



Patient and public summary of:

Consultation on the proposal for the supply and administration of medicines under exemptions within the Human Medicines Regulations 2012 by dental hygienists and dental therapists across the United Kingdom

October 2020

This is a summary of the full consultation guide '*Consultation on the proposal for the supply and administration of medicines under exemptions within the Human Medicines Regulations 2012 by dental hygienists and dental therapists across the United Kingdom*'.

This summary guide is much shorter and **does not** contain all the detail on the proposed changes.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please email england.cpomedicinesmech@nhs.net.

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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1 Introduction to the consultation

1.1 What are we consulting on?

In collaboration with the Scottish, Welsh and Northern Ireland governments, we are consulting on proposed changes to enable dental hygienists and dental therapists to supply and administer a number of specific medicines to their patients under exemptions within the Human Medicines Regulations 2012.

Certain health professions can supply and administer particular medicines as listed in the medicines law without a prescription. These are known as exemptions.

As listed below, some of the medicines are for administration only which means that they are given to the patient during treatment; some are for supply which means that they are given to the patient to take away and use.

Medicines for administration only:

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

Medicines for supply:

- sodium fluoride (dental paste)
- nystatin oral suspension

In addition, we are proposing changes to allow for the supply of all general sales list and pharmacy medicines, within the dental hygienists' and dental therapists' scope of practice.

Dental hygienists and dental therapists already supply and administer the proposed medicines to their patients in the course of their professional practice. They currently have to either ask dentists to write a patient specific direction (PSD) for the medicines or use a document called a patient group direction (PGD) if one is available, before they can supply or administer the medicine.

See appendix A in the full consultation guide for further detail about the proposed medicines.

There are two options for consideration in this consultation:

Option 1: no change.

Option 2: enabling the supply and administration of medicines under exemptions within the Human Medicines Regulations by dental hygienists and dental therapists.

The proposed changes require amendment to the Human Medicines Regulations. The Human Medicines Regulations apply UK-wide so subject to the agreement of Ministers, changes to them will apply across the four countries.

Should legislation be amended, the changes would apply in any setting in which dental hygienists and dental therapists work including the NHS, independent and voluntary sectors.

1.2 Why are the proposed changes being considered?

Dental hygienists and dental therapists have been able to supply and administer medicines to patients for many years, through the use of:

- patient specific directions (PSDs) since 1968
- patient group directions (PGDs) since 2010

[Section 4.2](#) of this guide contains more information about these mechanisms.

Patients treated by dental hygienists and dental therapists who could use exemptions in medicines legislation would have more timely and efficient dental care by avoiding delays whilst dental hygienists and dental therapists obtain a prescription, and would need fewer additional appointments just to receive the correct medicine. This could also free up dentists, dental hygienists and dental therapists to see more patients.

Further information on the benefits of this proposal and potential risks and measures in place to manage the risks are presented in section 4.2 and section 4.5 of the full consultation guide respectively.

1.3 Supporting documents

The following documents provide additional information about the proposal:

- The *Consultation Stage Impact Assessment* which focuses on what impact the proposed policy change is likely to have and highlights the costs, benefits and risks of the proposed changes.
- The [Draft Practice Guidance for Dental Hygienists and Dental Therapists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012](#) contains guidance which describes how dental hygienists and dental therapists would supply and administer medicines under exemptions to patients safely.
- The [Draft Outline Curriculum Framework for Education Programmes to Prepare Dental Hygienists and Dental Therapists to use Exemptions](#) which dictates the knowledge and skills that dental hygienists and dental therapists should have learned whilst on education programmes before being qualified to use exemptions as proposed.

1.4 What you will be asked about

The consultation questions ask:

- what you think about the proposal and whether you have additional information on any aspects not already considered as to why the proposal SHOULD or SHOULD NOT go forward
- what you think about the Consultation Stage Impact Assessment which accompanies the proposal

- whether you have any suggestions as to how the supporting documents could be improved including the Draft Practice Guidance and Draft Outline Curriculum Framework
- whether the proposal will have a positive or negative impact on people who are affected by equality and health inequality issues
- about yourself or your organisation so that the views of different groups can be better understood.

The consultation will run for 8 weeks and will close on **10th December 2020**.

You can find a glossary of terms used in this guide in [section 8](#) of this guide.

2 Background

A scoping project was undertaken in 2015 by NHS England and looked at the need for some regulated health professions to supply and administer medicines to their patients. The report of the project made a number of recommendations, including that the patients being treated by dental hygienists and dental therapists could benefit from them being able to use exemptions.

The Chief Professions Officers' Medicines Mechanisms (CPOMM) programme of work started in April 2017 to take forward the recommendations.

NHS England is leading consultations on proposals to change the medicines responsibilities for eight health professions, as follows:

- enabling **dental hygienists** and **dental therapists** to supply and administer specific medicines under exemptions within medicines legislation
- enabling **biomedical scientists**, **clinical scientists** and **operating department practitioners** to supply and administer medicines using patient group directions
- amending the current lists of controlled drugs that **podiatrist** and **physiotherapist** independent prescribers are legally able to prescribe
- amending the list of medicines that **paramedics** can administer in emergency situations using exemptions within medicines legislation

All the proposals share the same aim, to make it more convenient and safer for patients to get the medicines they need at the time and place when they need them. This will reduce the need for appointments with additional health professionals just to receive the medicines needed, which often results in unnecessary delays to the start of treatment.

The consultations can be found on the NHS England consultation hub website.

3 The dental hygiene and dental therapy professions

All dental hygienists and dental therapists must be registered with the General Dental Council (GDC), the regulatory body which sets the standards that dentists and other dental professionals are expected to meet. Dental hygienists and dental therapists must successfully complete either a diploma or degree in order to register with the GDC. Once registered, dental hygienists and dental therapists must show that they are completing regular education and that they continue to practise both safely and effectively within their scope of practice, in order to maintain their registration. There are currently 7685* dental hygienists and 3862* dental therapists registered with the GDC in the UK¹.

Dental hygienists and dental therapists work in a variety of places such as dental practices, large clinics with other professionals such as GPs and pharmacists, community dental clinics, schools, private clinics and universities. Some dental hygienists and dental therapists work for the NHS, others are employed by private dental practices and some are self-employed. No matter where they work, they must always meet the same high standard as set by the GDC. Likewise, their employers must use the same standard of systems and checks to ensure that patient safety is maintained.

The professional bodies representing dental hygienists and dental therapists across the United Kingdom are the British Society of Dental Hygiene & Therapy and the British Association of Dental Therapists.

* The numbers of registered dental hygienists and dental therapists may not truly reflect the total numbers working in the UK as a result of duplication of numbers due to some individuals being dual-registered.

3.1 Scope of practice

Many dental professionals are dual-qualified as both dental hygienists and dental therapists and so can carry out all of the following treatments.

3.1.1 Shared scope of practice of dental hygienists and dental therapists

Dental hygienists and dental therapists help patients to keep their mouths healthy by preventing and treating dental disease such as tooth decay. They also advise patients how to look after their mouths and teeth, for example by having a healthy diet and brushing regularly. They can examine patients' mouths, diagnose problems and plan treatment, which may include deciding on the need for, taking and interpreting x-ray images.

3.1.2 Specific additions to the scope of practice for dental hygienists

If registered as a dental hygienist, in addition to the shared scope of practice described in 3.1.1 they can also scale the surfaces and clean the roots of patients' teeth. However, they cannot carry out the treatments described below in section 3.1.3 unless they are dual-registered.

3.1.3 Specific additions to the scope of practice for dental therapists

If registered only as a dental therapist, in addition to the shared scope of practice described above, they can also carry out some treatments such as fillings, nerve treatments and the

¹ General Dental Council, registration report September 2020

removal of milk teeth. However, they cannot carry out the treatments described above in section 3.1.2 unless they are dual-registered.

4 Case for change

4.1 Identification of viable options

The report of the 2015 NHS England scoping project indicated the legal mechanism of administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities. The report recommended that work should be undertaken to enable dental hygienists and dental therapists to supply and administer a specific list of medicines under exemptions within medicines legislation. Whilst dental hygienists and dental therapists can already supply and administer the proposed medicines to their patients, they currently have to either ask a dentist to write a prescription for the medicines needed (also known as a patient specific direction or PSD) or use a document called a patient group direction (PGD), before they can do so.

Two options have been considered:

Option 1: no change

There would be no change to legislation; dental hygienists and dental therapists would continue to use PSDs and PGDs to supply and administer medicines to their patients.

Benefits

For some patients the existing legislation works well, e.g. for those patients whose medicines needs can be anticipated in advance of their treatment.

Limitations

Existing arrangements may not best support the needs of patients who need a different medicine such as a different local anaesthetic than anticipated because of pre-existing medical conditions or allergies, or whose oral health problem was not anticipated such as oral thrush. More detail on the impact of this option and the limitations of the current mechanisms available to dental hygienists and dental therapists can be found in [section 4.2](#) of this guide.

Option 2: amend legislation to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions

Benefits

Patients who receive oral health treatment from dental hygienists and dental therapists would be able to receive all the treatment they require without delays or the need for additional appointments with another dental professional to receive their medicines. Further information about the anticipated benefits can be found in [section 4.3](#) of this guide.

Limitations

Should dental hygienists and dental therapists be required to use medicines additional to those proposed, they may still need to use PSDs and PGDs. The list may need to be updated in the future to ensure that it remains aligned with best practice guidance.

4.2 Limitations of the current supply and administration mechanisms

Dental hygienists and dental therapists are currently able to use patient specific directions (PSDs) and patient group directions (PGDs) to supply and administer medicines to their patients. These mechanisms are legal arrangements that allow health professionals to supply or administer medicines to patients.

4.2.1 Patient specific directions (PSDs)

A PSD is a written instruction from a prescriber to administer or supply a medicine to a named patient who has been assessed by the prescriber. PSDs are very useful; they are written to treat a single patient, and can be used for a wide range of medicines. However, there are some difficulties such as that they require direct input from a prescriber (usually a dentist) which can be a problem when a prescriber is not available.

4.2.2 Patient group directions (PGDs)

PGDs are written instructions for medicines to be supplied and/or administered by groups of health professionals to certain groups of patients. They contain information as to which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor or dentist.

There are difficulties with the use of PGDs in dental services because 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.

Dental hygienists and dental therapists are already experienced in supplying and administering some medicines for their patients using PGDs and PSDs, but for a number of reasons not all patients can benefit from the use of these mechanisms. This means that patients might need to wait or need extra appointments just to receive the medicines they need. More detailed information about how dental hygienists and dental therapists currently provide patients with medicines can be found in section 3 of the full consultation guide.

4.3 Benefits of the proposal

Benefits of the proposed use of exemptions by dental hygienists and dental therapists would include patients getting the medicines they need at the right time and in the right place for maximum benefit. This would be more convenient for patients by reducing the number of appointments they need and the number of healthcare professionals they need to see to get the medicines.

Tooth decay can cause pain and difficulties when eating or drinking and people with poor oral health say they have a lower sense of wellbeing, higher levels of depression and poorer satisfaction with their life overall². Dental hygienists and dental therapists who could supply and administer medicines under exemptions may provide a good result for patients by doing the treatment they need without unnecessary delays. This would then reduce pain and improve overall quality of life.

² British Dental Health Foundation survey, 2014: Which of these oral health problems would keep you off of work? cited in British Society of Dental Hygiene and Therapy [Work missed due to oral health problems costs the UK economy more than £36 million each year](#)

The proposed use of exemptions would also reduce the number of times that dental hygienists and dental therapists need to interrupt the dentist to ask them to prescribe a medicine. This would help dentists, dental hygienists and dental therapists to provide safer care for their patients.

Examples of how some of the medicines will be administered and supplied under exemptions by dental hygienists and dental therapists can be found in section 4.4 of the full consultation guide.

4.4 Management of potential risks of the proposal

Whenever there is any extension of medicines supply, administration and prescribing responsibilities to regulated health professions there will be associated risks with the enhanced responsibilities. Identification of the risks informs the development of governance and patient safety measures that are necessary to keep patients safe.

There are a number of potential risks to the proposal enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions. The risks perceived are similar to those for other professions that use exemptions to supply and administer medicines. As such, they can be managed by the governance and patient safety measures that are already in existence and described in section 5 below.

The potential risks of the proposal are included in table 1 in the full consultation guide.

5 Governance and patient safety

5.1 Safe use of exemptions within medicines legislation

Health professionals working under exemptions within medicines legislation must only supply and administer those medicines that are listed in legislation for use by their profession. For example, dental hygienists and dental therapists would only be allowed to supply and administer medicines under exemptions that are listed in legislation as exempt for dental hygienists and dental therapists. They would not be able to supply and administer any other medicines without either a PGD or PSD being in place.

Furthermore, if the proposal is approved, dental hygienists and dental therapists would need to ensure they only supply and administer the medicines that fall within the limits of their competence. National and local policies and guidelines may limit the proposed list of medicines even further.

For further information about the safe use of exemptions, see section 5.1 of the full consultation guide.

5.2 Eligibility to train to use exemptions within legislation

The safety of patients is very important and therefore only those who meet all the entry eligibility requirements would be able to undertake training to use exemptions. For a full list of entry requirements see section 5.2 of the full consultation guide.

Under the proposal, only dental hygienists and dental therapists who have successfully completed their education in the use of exemptions will be able to supply and administer medicines to their patients. Dental hygienists and dental therapists using exemptions must be able to show their employer and the GDC that they are up to date by undertaking appropriate continuing professional development and demonstrating that they continue to practise both safely and effectively.

5.3 Communication of decision to supply and administer medicines using exemptions

If the proposed changes are approved, before supplying and/or administering medicines to a patient using exemptions, dental hygienists and dental therapists would have to assure themselves that they have all the information they need to make a safe and effective decision. Dental hygienists and dental therapists have access to the patient's dental records but would also have to obtain additional information from the patient and other health professionals as required.

Any medicines administered by dental hygienists and dental therapists for prevention or treatment purposes are recorded within the patient's dental notes. The patient's GP is not usually informed but the record is available to all members of the dental team. Information about medicines supplied will be shared with the patient's GP.

6 Equality and health inequality considerations

We have undertaken an Equality and Health Inequalities Screening Tool in accordance with NHS England requirements. A review of the screening tool by the specialist NHS England team indicated that a full Equality and Health Inequalities assessment was not required prior to the launch of the consultation but will be undertaken alongside the consultation to collate responses.

During the consultation we will assess if the proposal will make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines. This may remove or minimise disadvantages suffered by vulnerable people when accessing medicines.

6.1 Public sector equality duty

Public bodies across England, Scotland and Wales have legal obligations under the Equality Act 2010³, and are specifically required to consider the aims of the Public Sector

³ [Equality Act 2010](#)

Equality Duty⁴, as set out at section 149 of the Equality Act 2010 when making decisions. This means that NHS England and NHS Improvement should understand the potential effect of the proposal on people with characteristics that have been given protection under the Equality Act 2010, especially in relation to their health outcomes and the experiences of patients, communities and the workforce. This will help us to consider whether the policy or practice will be effective for all people.

As this consultation is UK-wide, appropriate consideration has also been given to the requirements of the Northern Ireland Act 1998⁵.

6.2 Health inequality duties

NHS England and NHS Improvement also have duties to consider the need to reduce health inequalities between patients' access to, and outcomes from healthcare services, and to ensure services are provided in an integrated way.

The consultation process provides a further opportunity to consider the potential positive and negative impact of the proposed changes on equality and health inequalities and to seek the views of responders. We and the devolved administrations will give due regard to responses received and we will be developing a fuller Equality and Health Inequalities impact assessment alongside the consultation.

For further information about our duties, see section 6 of the full consultation guide.

7 Consultation format

7.1 Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients, patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, dentists, doctors, pharmacists, allied health professionals, dental care professionals, nurses, regulators, the Royal Colleges and other representative bodies.

We are grateful to individuals and organisations who take the time to respond to this consultation.

7.2 How to respond

If you would like to respond to this consultation you can do so by:

- completing the online survey
- asking for a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net

⁴ [Public Sector Equality Duty 2011](#)

⁵ [Northern Ireland Act 1998](#)

Please complete this form and return it to:

CPOMM Programme Team
NHS England and NHS Improvement
5W06 Quarry House
Leeds
LS2 7UE

Responses should be sent to arrive no later than 10th December 2020.

7.3 Alternative formats

- A paper copy of this summary consultation guide is available on request. It can also be made available in formats such as large print and easy read, and may be available in alternative languages, upon request. Please contact england.cpomedicinesmech@nhs.net

7.4 Engagement events

Engagement events will be held online during the consultation period. These will provide an opportunity for those attending to find out more about the proposals and the consultation process.

To register or find out more information about any of these events please go to: <https://www.england.nhs.uk/medicines-2/chief-professions-officers-medicines-mechanisms-programme/>.

7.5 How your responses will be used

Following close of the consultation, we will look at all responses received and a summary of the responses will be published on the NHS England website.

Under the General Data Protection Regulation, NHS England will be data controller for any personal data you provide as part of your response to the consultation. NHS England has statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions.

If you respond as an individual, we will anonymise your response but we may publish your response in part or full unless you tell us not to. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you would like any part of your response to stay confidential, you should explain why you believe the information you have given is confidential. NHS England may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

7.6 Next steps

The proposed changes to medicines legislation and the findings of the consultation will be presented to the Commission on Human Medicines who make recommendations to Ministers regarding changes to the Human Medicines Regulations. Subject to the agreement of the proposed changes by Ministers; the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments. The Human Medicines Regulations apply UK-wide so changes to them will apply across the four countries.

If all elements of the proposal are approved and all relevant organisations are in a position to complete their elements of the work at the earliest possible point without delay, the proposed changes to the Human Medicines Regulations could come into force in 2021.

Each of the four devolved administrations in the United Kingdom is responsible for making amendments to the NHS Pharmaceutical regulations in their own country. The NHS regulations in that country must be amended before the changes can be implemented. Changes to NHS regulations for the implementation of the amendments in Scotland, Wales and Northern Ireland and the resultant focus and pace of this in each respective country are matters for devolved administrations.

8 Glossary

Term	Explanation
Administration of medicines:	Process by which a medicine is introduced into, or applied onto, the patient's body, for example by giving a local anaesthetic to have a filling.
Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme:	An NHS England and NHS Improvement programme of work to extend the supply, administration or prescribing responsibilities to regulated health professions where there is an identified need and benefit to patients. The programme aims to make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines.
Commission on Human Medicines:	Advises the government on the safety, effectiveness and quality of medicinal products, and on changes to medicines law.
Continuing professional development (CPD):	Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively.
Department of Health and Social Care (DHSC):	The central government department with responsibility for leading the nation's health and social care system to help people live more independent, healthier lives for longer.
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 PGD.
Faculty of Dental Practice (UK):	The professional membership body in the UK specifically for general dental practice; its aim is to improve the standard of care delivered to patients through provision of clinical standards, publications, postgraduate training and assessment, education and research.
General Dental Council (GDC):	The regulator of the dental professionals in the UK. The GDC sets the standards that all dental hygienists and dental therapists have to meet regarding the way they are educated and work. It is compulsory that dental therapists register with the GDC in order to practise.
General sales list medicine:	Medicines that may be bought in specified packs from a wide range of lockable retail premises without a prescription.
Medicines and Healthcare products Regulatory Agency (MHRA):	Responsible for regulating all medicines and medical devices in the UK by ensuring they work and are as safe as possible. They are also responsible for making changes to medicines legislation that have been agreed by government. The MHRA is a part of the DHSC.
Patient group direction (PGD):	A written instruction for medicines to be supplied and/or administered by groups of health professionals to groups of patients. They contain information about which health professionals can supply or administer the medicine, which

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Term	Explanation
	patients they can see, and when they should involve a doctor.
Patient specific direction (PSD):	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.
Pharmacy medicine:	Medicines that are available only from a pharmacist but without a prescription. A pharmacist must make or supervise the sale.
Prescription only medicine:	Medicines that normally need to be prescribed by a doctor or another prescriber before they can be administered or supplied to a patient.
Supply of medicines:	The processes undertaken, in response to formal orders, to issue medicines directly to the patient to take away. Patients then administer the medicine to themselves or allow others to help them

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