leaflets; dentists supplying medicines to their patients are responsible for ensuring these requirements are met. Containers of dispensed medicines must always be labelled to show:

- the name of the person to whom the medicine is to be administered
- the name and address of the supplying dentist
- the date of dispensing
- the words "keep out of the reach of children" or words of similar meaning
- the phrase "For external use only" if the medicine is a liquid preparation or gel and is for external use only and is not on a general sales list.

You must also add the following information, which can be found in the BNF:

- the name of the product
- the directions for use
- precautions relating to the use of the medicine.

Storage of medicines

Medicines may undergo chemical or physical deteriorations, especially when stored in extremes of temperature, damp or in direct sunlight. Change usually takes the form of reduced therapeutic effectiveness and can, if significant, sometimes have serious implications. For example, incorrect storage of adrenaline may make it inactive, which could have serious implications in the treatment of anaphylactic shock. Medicines should always be stored, therefore, according to the manufacturers' recommendations.

Manufacturers are required to label all medicines products with expiry dates. These dates are based on the results of degradation studies but the predicted half-life is only valid if the medicine is stored as recommended.

Stocks of medicines should be kept to the minimum required for routine needs and foreseeable emergencies. Accurate record keeping and stock checks will identify out of date medicines, which can then be disposed of.

It is good practice to keep all medicines in a locked cupboard. Police crime prevention officers are available and willing to give advice on this matter.

Good prescribing practice

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The following information has been adapted from the BNF 48, © September 2004 (British Medical Association and the Royal Pharmaceutical Association of Great Britain).

Medicines should be prescribed only when they are essential and, in all cases, the benefit of administering the medicine should be considered in relation to the risk involved. This is particularly important during pregnancy where the risk to both mother and foetus must be considered (for further details see Appendix 4 of the BNF, Pregnancy).

Medical histories should be checked and updated at the start of each new course of treatment and, ideally, reviewed at each patient visit. Knowledge of the medicines being taken by a patient will allow you to check for any drug interactions before prescribing or supplying medicines in connection with the patient's dental treatment.

All patients should be told how to dispose of any medicines that are no longer required, for example, by returning them to the community pharmacist. Medicines should not be disposed of via the sewerage system (for environmental reasons), through the domestic waste system or shared with others.

The doses stated in the BNF are intended for general guidance and represent, unless otherwise stated, the usual range of doses that are generally regarded as being suitable for adults. Medicines suitable for use with children will have the recommended range of doses against individual entries in the BNF. Only the minimum amount required to meet the patient's need should be prescribed.

Prescription writing

✓ Prescriptions should:

- be written legibly in permanent ink
- be dated
- state the full name and address of the patient
- state the age and date of birth of the patient (a legal requirement for children under 12 years)
- be signed in ink by the prescribing dentist
- bear the address of the prescribing dentist and an indication of his/her profession – practice headed paper can be used for private prescriptions

✓ When writing prescriptions, the following guidelines should be followed:

- the unnecessary use of decimal points should be avoided:
 - quantities of 1 gram or more should be written as 1g etc
 - quantities of less than 1 gram should be written in milli-grams eg 500mg, not 0.5g
 - quantities of less than 1mg should be written in micrograms eg 100 micrograms and not 0.1mg

- when decimals are unavoidable, a zero should be written in front of the decimal point where there is no other figure eg 0.5ml, not .5ml
- dose and dose frequency should be stated; in the case of preparations to be taken 'as required' a minimum dose interval should be specified
- the names of medicines and preparations should be written clearly and not abbreviated, using approved titles only
- the quantity to be supplied may be stated by indicating the number of days treatment required in the box provided on the NHS forms. In most cases, the exact amount will be supplied. This does not apply to items directed to be used as required - if the dose and frequency are not given the quantity to be supplied needs to be stated

Prescription forms

- ✓ Blank NHS prescription forms are of considerable value and should be stored securely. The stealing and misuse of prescription forms could be minimised by the following precautions:
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- do not leave the prescription pad visible or unattended if called away from the surgery; when not in use, keep prescription forms in a locked drawer within the surgery
 - draw a diagonal line across the blank part of the form under the prescription
 - write the quantity in words and figures when prescribing medicines that might be prone to abuse – this is obligatory for Controlled Drugs
 - alterations are best avoided but if any are made they should be clear and unambiguous; add initials against alterations
 - if prescriptions are to be collected they should be kept in a safe place in a sealed envelope

Prescribing during pregnancy

- ✓ Medicines can have a harmful effect on the foetus at any time during pregnancy. It is important to bear this in mind when prescribing for a woman of childbearing age.
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Medicines should be prescribed in pregnancy only if the expected benefit to the mother is thought to be greater than the risk to the foetus and all medicines should be avoided if possible during the first trimester. Medicines that have been extensively used in pregnancy and appear to be usually safe should be prescribed in preference to new or untried medicines and the smallest effective dose should be used.

Medicines can have a harmful effect on the foetus at any time during pregnancy

During the first trimester, medicines may produce congenital malformations (teratogenesis) and the period of greatest risk is from the third to the eleventh week of pregnancy.

During the second and third trimesters, medicines may affect the growth and functional development of the foetus or have toxic effects on the foetal tissues. Medicines given shortly before term or during labour may have adverse effects on labour or on the neonate after delivery.

Few medicines have been shown conclusively to be teratogenic in humans but no medicine is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

The BNF lists medicines that may have harmful effects in pregnancy and indicates the trimester of risk. It is based on human data but information on animal studies has been included for some newer drugs when its omission might be misleading. It provides independent advice and may not always agree with the product literature. Absence of a drug from the list does not imply safety. Information on medicines and pregnancy is available from the National Teratology Information Service (telephone 0191 232 1525 or visit www.nyrdtc.nhs.uk).

Prescribing during breast feeding

- ✓ The administration of some medicines to nursing mothers may cause toxicity in the infant whereas others have little effect. Some medicines inhibit lactation.
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Toxicity to the infant can occur if the medicine enters the milk in pharmacologically significant quantities. The concentration in the breast milk of some medicines may exceed those in the maternal plasma so that therapeutic doses in the mother may cause toxicity in the infant. Some medicines inhibit the infant's sucking reflex. Medicines in breast milk may, at least theoretically, cause hypersensitivity in the infant even when concentrations are too low for a pharmacological effect.

For many medicines there is insufficient evidence to provide guidance and it is advisable to administer only essential medicines to a mother during breast-feeding. The BNF contains a table of medicines excreted in breast milk. Because of the inadequacy of information on drugs in breast milk this table should be used only as a guide; absence from the table does not imply safety.

Prescribing for the elderly

- ✓ Old people, especially the very old, require special care and consideration when they are being prescribed medicines. Drug therapy of this group is complicated by the physical and mental changes that accompany old age.
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Polypharmacy — elderly patients often receive multiple medicines for their multiple diseases. This greatly increases the risk of medicine interactions as well as adverse reactions and may affect compliance (see Taking Medicines to Best Effect under General Guidance of the BNF, page 1). Moreover, symptoms such as headache, sleeplessness and light-headedness may be associated with social stress (widowhood, loneliness etc) and can lead to further prescribing. The use of medicines in such cases can be a poor substitute for effective social measures and can pose a serious threat from adverse reactions. Whilst unnecessary treatment should be avoided, elderly patients should not be denied effective treatments.

Form of medicine — frail elderly patients may have difficulty swallowing tablets and if left in the mouth, ulceration may develop. They should always be encouraged to take their tablets or capsules with enough fluid and, in some cases, it may be helpful to discuss with the patient the possibility of prescribing a medicine as a liquid (if available).

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- ✓ Always question whether a medicine is indicated at all. If it is:
 - prescribe from a limited range of medicines and be thoroughly familiar with their effects in the elderly
 - dosages should generally be substantially lower than for younger patients and it is common to start with about 50% of the adult dose
 - review repeat prescriptions regularly
 - prescribe medicines with simple treatment regimens ie that are given once or twice daily
 - write full instructions on every prescription so that containers can be properly labelled with full directions. Avoid imprecisions like 'as directed'. Child-resistant containers may be unsuitable.
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Prescribing for children

Children, and particularly neonates, differ from adults in their response to the medicines. Children's doses in the BNF are stated in the individual drug entries as far as possible, except where paediatric use is not recommended, or information is not available, or there are special hazards.

Prescription writing - when writing prescriptions for children, you must include the age for children under 12 years and, preferably, for all children. It is particularly important to state the strengths of capsules or tablets. Liquid preparations are particularly suitable for children but may contain sugar. Sugar-free alternatives may be available.

Many children are able to swallow tablets or capsules and may prefer a solid dose form; involving the child and parents in choosing the formulation is helpful. Parents should be advised not to add any medicines to the infant's feed since the medicine may interact with milk or other liquid in it. Also the ingested dose may be reduced if the child does not drink all the contents. Parents must be warned to keep all medicines out of the reach of children.

Adverse reactions

Any medicine may produce unwanted or unexpected adverse reactions. It is vital that these are reported to the Medicines and Healthcare Products Regulatory Agency (MHRA), CSM Freepost, London SW8 5BR (0800 731 6789). Pre-paid yellow cards for reporting can be found in the BNF.

Detailed information about the Yellow Card Scheme can be found on the MHRA website at www.mhra.gov.uk. A 24-hour Freephone service is also available to all parts of the UK for advice and information on suspected adverse drug reactions (telephone 0800 731 6789). Outside office hours a telephone answering machine will take messages.

Drug information services

Information on any aspect of drug therapy relating to dental treatment can be obtained by telephoning 0151 794 8206. Your local community pharmacist may also be able to provide advice.

The BNF is updated every six months. The most recent edition can be found at www.bnf.org

The Misuse of Drugs Act 1971 controls the use of certain medicines that, if misused, can cause social problems and lead to criminal offences including unlawful production, supply and possession.

The Misuse of Drugs Regulations 2001 detail those who may lawfully produce, supply, prescribe, possess, import and export Controlled Drugs. The Regulations allow dentists to prescribe or administer Controlled Drugs to their patients but only in relation to their dental treatment.

The use of Controlled Drugs for dental treatment provided under the NHS is limited to pethidine and temazepam. Under private arrangements any medicine in schedules 2, 3 or 4 may be prescribed to meet the **dental** needs of the patient.

✓ Under The Misuse of Drugs Regulations 2001, prescriptions for Controlled Drugs in Schedule 2 or 3 (whether NHS or private) must be signed and dated by the prescribing dentist and specify the dentist's address. The prescription must always state in the prescribing dentists own handwriting in ink:

- the name and address of the patient
- in the case of a preparation, the form (eg tablets) and, where appropriate, the strength of the preparation
- the total quantity of the preparation or the number of dosage units to be supplied in both words and figures
- the dose to be taken
- the words 'for dental treatment only'.

It is an offence to issue an incomplete prescription and a pharmacist cannot dispense a Controlled Drug unless all the information required by law is given on the prescription.

Controlled drugs (CDs)

Following the Shipman Inquiry into the safer management of Controlled Drugs, new requirements for **private** prescriptions have been introduced requiring dedicated prescription forms. In England, dentists must apply to their local Primary Care Trust, which in turn informs the Prescription Pricing Division of the NHS Business Services Authority. Identifiable prescription forms (FP10PCD) for Controlled Drugs are then issued to the prescribing dentist containing the unique code of the PCT being used. The cost of producing and issuing the forms will be met by the requesting dentist. Arrangements for Scotland, Wales and Northern Ireland are similar.

Prescriptions for schedule 2, 3 and 4 Controlled Drugs are valid for 28 days and prescriptions should be limited to the quantity necessary for up to 30 days. Where there is a clinical need to prescribe for more than 30 days, the clinical reason for this must be recorded in the patient records. PCTs monitor the prescribing of Controlled Drugs.

✓ If you prescribe a medicine that is likely to cause dependence or misuse, you have three main responsibilities:

- 1 to avoid creating dependence by prescribing such medicines without sufficient reason
- 2 to ensure that the patient does not gradually increase the dose of a medicine (prescribed for good reason) to the point where dependence becomes more likely
- 3 to avoid being an unwitting source of supply for addicts; you should therefore be wary of treating new unknown patients requiring medicines.

The Misuse of Drugs Regulations 2001

The Misuse of Drugs Regulations 2001 define those professionals who are authorised to supply and possess Controlled Drugs and describe the conditions under which this might occur. The Regulations divide Controlled Drugs into five schedules each specifying the requirements governing such activities as import, export, production, supply, possession, prescribing and record keeping which apply to them.

Schedule 1 drugs include cannabis and lysergide. Possession and supply are prohibited except in accordance with Home Office authority.

Schedule 2 drugs include diamorphine (heroin), morphine, pethidine, secobarbital, glutethimide, amphetamine and cocaine and are subject to the full Controlled Drug requirements relating to prescriptions, safe custody (except for secobarbital), the need to keep registers etc (unless exempted in schedule 5).

Schedule 3 drugs include the barbiturates (except for secobarbital, now schedule 2), buprenorphine, diethylpropion, flunitrazepam, mazindol, meprobamate, pentazocine, phentermine and temazepam. They are subject to the special prescription requirements (except for phenobarbitone and temazepam) but not to the safe custody requirements (except for buprenorphine, diethylpropion, flunitrazepam and temazepam) nor to the need to keep registers (although there are requirements for the retention of invoices for two years).

Schedule 4 drugs include 33 benzodiazepines (flunitrazepam and temazepam are now in schedule 3) and pemoline, which are subject to minimal control. Part I includes androgenic and anabolic steroids, clenbuterol, chorionic gonadotrophin (HCG), non-human chorionic gonadotrophin, somatotropin, somatrem and somatropin. Controlled Drug prescription requirements do not apply and schedule 4 Controlled Drugs are not subject to safe custody requirements.

Schedule 5 drugs include those preparations which, because of their strength, are exempt from virtually all Controlled Drug requirements other than retention of invoices for two years.



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