When can dentists supply medicines?

Prepared by UK Medicines Information (UKMi) pharmacists for NHS healthcare professionals

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Summary

♦ The Human Medicines Regulations 2012 allow dentists to supply any medicine (PoM or P) directly to a patient but this only applies if patients are receiving private treatment.
♦ The current NHS terms of service do not allow dentists to supply any medicines, other than those for immediate use before the issue of a prescription, directly to a patient.
♦ The NHS regulations as set out in the NHS Act 2006 do not allow dentists providing an NHS service to provide any form of pharmaceutical service.
♦ Prescription only Medicines issued by a dentist directly to a patient must be labelled as directed by the Human Medicines Regulations 2012.
♦ The Human Medicines Regulations 2012 enable dental therapists and dental hygienists to sell, supply and administer specified medicines under a Patient Group Direction (PGD).
♦ The supply and administration of General Sales List (GSL) medicines is not regulated by the Human Medicines Regulations 2012 but for clinical governance purposes simple protocols are recommended.
♦ The Appendix helps to put the legal framework into a practical context.

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. This situation is different to general medical practice where medical practitioners cannot* provide private medical services to their registered NHS patients.

*except where specifically permitted in their individual contract or laid down in their terms of service. Exemptions include travel vaccinations, malaria prophylaxis and blacklisted medicines.

This 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

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 [1]. Dental practitioners treating patients within the NHS General Dental Service or Personal Dental Service must also comply with the terms of their NHS contracts 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 [2].

How are medicines classified?

Licensed medicines in the UK fall into one of three categories;
♦ Prescription only Medicine (PoM). PoMs may only be supplied against a prescription (patient specific direction) issued by an appropriate practitioner (doctor, dentist or recognised supplementary/independent prescriber). However, dentists and doctors may sell or supply PoMs
Pharmacy medicine (P). Pharmacy medicines may only be supplied from a pharmacy under the supervision of a pharmacist. Pharmacy medicines can also be prescribed by a doctor, dentist or recognised supplementary/independent prescriber. However, dentists and doctors may sell or supply P medicines to private patients (see below). As with PoMs, P medicines can be supplied under a Patient Group Direction by dental hygienists and dental therapists (for further information see below).

General Sales List medicine (GSL). GSL medicines may be sold from a variety of retail outlets, including dental practices. GSL pack sizes and tablet strengths are often smaller/lower than when available as a P medicine available from a pharmacy.

The lists detailing PoM/P/GSL medicines are constantly being amended and updated as new medicines are licensed and established medicines are reclassified from PoM to P and from P to GSL.

Some commonly used preparations are licensed as medical devices rather than medicines and are not subject to the Human Medicines Regulations 2012. Examples include some chlorhexidine mouthwashes (e.g. Curasept), Duraphat Daily Mouthwash, Colgate FluoriGard Alcohol Free Mouth Rinse, and some fluoride varnishes (e.g. Sodium Fluoride Varnish (Sultan Healthcare), Fluor Protector S (Ivoclar Vivadent), Clinpro White 5% Sodium Fluoride Varnish (3M ESPE)).

Patient Group Directions
Patient Group Directions (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 dental therapists and dental hygienists [3].

A NICE Medicines Practice Guideline [4] provides good practice recommendations for individuals and organisations involved with PGDs and addresses the need for developing, authorising, using and updating PGDs. It reflects new medicines legislation, new NHS organisational structures and the range of providers of services for NHS patients. NICE have also produced competency frameworks for people developing and/or reviewing and updating PGDs [5], people authorising PGDs [6] and health professionals using PGDs [7].

Further information about use of PGDs in dental practice can be found in the UKMi Medicines Q&A Patient Group Directions in dental practice [8].

What do the Human Medicines Regulations 2012 say?
The Human Medicines Regulations 2012 [1] governs all aspects of medicinal products including the licensing, sale and supply of medicines, plus the labelling requirements for containers and packaging of medicines.

A medicinal product is defined as any substance or combination of substances [9]:
- 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 are not included in the definition; they are registered as medical devices and carry a CE mark.

The Regulations require that medicines that are not on the General Sales List must be sold or supplied only from a registered pharmacy under the supervision of a pharmacist. 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 (see below).

The Human Medicines Regulations 2012 dentists are allowed to supply prescription only and pharmacy 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 only applies to private treatment, for NHS treatment further restrictions apply (see below).
What are the restrictions imposed on dentists by their NHS terms of service?
The General Dental Services [11] and Personal Dental Services [12] contracts and Community Dental Service (National Health Service Act 1977: Primary Care Trust Dental Services Directions 2006) regulations [2] all include almost identical wording to describe the prescribing and supply of medicines:

Supply of drugs
(1) A prescriber may supply to a patient such listed drugs, medicines or appliances (from the list approved by the Secretary of State [a]) 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 listed (as above) drugs, medicines or appliances (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/contractor is providing services.

[a] The appropriate Secretaries of State (England, Scotland, Wales) approve the medicines prescribable on an NHS prescription, known as the Dental Practitioners’ Formulary.

These directions do not allow for the supply of medicines to patients other than on a prescription, the exception being medicines required for immediate use before the issue of a prescription. This 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. The implication is that a prescription would be issued for the remainder of the course. However, in the broader NHS the supply of medicines ‘out-of-hours’ has been addressed and comprehensive guidance has been issued [13]. A basic requirement of this guidance is that a full course appropriate to the presenting condition should be supplied i.e. the amount that would otherwise have been prescribed. Any medicines issued in this way would need to be labelled appropriately (see below).

In addition to the regulations specifically stated in the dental contracts, The NHS Act 2006 (Part 7 Pharmaceutical services and local pharmaceutical services, Chapter 1 Provision of pharmaceutical services) [14] states:

132 - Persons authorised to provide pharmaceutical services
(1) Except as may be provided for by or under regulations, no arrangements may be made by a Primary Care Trust with a medical practitioner or dental practitioner under which he is required or agrees to provide pharmaceutical services to any person to whom he is rendering primary medical services or primary dental services.
(2) Except as may be provided for by or under regulations, no arrangements for the dispensing of medicines may be made under this Chapter with persons other than persons who—
(a) are registered pharmacists or persons lawfully conducting a retail pharmacy business in accordance with section 69 of the Medicines Act 1968 (c. 67), and
(b) undertake that all medicines supplied by them under the arrangements will be dispensed either by or under the supervision of a registered pharmacist.

This means that dentists providing NHS services are not allowed to provide pharmaceutical services (supply medicines) except in circumstances set out in their NHS contracts – they may only supply medicines for emergency use and cannot routinely supply medicines to their patients or to individuals not registered as their patients.
How should dentists label medicines?
Prescription only Medicines issued by dentists in any circumstance (to a patient treated privately or within the NHS 'for immediate use' see above) must be labelled as dispensed medicines as required by the Human Medicines Regulations 2012 [15,16]. 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 when considered appropriate by the dentist (i.e. when not detailed on the manufacturers packaging)
  - the name of the product
  - the directions for use
  - precautions relating to the use of the medicine.

Pharmacy and GSL medicines do not require additional labelling if they are issued in a manufacturer’s original pack which complies with Schedule 24 of the Human Medicines Regulations 2012 [17].

All solid dose and all oral and external liquid preparations should be dispensed in a reclosable child-resistant container unless [18]:

- 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 the required packaging and labelling all medicines dispensed to patients must be accompanied by a Patient Information Leaflet (PIL) [19,20]. Manufacturers’ original packs all include a PIL.

Can GSL medicines be sold, supplied or administered by any member of the dental practice team?
Provided that the supply takes place from lockable premises and the medicines are pre-packed and fully labelled, the Human Medicines Regulations 2012 do not specify who can supply or administer a GSL medicine. Therefore, neither a prescription nor a PGD is required. However, for organisations supplying GSL medicines, good practice (from a clinical governance perspective) is to use a simple protocol; simple protocols are not part of medicines legislation [4].

The Appendix addresses a number of questions to help put this 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 health professional/dental defence organisation.

References


Quality Assurance

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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
Dental Defence Union
Department of Health
General Dental Council
Medicines and Healthcare products Regulatory Agency
Medicines, Ethics and Practice
National Prescribing Centre
NICE
Royal Pharmaceutical Society of Great Britain
www.legislation.gov.uk/
www.evidence.nhs.uk
www.ukmi.nhs.uk
**Appendix**

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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| **Can you tell what the legal classification of a medicine is from its packaging?** | **Prescription only medicines**  
Manufacturers' original packs of prescription only medicines must always be marked with the initials PoM within a box.  
**Pharmacy medicines**  
Manufacturers original packs of pharmacy medicines must always be marked with the initial P within a box.  
**General sales list medicines**  
There is no marking for a GSL medicine but all medicines will be marked with their Product Licence number (PL xxxxx/xxxx).  
**Medical devices**  
Not medicines but packaging must include the CE mark.  |
| **What are the legal classifications of medicines commonly used in dentistry?** | **Prescription only medicines**  
All oral antibiotics  
Aciclovir tablets and suspension  
Betamethasone soluble tablets  
Duraphat toothpaste (both strengths)  
Duraphat Varnish (N.B. other fluoride varnish brands may be medical devices)  
All dental local anaesthetics injections  
Diclofenac tablets (25mg, 50mg and 75mg)  
**Pharmacy medicines**  
Aciclovir cream (2g, some brands GSL)  
Chlorhexidine dental gel (e.g. Corosyld dental gel)  
Diffiam mouthwash/spray  
Fluoride drops  
Fluoride tablets  
Hydrocortisone muco-adhesive buccal tablets  
Ibuprofen (>16 tab/cap packs)  
Miconazole oral gel  
Paracetamol (up to 32 tab/cap packs)  
**General sales list medicines**  
Aciclovir cream (2g, not all brands)  
Chlorhexidine mouthwash (e.g. Corosyld)  
Chlorhexidine oral spray  
Fluoride mouthwash 0.05% (e.g. Colgate FluoriGuard, En-De-Kay Mouthrinse)  
Ibuprofen (up to 16 tab/cap packs)  
Paracetamol (up to 16 tab/cap packs)  
Peroxyl mouthwash  |
| **Can Duraphat toothpaste be sold or supplied directly to:** | **NHS patients**  
No. Duraphat toothpaste is a prescription only medicine (POM) and a prescription must be issued except when supplied under a PGD (see below)  
**Private patients**  
Yes. Duraphat toothpaste may be supplied directly to private patients BUT only after a documented recommendation from the dentist and it must be labelled with the following details  
◆ 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  
**Patients under a Patient Group Direction (PGD)**  
Yes. In both NHS and private dental practice Duraphat toothpaste may be issued by a hygienist or therapist (not dentists) if a valid PGD has been set up.  |
| **Can Corsodyl gel be sold or supplied directly to:** | **NHS patients**  
Yes. Chlorhexidine mouthwash is licensed as either a General Sales List (GSL) medicine or Medical Device and can be sold to any patient without first seeing the dentist and without the requirement for further labelling.  
**Private patients**  
Yes. Chlorhexidine mouthwash is licensed as either a General Sales List (GSL) medicine or Medical Device and can be sold to any patient without first seeing the dentist and without the requirement for further labelling.  |
| **Can dentists prescribe any item in the BNF to:** | **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 (Dental Practitioners’ Formulary (DPF) – see the current BNF).  
**Private patients**  
Yes. Chlorhexidine mouthwash is licensed as either a General Sales List (GSL) medicine or Medical Device and can be sold to any patient without first seeing the dentist and without the requirement for further labelling.  |
<table>
<thead>
<tr>
<th><strong>Q&amp;A 193.4 When can dentists supply medicines?</strong></th>
<th><strong>May 2015</strong></th>
<th><strong>Available at</strong> <a href="http://www.sps.nhs.uk">www.sps.nhs.uk</a></th>
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<tr>
<td><strong>BUT if a medicine not on the list is required, the dentist is allowed to prescribe it on a private prescription (the medicine must NOT be supplied directly to the patient).</strong></td>
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<td><strong>Private patients</strong></td>
<td>Yes. Legally dentists can prescribe any medicine on a private prescription however, ethically dentists should restrict prescribing to areas in which they are competent (i.e. medicines that are used in dentistry).</td>
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<td><strong>Can NHS prescription forms be issued to private patients?</strong></td>
<td>No. If a patient is being treated as a private patient they must always be given a private prescription even if the medicine required is on the DPF list.</td>
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<td><strong>Can dentists use medicines within the surgery that are not on the DPF list?</strong></td>
<td>Dentists can use any medicine within the surgery as long as they are competent in its use and that it has a use in dentistry, e.g. any analgesic may be given to a patient perioperatively. N.B. all local anaesthetic cartridges are PoMs but are not on the DPF list.</td>
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<td><strong>If an emergency supply of analgesics or antibiotics is required how should they be supplied?</strong></td>
<td><strong>NHS patients</strong> In an emergency out of hours (e.g. middle of the night) it may be impossible for the patient to obtain the required prescribed medicine from a pharmacy. In this case an emergency supply may be issued. Medicines supplied in an emergency must be supplied as a dispensed medicine and must be suitably packaged in a child resistant container, be accompanied by a patient information leaflet 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 Plus the following if not included on the pack issued (manufacturers’ original packs may include some (PoMs) or all (P) of these): ♦ the name of the product ♦ the directions for use ♦ precautions relating to the use of the medicine.</td>
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<td><strong>Private patients</strong> Private patients may either be issued with a private prescription or supplied with the whole course of the required medicine. The medicine must be supplied as a dispensed medicine and must be suitably packaged in a child resistant container, be accompanied by a patient information leaflet 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 Plus the following if not included on the pack issued (manufacturers’ original packs may include some (PoMs) or all (P) of these): ♦ the name of the product ♦ the directions for use ♦ precautions relating to the use of the medicine.</td>
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