**When and how can dentists supply medicines?**

Prepared by UK Medicines Information ([UKMi](http://www.ukmi.nhs.uk/ukmi/about/default.asp?pageRef=1)) pharmacists for NHS healthcare professionals

Before using this Q&A, read the disclaimer at [*www.sps.nhs.uk/articles/about-ukmi-medicines-qas/*](http://www.sps.nhs.uk/articles/about-ukmi-medicines-qas/)

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**Background**

Lack of awareness of the laws and regulations that apply to the sale and supply of medicines by dentists was highlighted following the introduction of Duraphat toothpaste which, as a Prescription Only Medicine (POM), cannot be sold in the same way as ordinary toothpastes.

Confusion arises because dentists are bound by two sets of rules depending on whether they are providing private or NHS services to an individual patient. Dentists are allowed to mix private and NHS work and can provide and charge for private treatment to patients for whom they also provide NHS treatment (1,2). As such, dentists can issue private prescriptions for NHS patients.

This situation is different to general medical practice where medical practitioners may only issue private prescriptions to NHS patients in certain situations such as for malaria prophylaxis, medicines in travel kits and blacklisted medicines (3,4,5).

This Medicines Q&A aims to explain the legal status of medicines in the UK and when and how they may be supplied by dentists to patients.

**Answer**

This answer is divided into separate questions, followed by an Appendix that puts the legal framework into a practical context.

**What legislation controls how medicines can be sold or supplied and by whom?**

The law outlining who can sell or supply medicines is set down in the *Human Medicines Regulations 2012,* which came into force in August 2012 (6). Dental practitioners treating patients within the NHS General Dental Service or Personal Dental Service must also comply with the terms of their NHS contract and, those treating NHS patients within the Community Dental Service must comply with regulations governing medicines set down by the *National Health Service Act 1977: Primary Care Trust Dental Services Directions 2006* (1,2,7,8).

**How are medicines classified?**

Licensed medicines in the UK fall into three categories:

* **Prescription Only Medicines (POM)**. POMs may only be supplied against a prescription (or ‘patient specific direction’) issued by an appropriate practitioner (doctor, dentist or recognised supplementary/independent prescriber) (9). However, dentists and doctors may sell or supply POMs to private patients (10). POMs can also be supplied under a Patient Group Direction (PGD) (11).
* **Pharmacy (P) medicines**. P medicines may only be supplied from a pharmacy under the supervision of a pharmacist (12). P medicines can also be prescribed by a doctor, dentist or recognised supplementary/independent prescriber (10). Dentists and doctors may sell or supply P medicines to private patients (10). As with POMs, P medicines can be supplied under a PGD (11).
* **General Sales List (GSL) medicines**. GSL medicines may be sold from a variety of retail outlets, including dental practices (13). GSL pack sizes and tablet strengths are often smaller/lower than those available as P medicines from a pharmacy (14,15).

The lists detailing POM, P and GSL medicines are continually amended and updated as new medicines are licensed and established medicines are reclassified, usually from POM to P or from P to GSL. For up to date information on the licensed status of a medicine, see its entry in the online British National Formulary (16).

Some commonly used preparations are regulated as medical devices rather than medicines and are not subject to the *Human Medicines Regulations 2012.* Devices are regulated under the *Medical Devices Regulations 2002* (17). Examples of devices include some saliva replacement products, some chlorhexidine mouthwashes (e.g. Curasept), and some fluoride varnishes (e.g. Fluor Protector S). Devices may be prescribed by dentists, but can only be prescribed at NHS expense if the product is listed in the Dental Practitioners’ Formulary (DPF) or matches a generic product listed in the DPF (16).

**Who can supply medicines under a Patient Group Direction in dental practice?**

PGDs allow the sale, supply or administration of named medicines in defined clinical situations. The individuals who are allowed to supply or administer the medicine are specified ‘registered health professionals’ and include registered dental therapists and registered dental hygienists (11).

A NICE Medicines Practice Guideline provides good practice recommendations for individuals and organisations involved with PGDs and covers the development, authorisation, use and updating of PGDs (18). It reflects medicines legislation, NHS organisational structures and the range of providers of services for NHS patients. NICE has also produced competency frameworks for people developing and/or reviewing and updating PGDs (19), people authorising PGDs (20) and health professionals using PGDs (21).

Further information about use of PGDs can be found in the PGD section of the Specialist Pharmacy Services website at [www.sps.nhs.uk/category/services/guidance-and-governance/patient-group-directions/](http://www.sps.nhs.uk/category/services/guidance-and-governance/patient-group-directions/) .

**What do the *Human Medicines Regulations 2012* say about supplying medicines?**

The *Human Medicines Regulations 2012* (6)govern all aspects relating to medicinal products for human use, including licensing, manufacture, sale and supply, plus labelling requirements for containers and packaging of medicines.

A medicinal product is defined as any substance or combination of substances (22):

* used for preventing, diagnosing or treating disease in human beings, or
* altering physiological function by a pharmacological, immunological or metabolic action.

Dental materials, such as cavity liners and filling materials do not meet this definition; they are registered as medical devices and carry a CE mark (19).

The *Regulations* require that medicines that are not GSL (i.e. POM and P medicines) must be sold or supplied only from a registered pharmacy under the supervision of a pharmacist (12). Dentists (and doctors) are specifically exempt from this requirement (10); dentists may sell or supply medicines to their patients, but they must comply with rules governing record keeping, labelling and container safety (23).

Therefore, under the *Human Medicines Regulations 2012,* dentists are allowed to supply POM and P medicines (e.g. a course of antibiotics, analgesics, fluoride tablets) directly to their patients as long as requirements for labelling and packaging are complied with. This applies only to private treatment; for NHS treatment further restrictions apply.

**What restrictions are imposed on dentists by their NHS terms of service?**

The General Dental Services (24) and Personal Dental Services (25) contracts, and Community Dental Service (*National Health Service Act 1977: Primary Care Trust Dental Services Directions 2006*) regulations (26), include almost identical wording to describe prescribing and supply of medicines:

**Supply of drugs**

(1) A prescriber may supply to a patient drugs, medicines or appliances from the list approved by the Secretary of State (i) as are required for immediate use before the issue of a prescription for such drugs, medicines or appliances in accordance with direction below (‘Issue of prescription forms’).

(2) A prescriber may personally administer to a patient any drug or medicine required for the treatment of that patient.

**Issue of prescription forms**

(1) A prescriber shall order drugs, medicines or appliances from the list approved by the Secretary of State (i) (other than those supplied in accordance with the direction above ‘supply of drugs’) as are needed for the treatment of any patient to whom they are providing services by issuing to the patient a prescription form.

(2) The prescription form shall—

(a) be signed by the prescriber; and

(b) be issued separately to each patient to whom the clinic or contractor is providing services.

(i) The appropriate Secretaries of State (England, Scotland, Wales) approve the list of medicines prescribable on an NHS dental prescription; the list is known as the Dental Practitioners’ Formulary (DPF) and is included in the British National Formulary.

These directions do not allow for the supply of medicines to patients other than on a prescription, unless medicines are required for immediate use before the issue of a prescription. The quantity considered necessary for immediate use is open to interpretation. It could cover enough medication for use in an emergency e.g. antibiotics or analgesics to enable the patient to start treatment immediately if pharmacies are likely to be closed. However, the implication is that a prescription would be issued for the duration of the course. Indeed, in the broader NHS, the supply of medicines ‘out-of-hours’ has been addressed and comprehensive guidance has been issued. A basic requirement of this guidance is that a complete course appropriate to the presenting condition should be supplied, i.e. the amount that would have been prescribed during normal hours (27,28). Any medicines issued in this way would need to be labelled appropriately.

**How should dentists label medicines?**

POMs issued by dentists in any circumstance (i.e. to a patient treated privately or within the NHS ‘for immediate use' must be labelled as dispensed medicines to comply with the *Human Medicines Regulations 2012* (23,28). The following need to be included on the label:

* the name of the person to whom the medicine is to be administered,
* the name and address of the supplying dentist,
* the date on which the medicine is sold or supplied,
* one or more of the following, as considered appropriate by the dentist (i.e. when not detailed on the manufacturer’s packaging or when the medicine is dispensed from a bulk container):
  + the name of the product or its common name,
  + directions for use,
  + precautions relating to use of the medicine.

P and GSL medicines do not require labelling if they are issued in a manufacturer’s original pack which complies with Schedule 24 of the *Human Medicines Regulations 2012* (30).

All solid dose and all oral and external liquid preparations must be dispensed in a reclosable child-resistant container unless (31):

* the medicine is in an original pack or patient pack such as to make this inadvisable,
* the patient will have difficulty in opening a child-resistant container,
* a specific request is made that the product shall not be dispensed in a child-resistant container,
* no suitable child-resistant container exists for a particular liquid preparation.

In addition to packaging and labelling requirements, all medicines dispensed to patients must be accompanied by a Patient Information Leaflet (PIL) (32,33). All manufacturer original packs will contain a PIL.

**Can GSL medicines be sold, supplied or administered by all members of the dental practice team?**

The *Human Medicines Regulations 2012* do not specify who can supply or administer a GSL medicine. Provided the supply takes place from lockable premises and the medicines are pre-packed and fully labelled, the supply can be made by any member of the dental team.

A prescription or PGD is not required to supply pre-packed GSL medicines. It is good practice to have a local policy or procedure for staff to follow (34).

**Summary**

* The *Human Medicines Regulations 2012* allow dentists to supply any medicine directly to a patient receiving private treatment.
* Current NHS terms of service do not allow dentists to supply medicines directly to NHS patients, except for medicines for immediate use before the issue of a prescription, and General Sales List (GSL) medicines.
* The *Human Medicines Regulations 2012* enable registered dental therapists and registered dental hygienists to sell, supply and administer specified medicines under a Patient Group Direction.
* Prescription Only Medicines issued directly to a patient must be labelled in accordance with the *Human Medicines Regulations 2012*.
* GSL medicines can be supplied by all members of the dental team; staff should follow simple protocols.
* An Appendix to this Medicines Q&A helps to put the legal framework into a practical context.

**Limitations**

* This document aims to be an accurate reflection of current medicines legislation interpreted for dental practice. It is not exhaustive and some scenarios may not have been addressed.
* The document is for general guidance only and has been prepared by pharmacists with no legal training. If more in-depth advice is required, please contact a legal professional/dental defence organisation.

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**Search strategy**

The following organisations and resources were used to prepare this or previous versions of this Q&A:

* British Dental Association
* Dale and Appelbe’s Pharmacy Law and Ethics 9th Edition
* Department of Health
* General Dental Council
* Medicines and Healthcare products Regulatory Agency
* Medicines, Ethics and Practice
* NHS Employers
* NICE
* Royal Pharmaceutical Society of Great Britain
* [www.legislation.gov.uk/](http://www.legislation.gov.uk/)
* [www.evidence.nhs.uk](http://www.evidence.nhs.uk)
* [www.sps.nhs.uk](http://www.sps.nhs.uk)

**Appendix**

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| **You can tell what the legal classification of a medicine is from its packaging** | |
| **POM** | Manufacturer original packs will be marked with the initials PoM within a box. They will also be marked with their Product Licence number (PL xxxxx/xxxx).  **PoM** |
| **P** | Manufacturer original packs will be marked with the initial P within a box. They will also be marked with their Product Licence number (PL xxxxx/xxxx).  **P** |
| **GSL** | GSL medicines do not have a specific marking, but will be marked with their Product Licence number (PL xxxxx/xxxx). |
| **Medical devices** | [http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/downloads/ce-marking-logo.jpg](http://www.google.co.uk/url?sa=i&source=imgres&cd=&cad=rja&uact=8&ved=0CAwQjRwwAA&url=http://ec.europa.eu/enterprise/policies/single-market-goods/cemarking/downloads/index_en.htm&ei=VdNQVa2XOMasswGz5YGwBg&psig=AFQjCNGrrLftb1mjTyKb-RBaLao9kpEfkg&ust=1431446741994452)Medical devices are not medicines. Their packaging will display the CE mark. |
| **Examples of medicines commonly used in dentistry** | |
| **POM** | All oral antibiotics  Aciclovir tablets and suspension  Betamethasone soluble tablets  Duraphat toothpaste (both strengths)  Duraphat Varnish (Note: some other fluoride varnish brands are medical devices)  All local anaesthetic injections  Diclofenac tablets (25mg, 50mg and 75mg strengths)  Nystatin oral suspension |
| **P** | Aciclovir cream 2g pack size (Note: some brands are GSL)  Chlorhexidine dental gel (e.g. Corsodyl Dental Gel)  Difflam Oral Rinse/Spray  Fluoride drops  Fluoride tablets  Hydrocortisone muco-adhesive buccal tablets  Ibuprofen packs contains more than 16 tablets or capsules  Miconazole oral gel 15g pack size (Note: POM for patients taking warfarin)  Paracetamol packs containing 17 to 32 tablets or capsules |
| **GSL** | Aciclovir cream 2g pack size (Note: some brands are P medicines)  Chlorhexidine mouthwash (e.g. Corsodyl Mouthwash)  Chlorhexidine oral spray  Fluoride mouthwash 0.05% (e.g. Colgate FluoriGuard, En-De-Kay Mouthrinse)  Ibuprofen packs containing up to 16 tablets or capsules  Paracetamol packs containing up to 16 tablets or capsules  Peroxyl Mouthwash |
| **Sale or supply of Duraphat toothpaste directly to patients** | |
| **NHS patients** | Not allowed.  Duraphat toothpaste is a POM and a prescription must be issued by a dentist except when supplied under a PGD by a dental hygienist or dental therapist (see below).  It must be supplied with a PIL and be labelled with the following:   * name of the person to whom the medicine is to be administered * name and address of the supplying dentist * date of supply * directions for use, if these differ from those on the packaging / PIL. |
| **Private patients** | Allowed.  Duraphat toothpaste may be supplied directly to private patients by dentists or following a documented recommendation (patient specific direction) from the dentist. It must be supplied with a PIL and be labelled with the following:   * 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 * directions for use, if these differ from those on the packaging / PIL. |
| **Patients under a PGD** | Allowed.  In both NHS and private dental practice, Duraphat toothpaste may be issued by a registered dental hygienist or registered dental therapist (but not an NHS dentist) if a valid PGD has been set up. |
| **Sale or supply of Corsodyl Dental Gel directly to patients** | |
| **NHS patients** | Not allowed.  Corsodyl Dental Gel is a P medicine and a prescription must be issued by a dentist |
| **Private patients** | Allowed.  Corsodyl Dental Gel may be supplied directly to private patients by dentists or following a documented recommendation from the dentist. No additional labelling is required. |
| **Patients under a PGD** | Allowed.  In both NHS and private dental practice, Corsodyl Dental Gel may be issued by a registered dental hygienist or registered dental therapist (but not an NHS dentist) if a valid PGD has been set up. |
| **Sale of chlorhexidine mouthwash directly to patients** | |
| **NHS patients AND**  **Private patients** | Allowed.  Chlorhexidine mouthwash is licensed as either a GSL medicine or medical device and can be sold to NHS and private patients without first seeing the dentist and without the requirement for further labelling. |
| **Can dentists prescribe any item in the BNF?** | |
| **NHS patients** | No. On an NHS prescription form (FP10D, WP10D, GP14) dentists are restricted to prescribing items from the list approved by the Secretaries of State. The list is called the Dental Practitioners’ Formulary (DPF).  BUT if a medicine is required that is not on the DPF list, the dentist can legally prescribe it on a private prescription.  (Note: POM or P medicines must NOT be supplied directly to the patient, unless the medicine is required for immediate use before the issue of a prescription). |
| **Private patients** | Yes. Legally dentists can prescribe any medicine. Ethically, however, dentists should restrict prescribing to areas in which they are competent (i.e. medicines that are used in dentistry). |
| **Can NHS prescription forms be issued to private patients?** | |
|  | No. If a patient is being treated as a private patient they must be given a private prescription, even if the medicine required is on the DPF list. |
| **Can dentists use medicines within the surgery that are not on the DPF list?** | |
|  | Yes. Dentists can use any medicine within the surgery as long as they are competent in its use and it has a use in dentistry. For example, they may use any appropriate analgesic perioperatively.  Note: Local anaesthetic cartridges are examples of medicines that are not on the DPF list. |
| **Emergency supply of analgesics or antibiotics to patients** | |
| **NHS patients** | In an emergency outside of normal working hours the patient may be unable to obtain the required prescribed medicine from a pharmacy. In this case an emergency supply may be issued for the complete course.  Medicines supplied in an emergency must be suitably packaged in a child- resistant container, be accompanied by a PIL and be labelled with the following:   * name of the person to whom the medicine is to be administered * name and address of the supplying dentist * date of supply   Plus the following if not already included on the medicine pack:   * name of the product or its common name * directions for use * precautions relating to use of the medicine. |
| **Private patients** | Private patients may either be issued with a private prescription or supplied with the whole course of the required medicine.  Medicines must be suitably packaged in a child-resistant container, be accompanied by a PIL and be labelled with the following:   * name of the person to whom the medicine is to be administered * name and address of the supplying dentist * date of dispensing   Plus the following if not already included on the medicine pack:   * name of the product or its common name * directions for use * precautions relating to use of the medicine. |