

Practice Guidance for Dental Hygienists and Dental Therapists for the supply and administration of medicines under Exemptions

DRAFT

This is not a live document and requires legislative change before it can have effect



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Contents

Introduction	3
Supply and administration of medicines by dental hygienists and dental therapists	5
Guidance on supply and administration of medicines under exemptions by dental hygienists and dental therapists	7
Before using exemptions	7
1. Authorised to use exemptions	7
2. Accountability.....	8
Patient consultation.....	8
3. Assessment.....	8
4. Consent.....	9
5. Communication	10
6. Record keeping.....	11
7. Information given to patients when medicines are supplied	12
8. Adverse events	12
Using medicines responsibly.....	13
9. Evidence based use of medicines in the patient’s best interests.....	13
10.Delegation	14
11.Administration and supply of medicines on the request of others	14
12.Reviewing Medications	14
13.Children	14
14.Complementary, herbal and homeopathic products.....	15
Storage, transport and disposal of medicines	15
15.Storage	15
16.Transportation.....	15
17.Disposal	16
18.Clinical Governance	16
19.Continuing Professional Development.....	16

20. Peer support	16
21. Conflict of interest	17
Glossary	18
APPENDIX	19
Key Legislation & Terminology	19
Supply and Administration Frameworks	19
22. Patient specific directions (PSDs)	19
23. Patient group directions (PGDs)	20
24. Exemptions	21
Categories of Medicines	22
25. General Sales List Medicines (GSL)	22
26. Pharmacy sale medicines (P)	22
27. Prescription Only Medicines (POMs)	22
28. Acknowledgements	25

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Introduction

This is a draft document and will not apply unless legislation is changed to allow dental hygienists and dental therapists to utilise exemptions within schedule 17 of the Human Medicines regulations 2012 to supply and administer certain medicines.

It aims to provide information which should underpin the decision-making and actions of dental hygienists and therapists who have successfully completed additional education to use exemptions within Human Medicines Regulations 2012.

The document is 'guidance'. 'Guidance' is information which a dental hygienist and dental therapist has a duty to consider and is expected to take into account as part of their decision-making process. A dental hygienist and dental therapist is expected to follow the guidance, to use professional judgment, demonstrate insight at all times and be able to justify any decision that is not in line with the guidance.

The document provides advice on the behaviours and conduct expected of dental hygienists and dental therapists who are qualified to use exemptions. Throughout this document, the use of the word 'must' indicates a legal and/or regulatory requirement and describes a mandatory action and/or behaviour. The use of the word 'should' indicates behaviours and/or actions that would be expected to occur in all normal circumstances. 'Should' is also used when we are providing an explanation of how you will meet the overriding duty. Each section of this guidance carries equal weight, and the document is not ordered in any priority.

If a dental hygienist or dental therapist using exemptions from medicines legislation deviates from the advice given in this document, the clinical judgement for so doing must be carefully recorded. You should comply with this practice guidance, other guidance issued by the British Society of Dental Hygiene and Therapy (BSDHT) and British Association of Dental Therapists (BADT) and with any statutory requirements applicable to the use of exemptions in practice. Failure to do so may put your GDC registration at risk if concerns are raised about your fitness to practice. If a complaint is made against you, a GDC fitness-to-practice committee may take account of this document and those to which it makes reference. A dental hygienist or dental therapist accessing exemptions will be expected to justify any decision to act outside the terms of this guidance. Specifically, if the dental hygienist or dental therapist undertakes a course of action not recommended by this guidance there

must be sound justifications for doing so. This guidance document should be read in conjunction with the GDC Standards for the Dental Team¹.

The advice in this document applies to all sectors of health and social care provision in the United Kingdom where medicines use by dental therapists and dental hygienists occurs.

At the current time the supply and administration of medicines under exemptions is not permitted outside of the UK and therefore a dental hygienist or dental therapist permitted to use exemptions cannot perform this activity outside of UK jurisdiction.

¹ General Dental Council Standards for the Dental Team 2013

Supply and administration of medicines by dental hygienists and dental therapists

The purpose of the use of exemptions by dental hygienists and dental therapists is to support and enhance the delivery of care to patients by expanding the current mechanisms by which they deliver care related to oral disease, maintenance of the dentition and prevention of further dental disease.

Dental hygienists and dental therapists work within a scope of practice developed by the GDC and can carry out certain procedures if they are adequately trained, competent and indemnified. The use of exemptions is an option for certain clinicians and is not mandatory. Those registrants who prefer to continue to provide treatment by using patient specific directions (PSDs) or patient group directions (PGDs) may do so. Those who choose to utilise this mechanism are required to gain entry to and successfully complete an education programme, before using exemptions.

Eligibility to access education programmes

All entrants to an exemptions training programme would need to meet the following requirements:

- a) be registered with the GDC as a dental hygienist or dental therapist
- b) be practising in an environment where there is an identified need for the individual to regularly use exemptions in legislation
- c) be able to demonstrate that medicines and clinical governance arrangements are in place to support safe and effective use of exemptions.
- d) be able to demonstrate support from an employer or, if self-employed, be able to demonstrate an identified need for the use of exemptions and that all appropriate governance arrangements are in place.
- e) be able to demonstrate how they reflect on their own performance and take responsibility for their own CPD
- f) in England and Wales, provide evidence of a Disclosure and Barring Service (DBS) or in Northern Ireland, an Access NI check within the last three years or, in Scotland, be a current member of the Protection of Vulnerable Groups (PVG) scheme

Dental hygienists and dental therapists will need to ensure they have adequate indemnity arrangement in place to cover the use of exemptions for their practice.

The list of medicines

The medicines in the list below are medicines regularly used by dental hygienists and dental therapists and can be supplied and administered under exemptions within schedule 17 of the Human Medicines regulations 2012

Medicines for administration only:

- lidocaine with adrenaline
- articaine hydrochloride with adrenaline
- mepivacaine hydrochloride
- prilocaine with felypressin
- lidocaine and prilocaine (periodontal gel)
- sodium fluoride (varnish)
- minocycline periodontal gel

Medicines for supply:

- sodium fluoride (dental paste)
- nystatin oral suspension

In addition, the supply of all general sales list (GSL) and pharmacy (P) medicines, within the dental hygienists and therapists' scope of practice.

Guidance on supply and administration of medicines under exemptions by dental hygienists and dental therapists

This section provides advice and guidance on the supply and administration of medicines with exemptions. Having achieved the competencies for this, dental hygienists and dental therapists should follow this advice in their practice.

The advice and guidance provided in this document applies to all settings in which a dental hygienist or dental therapist may use exemptions – within the NHS, hospital, general dental practice, community dental service, private practice, prison service, armed forces or any other clinic, environment or situation.

The BSDHT and BADT consider it good practice, where dental hygienists and dental therapists are employed, that the employing organisation must know and have agreed with the dental hygienist and dental therapist which of the medicines on the list can be supplied/administered using exemptions. This is overarching guidance for the use of exemptions by dental hygienists and dental therapists; they are also expected to take into consideration local and organisational policies and procedures.

Before using exemptions

1. Authorised to use exemptions

- 1.1 You must only use exemptions once you have successfully completed an education programme, qualified and added to the Register held by FGDP(UK) to use exemptions.
- 1.2 You must only use exemptions for the identified medicines listed within schedule 17 of the Human Medicines Regulations (2012) within your scope of practice and competency.
- 1.3 You must understand which legal framework you are using to supply and administer medicines and understand which medicines you are permitted to supply and/ administer within that framework.

2. Accountability

- 2.1 You are professionally accountable for your decisions regarding the supply and administration of medicines under exemptions, including actions and omissions.
- 2.2 You cannot delegate to someone else the responsibility to administer or supply a medicine using exemptions.
- 2.2 You must only supply or administer medicines under exemptions within your scope of practice and competence.
- 2.3 Whilst you are legally permitted to supply or administer any of the approved medicines on the relevant exemptions list provided they fall within your individual area of competence and respective scope of practice, there may be further locally approved restrictions in place. For example, an employer may restrict dental therapists and dental hygienists to supply and administer only a number of the listed medicines. These restrictions would only apply to practice for that employer. You must work to such locally agreed written protocols and procedures at all times in addition to the standards set by the regulator and any guidance provided by your professional body.
- 2.4 The development of a personal formulary by each dental hygienist and dental therapist in collaboration with their employer is recommended, to include only the medicines that are routinely used by that clinician. This formulary should be updated and reviewed on an annual basis. Self-employed dental hygienists and dental therapists should set a personal formulary between themselves and their contractor. Dental hygienists and dental therapists that work independently should include their personal formulary as part of their policies and protocols.

Patient consultation

3. Assessment

In order to supply or administer medicines to a patient under exemptions you must satisfy yourself that you have undertaken a full assessment of the patient.

- 3.1 You should supply or administer medicines to a patient under exemptions only where you have relevant knowledge of the patient's health and medical history commensurate with the medicines decisions you are taking.

- 3.2 You should ensure you have considered the patient's current medication including over-the counter and herbal preparations and any potential interactions with other medicines before supplying or administering medicines.
- 3.3 You should ensure that you are aware of the patient's known medical conditions, other treatments or investigations that would contraindicate the use of any medicine.
- 3.4 You should ensure you consider the effects of your patient's lifestyle and socio-behavioural history which may affect the safety of the medicines you supply or administer. This will include the effects of over-the-counter medicines including herbal preparations, recreational or non-therapeutic use of medicines.
- 3.5 You should refer to an appropriate prescriber if you do not fully understand the implications of the actions of your medicines use even though you may be able to take a thorough and appropriate history which leads to a diagnosis.
- 3.6 Each patient must be assessed on an individual basis. You must only supply or administer medicines when you have assessed the patient and there is a genuine clinical need.
- 3.7 You should never supply or administer medicines for your own convenience or simply because a patient demands that you do so.

4. Consent

You should explain to the patient, or their representative, the role you play in their treatment and undertake appropriate informed consent. You should provide your patient with sufficient information relating to the risks, benefits, possible side effects, possible costs and outcomes of the medicines supply and administration that you are considering, as well as the comparative risks of alternative treatment options to medication that may be considered, in order that the patient can give their informed consent to treatment.

- 4.1 You must ensure that patients (or their representatives) understand the decisions they are being asked to make.
- 4.2 You must discuss treatment options with patients and listen carefully to what they say. Give them the opportunity to have a discussion and to ask questions. You should consider patients' preferences and be sensitive to their individual needs and values.

- 4.3 You should be aware, to the best of your ability, of the variety of social, cultural and religious factors that may affect upon the choices your patient makes in agreeing medicines decisions with you.
- 4.4 You should obtain valid consent before starting treatment and make sure that the patient's consent remains valid at each stage of treatment plan.
- 4.5 You should act in accordance with guidance from the GDC and your indemnity provider and employer on the obtaining and documenting of consent.
- 4.6 The patient has the right to refuse to accept any medication you propose to supply and/or administer. If they do so, you should explain the risks, benefits and outcomes of their decision and record in the patients' records.
- 4.7 The patient should be provided with any relevant patient information leaflet (PIL) about any medicine you propose to supply in order to assist them in making an informed decision.
- 4.8 Patients with visual impairment should be made aware that they can call the number below to receive a large print, braille or audio versions from the RNIB medicines leaflet line.²

5. Communication

- 5.1 There is no statutory requirement for dental professionals to communicate with a patient's medical practitioner when administering medicines for dental use. There are, however, occasions when this would be in the patient's interest and such communication is encouraged.
- 5.2 It is good practice to inform the patient's medical practitioner when you supply a medicine to a patient to take home.
- 5.3 You should communicate effectively, using the most appropriate medium, with other practitioners involved in the care of the patient. This includes communication across NHS/ practice boundaries where necessary/possible. This can be hard copy or electronic depending on the practice.

²The Royal National Institute of Blind People (RNIB) Medicine Leaflet Line number is: 0800 198 5000

- 5.4 When transferring patient data, it is vital that the data is secure, and that the risk of data loss (including misdirection) is minimised.
- 5.5 The Information Commissioner's Office (ICO) is the regulator responsible for ensuring that organisations comply with the General Data Protection Regulations (GDPR) 2018. As some dental hygienists and dental therapists work independently for dental practices they can ascertain if they are a data controller and need to register with the ICO. You can do this via the website www.ico.org.uk
- 6.4 NHS Digital have produced a Data Security and Protection Toolkit³ The Toolkit is an online self-assessment tool that enables organisations to measure and publish their performance against the National Data Guardian's ten data security standards.

All organisations that have access to NHS patient data and systems must use this toolkit to provide assurance that they are practising good data security and that personal information is handled correctly.

6. Record keeping

- 6.1 This practice guidance relates specifically to the record keeping of your supply and administration of medicines under exemptions. You should refer to other standards and guidance for information relating to clinical record keeping in general. Guidance can be found in the GDC Standards for the Dental Team (principle 4)⁴ and FGDP (UK)⁵
- 6.2 Documentation of the supply or administration activity should be recorded in the clinical records at the time of administration or supply. It is not good practice to document medicines supply/administration after the event e.g. at the end of the clinic session or at the end of the day.
- 6.3 Records must include details of the medicines supplied and/or administered, together with relevant details of the consultation with the patient.

³ <https://digital.nhs.uk/data-and-information/looking-after-information/data-security-and-information-governance/data-security-and-protection-toolkit>

⁴ <https://standards.gdc-uk.org/pages/principle4/principle4.aspx>

⁵ Clinical Examination and Record-Keeping: Good Practice Guidelines. FGDP(UK) A.M.HADDEN 2016
<https://www.fgdp.org.uk/clinical-examination-record-keeping-standards>

- 6.4 Patient records whether paper or electronic, must be stored in a manner that protects their security.

7. Information given to patients when medicines are supplied

- 7.1 You should tell the patient that supplied medicines will come with manufacturer's patient information Leaflet (PIL) which will give them additional information. In settings where the PIL is not routinely supplied patients can request such information if they wish. Patients with visual impairment should be made aware that they can view this online as an X-PIL or can receive large print, braille or audio versions from the RNIB medicines leaflet line.

8. Adverse events

- 8.1 If you discover that you have made an error in supply or administration you must take immediate action to prevent potential side effects to the patient and you must report the error as soon as possible according to local/practice policy.
- 8.2 If a patient experiences an adverse reaction to a medication you should record this in the patient notes and notify the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card Scheme as soon as possible. Yellow cards are found in the back of the British National Formulary and online at www.yellowcard.gov.uk. You may also be required to report the incident through local incident reporting procedures.
- 8.3 You should also inform the patient that they can report adverse reactions independently to the Yellow Card Scheme⁶.
- 8.4 You can also report adverse reactions via the MHRA website at www.mhra.gov.uk and serious incidents for investigation within NHS England (previously known as Serious Untoward Incidents (SUIs) can be reported via 'Serious Incidents Reporting and Learning Framework' (2015) which can be accessed via the following link: <https://improvement.nhs.uk/resources/serious-incident-framework/>

⁶ <https://www.gov.uk/report-problem-medicine-medical-device>

- 8.5 You should review incidents within your local team and/or medicines management committee (or equivalent) to enable learning and where necessary change practice.

Using medicines responsibly

9. Evidence based use of medicines in the patient's best interests

- 9.1 You should use nationally recognised best practice sources of evidence as your primary source of evidence based medicines use. Reference to the evidence base can minimise the risk of adverse drug reactions and ensure the most appropriate medicines are chosen in line with the patient's needs.
- 9.2 When administering or supplying antimicrobials you should take the requirements of antimicrobial stewardship into consideration, in line with national guidance⁷ in order to ensure the good infection prevention and prudent antimicrobial use that are essential to ensure safe and effective care⁸. Effective prevention of infection must be part of the everyday practice of dental therapists and dental hygienists as preventing infections helps to reduce the need for antimicrobials.
- 9.3 Dental therapists and dental hygienists should follow local policies for antimicrobial use, which are required to be based on national guidance and should be evidence-based, relevant to the local healthcare setting and take into account local antimicrobial resistance patterns. They should cover diagnosis and treatment of common infections and prophylaxis of infection.
- 9.4 Resources^{9 10} are available to inform dental hygienists and dental therapists about their role in the prevention of antimicrobial resistance including audit of their use, alternative treatments and accurate identification of need. Dental therapists and dental hygienists should undertake training to inform them of their responsibilities with regard to the use of antimicrobial medicines.

⁷ NICE (2015) [Guidance NG 15: antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#)

⁸ Department of Health (2015) [The Health and Social Care Act 2008: code of practice on the prevention and control of infections and related guidance](#)

⁹ Faculty of General Dental Practitioners (2012) [Antimicrobial Prescribing for General Dental Practitioners](#)

¹⁰ Public Health England (2016) [Dental antimicrobial stewardship: toolkit](#)

10. Delegation

- 10.1 You cannot delegate the administration of a medicine to another healthcare worker or to the patient/their legal representative.

11. Administration and supply of medicines on the request of others

- 11.1 You should only use exemptions to supply or administer medicines to patients in your direct care. You must not use exemptions for any patients upon whom you have not undertaken an appropriate assessment.
- 11.2 You must not use exemptions for a patient unknown to you simply because you are the only dental hygienist or dental therapist available with the qualification to use exemptions.

12. Reviewing Medications

- 12.1 Where using an exemption to supply a course of treatment you should review the patient as appropriate.

13. Children

- 13.1 Medicines are potent treatments and using them can present significant risk to patients. This is especially so for children whose responses may differ from adults. You must have relevant education, training and competence in treating children in order to supply and/or administer medicines to them. You should recognise the unique implications of supplying and administering medicines to children and young people. Caution should also be used when supplying or administering medicines for pregnant and lactating women.
- 13.2 You should make reference to the following appropriate documents that address medicine management issues in paediatrics:
- The BNF for children <http://www.bnfc.nice.org.uk> ¹¹

¹¹https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/601833/delivering_better_oral_health_summary.pdf

- SDCEP Drug Prescribing For Dentistry Dental Clinical Guidance Third Edition, January 2016¹²

14. Complementary, herbal and homeopathic products

- 14.1 Complementary, herbal and homeopathic products may interact with other medicinal products. You should ensure you obtain, and record, information from the patient as to whether they are using any such products. Where there is evidence that you should do so, you may need to advise that your patient stops using a complementary, herbal or homeopathic product prior to starting taking a medicine supplied using exemptions or undergoing a dental procedure.

Storage, transport and disposal of medicines

15. Storage

- 15.1 You should ensure all medicinal products are stored in accordance with the information within the Summary of Product Characteristics or Patient Information Leaflet or information found on the label. Some medicines may require refrigerated storage.
- 15.2 When not in use, medicines should be stored in lockable containers or cabinets
- 15.3 You must follow local protocols agreed by the governance lead for the practice/organisation for carrying medicines to various settings when outside clinical practice, for example care homes, outreach centres.
- 15.4 All storage environments must meet the prevailing storage requirements and it is your responsibility to find out what these requirements are. You must ensure correct storage policies are in place and are being adhered to.

16. Transportation

- 16.1 You may transport medicines for use elsewhere from the dental surgery to their place of use.

¹² <http://www.sdcep.org.uk/published-guidance/drug-prescribing/>

- 16.2 You must not leave medicines unattended in your vehicle at any time.

17. Disposal

- 17.1 You must dispose of used, partially used and unused medicines in accordance with current legislation and your local practice policy.

18. Clinical Governance

- 18.1 You must follow the governance arrangements related to medicines that are in place where you work.
- 18.2 Clinical audit is an important part of clinical governance and you should audit your activities in the use of exemptions.
- 18.3 If you are working in private practice it is expected that your clinical governance systems are equivalent to those within the NHS. For example, you need to be able to demonstrate how you audit your practice, keep up-to-date with current guidance and how you safeguard the patients in your care.
- 18.4 You should ensure that you have information about national guidelines (e.g. NICE guidelines, NSFs, BNF, BNFC), local guidelines, local agreements and formularies to ensure you make the best decision for your patients.

19. Continuing Professional Development

- 19.1 You must remain up-to-date with appropriate knowledge and skills to enable you to supply and administer medicines competently and safely within your scope of practice.

20. Peer support

- 20.1 You might find it useful to obtain support from another dental hygienist or dental therapist who qualified and is using exemptions to supply and administer medicines, or from a dentist.

21. Conflict of interest

- 21.1 If you have a commercial or financial interest in any pharmaceutical product or company then you should ensure that your interest does not affect your ability to use exemptions in the patient's best interest.
- 21.2 You must not allow your own, or your employer's (if applicable) commercial or financial interests in a pharmaceutical company or product influence the way you advise or treat your patients.
- 21.3 You must declare any conflict of interest in a 'register of interests' either within your personal portfolio, or within your employer's register which should be produced on request for audit purposes.

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Glossary

Term	Explanation
Administration	Process by which a medicine is introduced into, or applied onto, the patient's body.
British Association of Dental Therapists (BADT)	Professional body representing dental hygienists and dental therapists in the UK
British Society of Dental Hygiene and Therapy (BSDHT)	Professional body representing dental hygienists and dental therapists in the UK
British National Formulary (BNF)	A joint publication of the British Medical Association and the Royal Pharmaceutical Society. It is aimed at health professionals involved with prescribing, monitoring, supplying and administering medicines.
British National Formulary for Children (BNFC)	BNF for children
Clinical Governance	Quality assured activities that ensure that pre-determined clinical standards that have been set, are maintained by practitioners, and are evident within health care settings.
Competence	The ability of an individual to demonstrate their capability in a certain skill area at a defined level of ability at a set point in time.
Disposal	The removal and disposal of medicines that are no longer required or are no longer suitable for their intended use and /or the removal of unwanted medicines or spent materials from the clinical site.
FGDP (UK)	Faculty of General Dental Practice UK – They seek to improve the standard of care delivered to patients through standard setting, publications, postgraduate training and assessment, education and research
General Dental Council (GDC)	Regulators of the dental professions
Guidance	Document containing recommendations for the use of a particular treatment and/or modality; the circumstances when it should be used and the population/patient groups who should receive it. Health professionals have a duty to take guidance fully into account where it is published, but they are not bound by its contents and may deviate from it where there is a clear indication to do so.

Medicine	Defined by MHRA as: “a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; b) Any substance or combination of substances which may be used in, or administered to, human beings, either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis”. A medicine could fall under either point a) or b) above, or both.
MHRA	The Medicines and Healthcare products Regulatory Agency regulates medicines, medical devices and blood components for transfusion in the UK.
Summary of product characteristics	Information available for individual licensed medicines produced by the manufacturer and, forming an integral part of the marketing authorisation (licence). It provides information for health professionals on how to use the medicinal product safely and effectively.
Supply	The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used, or supplied directly to the patient.

APPENDIX

Key Legislation & Terminology

Medicines use in the UK is controlled by the terms of the Human Medicines Regulations 2012, which provide the legislative framework for medicines use in the UK.

Dental hygienists and dental therapists must understand the distinctions between the three core frameworks for supply and administration that are available to them.

Supply and Administration Frameworks

22. Patient specific directions (PSDs)

A PSD is a prescriber’s written instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis

In dental practice, the PSD/prescription is usually written in the patient's notes/treatment plan. A PSD is required before any medicine can be given to a patient as part of their private or NHS dental treatment by a dental hygienist or dental therapist who is not qualified in the use of exemptions or for any medicine which is not included in the exemptions list.

A PSD enables a dental hygienist or dental therapist to administer or supply the medicine under certain circumstances. Writing a PSD is a form of prescribing and must be undertaken by an authorised prescriber. Administering a medicine specified in a PSD is a responsibility delegated by the prescriber provided the professional delegating is satisfied that the person is competent to carry out the task. The delegating professional remains responsible for all aspects of the administration.

PSDs are useful in many care settings; they are individually tailored to the needs of a single patient, wide-reaching and can encompass controlled drugs.

A PSD is required for each treatment episode within a course of treatment referred to the dental hygienist or dental therapist. For example, a course of periodontal treatment can be split over four visits. If the patient's mouth needs to be anaesthetised for each visit, the initial written referral will need to be written in sufficient detail to include a PSD for each visit in order that each treatment may take place.

23. Patient group directions (PGDs)

A PGD is a written instruction for the supply or administration of a named medicine in a defined clinical situation to groups of patients who may not have been identified before presenting for treatment. They provide a legal framework that allows the supply and/or administration of a specified medicine(s) without the need for prescription or an instruction from a prescriber. For more information about PGDs, see NICE guidance¹³

However, PGDs have been very difficult to develop in the dental primary care setting where most dental hygienists and dental therapists work.

As most dental therapists are "sub-contractors" to dentists, who are themselves not directly employed in the NHS but under contract to deliver dental service, there is no readily accessible governance framework within which to develop and implement PGDs. The national guidance on the writing and signing of PGDs requires the input of a senior pharmacist and most dental services do not have access to this expertise. The difficulties in

¹³ NICE (2017) [Patient group directions: medicines practice guideline](#)

drafting a PGD for the general dental practice setting has resulted in many working only with PSDs.

24. Exemptions

Refers to a specific piece of law allowing certain listed medicines to be supplied and/or administered to patients by certain health professional groups without the need for another appropriate prescribing or supply/administration framework.

Exemptions permit certain medicines listed in legislation to be sold, supplied and/or administered to patients by certain health professional groups without using a prescription or patient group direction (PGD). Exemptions may be used by paramedics, podiatrists, optometrists, orthoptists and midwives and, subject to changes in legislation, by dental hygienists and dental therapists.

The lists of medicines that can be supplied and administered by designated professions under exemptions are set out in schedule 17 of the Human Medicines Regulations 2012.

The lists are profession-specific; medicines from the lists must only be supplied or administered by the profession to which the list pertains. Exemptions are not a form of prescribing.

Categories of Medicines

Some medicines can be classified under more than one category and this can depend upon formulation, strength, quantity, indication or marketing authorisation.

25. General Sales List Medicines (GSL)

These products can be sold with reasonable safety without the supervision or advice of a doctor or pharmacist, and may be obtained through a variety of lockable outlets. All GSL medicines must hold a valid UK product licence and all the active ingredients must be listed in the product. Regulations restrict the pack sizes and quantities of the medicine that may be sold without supervision.

26. Pharmacy sale medicines (P)

These products can be sold with reasonable safety from premises that are under the supervision of a pharmacist but without the need for a written prescription. Both GSL and P class medicines are known as “over-the-counter” medicines as they can be sold and supplied (in some cases only at certain low volumes) without a written prescription for supply.

27. Prescription Only Medicines (POMs).

A prescription-only medicine (POM) is a medicine that is generally subject to the requirement of a prescription written by an appropriate practitioner (prescriber) before it can be administered or supplied to a patient.

There are several mechanisms that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation.

The Human Medicines Regulations 2012 define those medicines that are classified as POMs and include:

(a) a product for parenteral administration.

(b) a product that is a controlled drug, unless it is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale.

(c) cyanogenic substances, other than preparations for external use.

(d) medicinal substances that on administration emit radiation, or contain or generate any substance which emits radiation, in order that radiation may be used.

(e) a product that—

- (i) is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and
- (ii) consists of or contains aloxiprin, aspirin or paracetamol in the form of non-effervescent tablets or capsules;

(f) a product that—

- (i) is covered by a marketing authorisation in which the product is classified as a pharmacy medicine or as a medicinal product subject to general sale, and
- (ii) consists of or contains (in any pharmaceutical form) pseudoephedrine salts or ephedrine base or salts; and

(g) a product that—

- (i) is not covered by a marketing authorisation, and
- (ii) is a prescription only medicine by virtue of articles 5 and 10 of, and Schedules 1 and 2 to, the Prescription Only Medicines (Human Use) Order 1997(1).

POMs may only be sold, supplied and administered in accordance with a written prescription by an appropriate practitioner and dispensed from a registered pharmacy or dispensing doctor's practice.

The Human Medicines Regulations 2012 defines 'appropriate practitioner' for the purposes of issuing written prescriptions:

- Doctor
- Dentist
- Nurse Independent prescriber
- Pharmacist Independent prescriber
- Optometrist Independent prescriber,
- Physiotherapist Independent prescriber
- Podiatrist Independent prescriber
- Therapeutic radiographer independent prescriber

- Paramedic independent prescriber
- Supplementary prescriber acting under a written Clinical Management Plan (CMP)

Restrictions apply to some of the appropriate practitioners listed above regarding their prescribing permissions.

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28. Acknowledgements

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