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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 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.

A patient and public summary version of this consultation guide is available.

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?

This consultation is on proposals to enable dental hygienists and dental therapists to use exemptions.

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 prescribe the medicines or use a document called a patient group direction (PGD) if one is available, before they can supply or administer the medicine.

This UK-wide consultation is being led by NHS England and NHS Improvement on behalf of the four nations and relates to the proposal to enable dental hygienists and dental therapists to supply and administer specified medicines directly to patients, under exemptions listed in Schedule 17 of the Human Medicines Regulations 2012, in the course of their professional practice. The proposed medicines are:

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 licensed in the UK, within the dental hygienists and dental therapists' scope of practice.

Further information on the clinical use of the medicines listed above can be found in section 4.4 and appendix A.

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 throughout the UK, in any setting in which dental hygienists and dental therapists work including the NHS, independent and voluntary sectors.

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 9.

1.2 Why are the proposed changes being considered?

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. The use of exemptions to supply and administer medicines will:

- enable dental hygienists and dental therapists to deliver prevention, treatment and maintenance of oral health effectively and efficiently, in line with evidence-based practice and without unnecessary delays or hand-offs of care to other health professionals, namely dentists, just to access the medicines required
- ensure that patients receive the best care, first time and in the right place
- further improve patient safety by creating clearer lines of responsibility for decisions made regarding medicines

Further information about the benefits of this proposal can be found in section 4.3. Potential risks and measures in place to manage the risks can be found in section 4.5.

1.3 Who has been involved?

This consultation guide has been developed in partnership with Department of Health and Social Care; the Medicines and Healthcare products Regulatory Agency; the Northern Ireland Department of Health; the Scottish Department of Health and Social Care; and the Welsh Department of Health and Social Services.

The British Association of Dental Therapists (BADT) and the British Society of Dental Hygiene and Therapy (BSDHT), the two professional bodies representing dental hygienists and dental therapists across the UK have also collaborated in the development of this consultation guide and the supporting documents that accompany it. Informative discussions have taken place with key stakeholders including the General Dental Council, the British Dental Association and the Faculty of General Dental Practice (UK).

BSDHT and BADT consulted with their members and other key stakeholders to propose the list of medicines that dental hygienists and dental therapists would be able to supply and administer under exemptions.

In April 2018, NHS England also undertook pre-consultation engagement with a selection of stakeholders and professionals to further sense check the proposed list of medicines to ensure that the list was comprehensive and that governance arrangements had been fully considered.

1.4 Supporting documents

The following supporting documents are provided alongside this consultation to inform consideration of the options and questions:

- *Draft Practice Guidance for Dental Hygienists and Dental Therapists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*[1]
- *Draft Outline Curriculum Framework for Education Programmes to Prepare Dental Hygienists and Dental Therapists to use Exemptions*[2]
- *Consultation Stage Impact Assessment*

These supporting documents will remain in draft form until the consultation closes, when any necessary amendments will be made and final versions published as appropriate.

1.4.1 Practice guidance

The *Draft Practice Guidance* has been developed and published by BADT and BSDHT. The document provides information about the behaviours, actions, knowledge and skills which should underpin the decision-making and actions of dental hygienists and dental therapists who are qualified to supply and administer specific medicines under exemptions.

1.4.2 Outline curriculum framework

In collaboration with key stakeholders, the BADT and the BSDHT have developed a *Draft Outline Curriculum Framework* aimed at education providers intending to develop education programmes and individuals interested in education programmes for dental hygienists and dental therapists to supply and administer medicines under exemptions.

1.4.3 Consultation stage impact assessment

Impact assessments are an integral part of the policy making process; the purpose of an impact assessment is to focus on why the proposed intervention is necessary, what impact the policy change is likely to have and the highlighting of costs, benefits and risks. The *Consultation Stage Impact Assessments* contains evidence of the actual (where available) and estimated costs and benefits associated with the proposal. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

1.5 The questions being asked

Question 1

a) Should amendments to legislation be made to enable **dental hygienists** to supply and administer specifically listed medicines to their patients using exemptions?

b) Should amendments to legislation be made to enable **dental therapists** to supply and administer specifically listed medicines to their patients using exemptions?

Question 2

a) Do you have any additional information on any aspects not already considered as to why the proposal to enable **dental hygienists** to supply and administer specifically listed medicines to their patients using exemptions SHOULD go forward?

[1] British Association of Dental Therapists, British Society for Dental Hygiene and Therapy *Draft Practice Guidance for Dental Therapists and Dental Hygienists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*

[2] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

b) Do you have any additional information on any aspects not already considered as to why the proposal to enable **dental therapists** to supply and administer specifically listed medicines to their patients using exemptions SHOULD go forward?

Question 3

a) Do you have any additional information on any aspects not already considered as to why the proposal to enable **dental hygienists** to supply and administer specifically listed medicines to their patients using exemptions SHOULD NOT go forward?

b) Do you have any additional information on any aspects not already considered as to why the proposal to enable **dental therapists** to supply and administer specifically listed medicines to their patients using exemptions SHOULD NOT go forward?

Question 4

To what extent do you agree or disagree with each of the proposed medicines that dental hygienists and dental therapists would be able to *administer* under exemptions within the Human Medicines Regulations?

Question 5

To what extent do you agree or disagree with each of the proposed medicines that dental hygienists and dental therapists would be able to *supply* under exemptions within the Human Medicines Regulations?

Question 6

Do you have any suggestions as to how the *Draft Practice Guidance* could be improved?

Question 7

Do you have any suggestions as to how the *Draft Outline Curriculum Framework* could be improved?

Question 8

Does the *Consultation Stage Impact Assessment* give a realistic indication of the likely costs, benefits and risks of the proposal?

Question 9

Do you think that this proposal could impact (positively or negatively) on any of the protected characteristics covered by Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998?

Question 10

Do you feel that this proposal could impact (positively or negatively) on health inequalities experienced by certain groups?

You will also be asked questions about yourself and / or your organisation so that the views of different groups can be better understood.

2 Background

2.1 Context

The Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme is set in the context of the current direction of the NHS which puts patients and the public at the heart of everything we do. The Five Year Forward View[3] sets out the vision for the future of the NHS in England, a future in which access to health care is intuitive and simplified. The NHS Long Term Plan[4] envisions integrated care systems for England; within which redesigned services can enable a future where care can be personalised when people need it and can be joined-up with fewer appointments with health professionals to receive it.

NHS England and NHS Improvement are leading a number of key programmes of work which aim to put in place the infrastructure to make the vision a reality. The programmes include the Medicines Value Programme, which has been set up to improve health outcomes from medicines and ensure that the NHS in England gets the best value from the NHS medicines bill. Whilst the Medicines Value programme is focused on the NHS in England, similar types of work are taking place in Scotland, Wales and Northern Ireland.

The CPOMM programme aims to enable the selected professions to maximise their ability to improve the patient's care, experience and safety. Optimising medicines and improving access to the right medicines whilst maintaining safety for patients would also be consistent with the government's policy to focus on improved outcomes for all and to transform the way the NHS provides care. The CPOMM programme also supports the achievement of a number of current ambitions across the UK:

In Scotland: supports the delivery of *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*[5], *Health and Social Care Delivery Plan 2016*[6] and *Realising Realistic Medicine 2015/16*[7]

In Wales: supports the achievement of ambitions set out in *Taking Wales Forward 2016-2021*[8], *Prosperity for All: the national strategy*[9] and *A Healthier Wales: our Plan for Health and Social Care*[10]

In Northern Ireland: supports the delivery of *Health and Wellbeing 2026: Delivering Together*[11] and the *Medicines Optimisation Quality Framework*[12]

2.2 Programme of work

In 2015 NHS England undertook a scoping project to determine the need for prescribing, supply and/or administration of medicines responsibilities to be extended to a number of regulated health professionals. The resultant report indicated the legal mechanism of

[3] NHS England (2014) *Five year forward view*
[4] NHS England (2019) *The NHS long term plan*
[5] NHS Scotland (2011*) Achieving sustainable quality in Scotland's healthcare: a 20:20 vision*
[6] The Scottish Government (2016) *Health and social care delivery plan*
[7]The Scottish Government (2017) *Realising realistic medicine: Chief Medical Officer's annual report 2015-16*
[8] Welsh Government (2016) *Taking Wales forward 2016-2021*
[9] Welsh Government (2017*) Prosperity for all: the national strategy*
[10] Welsh Government (2018) *A healthier Wales: our plan for health and social care*
[11] DoH Northern Ireland (2016) *Health and wellbeing 2026: delivering together*
[12] DoH Northern Ireland (2016) *Medicines Optimisation Quality Framework*

administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities.

The CPOMM programme of work commenced on 1 April 2017 to take forward the identified priorities. A programme board was established to oversee this work (see appendix B) and a working group was also founded to support the development of this work (see appendix B).

We are leading consultations on behalf of the four nations on proposals which include changes to medicines responsibilities for 8 regulated 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 using exemptions

All the proposals share the same aim: 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.

Views are sought on the proposed changes for each of the eight professions separately because of the differences between the professions, any unique characteristics which apply to them and the changes being proposed for them. Furthermore, changes to medicines legislation need to be considered independently for each profession. However, only one consultation guide has been developed for both dental therapists and dental hygienists due to the similarity of the professions, although views will still be sought on these two professions separately.

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

3 Introduction to the dental hygiene and therapy professions

Dental hygienists and dental therapists are statutory regulated healthcare professionals. Both professions have been registered with the General Dental Council (GDC) for over 50 years. There are currently 7685* dental hygienists and 3862* dental therapists registered with the GDC in the UK[13]. The terms 'dental therapist' and 'dental hygienist' are protected titles by law.

3373[14] dental therapists and dental hygienists are dual-registered (i.e. registered with the GDC as both a dental hygienist and a dental therapist). This means that over 40% of dental hygienists and around 90% of dental therapists are dual-registered. Likewise, there are some registered dental therapists and dental hygienists who are not dual-registered and therefore must work within the competency of their single registration.

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

3.1 Scope of practice

There is considerable overlap between the scope of practice of dental hygienists and dental therapists with many being dual-registered. However, if they are only registered as a dental hygienist or dental therapist they can only carry out treatments within the scope of practice of that specific profession.

3.1.1 Shared scope of practice of all dental hygienists and dental therapists

Dental hygienists and dental therapists support patients to maintain their oral health by helping to prevent dental disease, treating periodontal (gum) disease and promoting good oral health practice. They carry out treatment for patients as part of a team, directly (without the patient having seen a dentist first) or under a written treatment plan from a dentist. Dental hygienists and dental therapists provide treatment to a wide range of patients of all ages for preventative advice and treatment.

They can carry out a clinical examination, diagnose and plan treatment within their scope of competence, and justify, take and interpret radiographs in compliance with the Ionising Radiation (Medical Exposure) Regulations - IR(ME)R 2017.

Using other mechanisms to supply and administer medicines, dental hygienists and dental therapists already supply and administer medicines including:

- use of local anaesthetics for pain relief during treatment
- use of appropriate anti-microbial therapy to manage plaque-related diseases, including the care of implants and peri-implant tissues
- application of topical fluoride products to reduce dental caries (tooth decay)
- administration of inhalation sedation (following further training) to help nervous patients cope with treatment

They can identify anatomical features, recognise abnormalities and interpret common pathology. They are able, if necessary, to refer to other healthcare professions, such as dentists, oral medicine departments and periodontists. They may also undertake scaling of

[13] General Dental Council, registration report September 2020
[14] General Dental Council, registration report December 2019

the teeth both above and below the gum margins and root surface debridement using manual and powered instruments. However, they cannot carry out the treatments described below in section 3.1.2 unless they are dual-registered.

3.1.2 Specific additions to the scope of practice for dental therapists

In addition to the shared scope of practice described above in section 3.1.1, if registered as a dental therapist they may also carry out direct restorations (fillings) on primary and secondary teeth, pulpotomies (nerve treatments) on primary teeth and extract primary teeth.

3.2 Where dental hygienists and dental therapists work

Dental hygienists and dental therapists work in a variety of settings such as:

- single-handed dental practices
- large multidisciplinary clinics
- community dental clinics
- schools
- private clinics
- universities

Many dental hygienists and dental therapists work in NHS and health service dental practices and whilst they deliver NHS treatment they are not directly employed by the NHS. Some are employed by independent providers and some are self-employed. The precise number of individuals within each of these categories in the UK is not known, although the professional bodies estimate that approximately 80% of their members work in a mixed NHS and private setting.

Since 2013, patients have been given the option to see dental hygienists and dental therapists directly without the need for a referral (also known as direct access). This means that dental hygienists and dental therapists can carry out their full scope of practice[15] without needing a treatment plan from a dentist. Both NHS and privately-owned practices are permitted to offer patients direct access to dental hygienists and dental therapists. However, not every practice will offer treatment via direct access, and they are not required to do so.

3.3 The professional bodies

The British Society of Dental Hygiene & Therapy (BSDHT) and British Association of Dental Therapists (BADT) are the professional bodies representing dental hygienists and dental therapists in England, Scotland, Wales, Northern Ireland and the Channel Islands. The role of the professional body is summarised in appendix C for information.

3.4 Professional regulation

The purpose of professional regulation is to protect the public. The General Dental Council (GDC) is an independent regulatory body that holds the register of dental hygienists and dental therapists in the UK and is responsible for the regulation of the UK dental workforce.

[15] General Dental Council (2017) *Scope of Practice*

It is mandatory that all dental hygienists and dental therapists are registered with the GDC in order to practise. The GDC sets the standards that all dental hygienists and dental therapists must meet in relation to their register entry education[16], performance, conduct and ethics[17] that they must meet relevant to their scope of practice to stay registered. These are the standards that the GDC considers necessary for safe and effective practice.

3.5 How dental hygienists and dental therapists are trained

There are currently 22 GDC-approved education programmes across the UK that lead to GDC registration as a dental hygienist and / or a dental therapist.

3.5.1 Dental hygienist (single registration)

There are several ways to qualify as a dental hygienist in the UK, namely:

- diploma in dental hygiene - two-year full-time course
- foundation degree in oral health sciences (dental hygienist) – 24 months full time

These courses allow individuals to register with the GDC as a dental hygienist.

3.5.2 Dental hygienist and dental therapist (dual registration)

There are several ways to qualify as both a dental hygienist and a dental therapist in the UK, namely:

- diploma in dental therapy - two year part-time for qualified dental hygienists only
- diploma in dental hygiene & therapy - 27-month full time course
- BSc in oral health science - three-year full-time course (or 1 year if already qualified as a dental hygienist)
- BSc (hons) (Edinburgh) - four-year course

These courses allow individuals to register with the GDC as a dental hygienist and dental therapist. Pre-registration dental therapy-only education programmes are not available.

3.6 Continuing professional development (CPD)

Each year, dental hygienists and dental therapists must provide confirmation of their indemnity and verifiable hours of CPD to maintain their registration. Verified CPD is education that has clear learning objectives, recorded hours, is quality assured, allows for the participant to give feedback and a certificate is provided.

The CPD requirements were updated for dental care professionals with effect from 1 August 2018. Dental hygienists and dental therapists are required to demonstrate that they have undertaken 75 hours of verifiable CPD per five-year cycle. They need to maintain a CPD record, which must include a personal development plan (PDP) and a record of the activities they have undertaken. The PDP encourages them to reflect on their learning, development needs, aims and plan CPD to help them achieve those aims and/or to maintain current skills. The 75 hours of CPD should be spread as evenly as possible over the five-year cycle and registrants must complete a minimum of 10 hours over every two-year period.

[16] General Dental Council (2010) *Standards for Education: Standards and requirements for providers*
[17] General Dental Council (2013) *Standards for the dental team*

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 further work should be undertaken to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions within medicines legislation. This is because, whilst dental hygienists and dental therapists are able to supply and administer medicines that have been prescribed by dentists (also known as patient specific directions or PSDs) or by using PGDs where they are available, dental hygienists and dental therapists often need to refer patients to dentists to receive the medicines they need.

Two options have been considered during the development of this proposal.

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, for example, 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 than anticipated such as a certain local anaesthetic because of pre-existing medical conditions or allergies, or whose oral health problem was not anticipated such as oral thrush. The full impact of this option and the limitations of the current mechanisms available to dental hygienists and dental therapists are outlined in section 4.2.

Option 2: proposal 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 need without additional appointments or delays to see another dental professional to receive their medicines. Further information about the anticipated benefits can be found in section 4.3.

Limitations
A small number of patients may still need additional appointments with other health professionals such as dentists to access medicines outside of those that dental hygienists and dental therapists would be permitted to administer or supply under exemptions. This is most likely to be because they need medicines for an oral health condition that is outside of the usual scope of practice of a dental hygienist and dental therapist.

4.2 Limitations of the current supply and administration mechanisms

4.2.1 Patient specific direction (PSD)

Dental hygienists and dental therapists can use PSDs to administer and supply a variety of preparations for patients with gum disease and tooth decay. A PSD is a written instruction from a prescriber to administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine[18]. The PSD then enables dental hygienists and dental therapists to administer or supply the medicine under certain circumstances.

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. However, there are certain limitations to their use:

- they require direct input from an independent prescriber, usually a dentist
- they can be restrictive when access to a prescriber is problematic or if the service provided is non-prescriber led
- organisations may limit locally who is authorised to supply and / or administer medicines using PSDs

The use of PSDs has inherent limitations to practice; for instance, when in situations, where a dentist may not always be immediately available or where a treatment plan may change but still be within the scope of practice of dental hygienists and dental therapists.

PSDs can be limiting and restrict the ability of dental hygienists and dental therapists to practise without the direct involvement of a dentist. Furthermore, a PSD is required for each treatment episode within a course of treatment referred to dental hygienists and dental therapists. 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. A survey undertaken by the BSDHT[19] demonstrated that only 20% of respondents said they received a PSD for each treatment episode and of those, 50% reported that they had not been able to treat patients because an appropriate PSD was not written for the patient.

4.2.2 Patient group directions (PGD)

Since 2010, dental hygienists and dental therapists have been able to supply and administer medicines to patients meeting certain criteria using PGDs. PGDs provide a legal framework that allows the supply and/or administration of a specified medicine(s), by named, authorised, registered health professions, to a pre-defined group of patients needing prophylaxis or treatment for a condition described in the PGD, without the need for prescription or an instruction from a prescriber. They are written instructions for the supply or administration of medicines to groups of patients who may or may not be individually identified before presentation for treatment. They are NOT a form of prescribing[20].

PGDs have been used by dental hygienists and dental therapists in NHS community dental settings and hospital dental services to administer certain medicines when required. In

[18] Specialist Pharmacy Service (2018) Questions about patient specific directions
[19] BSDHT (2015) *Member survey: Prescription only medicines in use* – Not published
[20] NICE (2017) *Patient group directions: medicines practice guideline*

these settings there is the appropriate governance framework to develop and implement PGDs effectively. However, PGDs have been very difficult to develop in the dental primary care setting, where most dental hygienists and dental therapists work because:

- most dental hygienists and dental therapists work with dentists who are themselves not directly employed in the NHS but under contract to deliver dental service Consequently, 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 encountered when developing and implementing PGDs for general dental practice settings has resulted in many dental hygienists and dental therapists working only with PSDs.

4.3 Benefits of the proposal

Although PSDs and PGDs have improved patient care and will continue to have a place in the provision of dental treatment, the impact of the proposed use of specific exemptions in medicines legislation for the supply and administration of medicines is anticipated to benefit patients, commissioners and providers in a number of ways.

4.3.1 Provision of best care, first time, in the right place

Appropriate access to the most commonly used medicines through the proposed use of exemptions would allow dental hygienists and dental therapists to provide effective care that enhances patient outcomes, in line with evidence-based practice and without unnecessary delays or hand-offs of care to other healthcare professionals. This will ensure that patients receive the best care, first time and in the right place. Patients will also have a better experience of dental care because of fewer hand-offs of care and fewer delays in their treatment.

4.3.2 Enhanced patient safety

Under current arrangements, when a PSD or PGD is not in place, dental hygienists and dental therapists are often required to interrupt a dentist during surgery to request a PSD or prescription for the medicines required. Such practice is not only professionally inappropriate for both parties, but it may affect the safety of both the patient under the direct care of the dentist and the patient under the care of the dental hygienist or dental therapist.

4.3.3 Improved outcomes

The proposed use of exemptions by dental hygienists and dental therapists would improve patient outcomes through ensuring they receive the right treatment, at the right time without delay. People with poor oral health report a lower wellbeing, higher levels of depression and poorer satisfaction with their life overall[21]. Dental caries can cause functional, physical and aesthetic impairment, often with repercussions on children's general health at an early age[22]. School performance may also decline. Thus, timely treatment from dental hygienists and dental therapists who can supply and administer medicines under exemptions may

[21] 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

[22] Public Health England (2017) *Health Matters: Child Dental Health*

provide a positive psychosocial impact on these patients, not only for recovering their oral health, but also for promoting an improvement in their quality of life.

4.3.4 Improved access

Effective use of the workforce is also essential in meeting the aims of the *Five Year Forward View*[23] and the *NHS Long Term Plan*[24] by enabling improved access to dental care, reducing duplication and fragmentation of care and making best use of the resources available. This would, in turn, improve patient outcomes and their experiences of dental care. The proposed use of exemptions would make more effective use of staff resources by reducing the need for patients to attend additional appointments with the dental hygienist or dental therapist and / or to see a dentist just to access medicines needed; and allowing dental hygienists and dental therapists have more availability to see more patients.

Use of exemptions will also enable dental hygienists and dental therapists to undertake routine practice outside of the clinical setting and traditional hours because they will be able to administer and supply certain medicines as part of the clinical care they offer, without the need for access to a dentist. Community-based dental screening clinics in schools and residential homes undertaken by dental hygienists and dental therapists would allow improved access to dental services for patients, which would lead to timely diagnosis, treatment and prevention of dental diseases.

4.3.5 Clearer lines of clinical responsibility and accountability

In addition to improving the quality of care patients receive, the proposed use of exemptions would define clearer lines of clinical responsibility, and a governance framework to ensure patient safety. The proposed use of exemptions would negate the need for PSDs for medicines cited on the exemptions list and therefore allow dental hygienists and dental therapists to be accountable for the decisions they make regarding the administration and supply of medicines following an assessment of the patient at the time of the visit.

4.3.6 Reduced absenteeism

A nationwide study of UK employees has discovered an estimated 415,000 people miss at least a day of work each year due to oral health problems, whilst one in five say they would be prepared to call in sick because of toothache, costing the UK economy an estimated £36.6 million each year[25]. Using exemptions as proposed would enable dental hygienists and dental therapists to provide treatment without delay which would reduce the need for additional appointments and therefore reduce absence from work, school and other such commitments.

[23] NHS England (2014) *Five year forward view*

[24] NHS England (2019) *The NHS long term plan*

[25] 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

4.4 Use in clinical practice

The scenarios below demonstrate how dental hygienists and dental therapists might use exemptions to administer or supply some of the proposed medicines within clinical practice and the benefits to be gained from this proposal.

Scenario 1- high strength fluoride

Fluoride is one of the best ways to prevent tooth decay and strengthen teeth, whilst it is widely available in toothpastes some patients are at a higher risk of tooth decay and need higher strengths of fluoride to strengthen and re-harden the tooth. The higher strength products are only available as prescription only medicines and are widely used by dental hygienists and dental therapists for patients of all ages.

The children's dental health survey[26] highlighted that almost a third of five-year-olds are suffering from tooth decay; it is the most common single reason why five- to nine-year-olds are admitted to hospital. Tooth and root decay also affects adults of all ages and can be a common side effect for those who are affected by a dry mouth which can be a consequence of treatments such as head and neck radiotherapy or some medicines. Tooth decay is preventable and dental hygienists and dental therapists use education and the application of fluoride varnish and/or other high strength fluoride toothpastes, for those who are susceptible.

Currently, dental hygienists and dental therapists use either a PGD or more commonly a PSD to supply or administer these medicines. If there is a clinical need for a patient to use one of these medicines which hasn't been identified in the treatment plan dental hygienists and dental therapists will either:

a) interrupt the referring dentist to write the PSD
b) request another dentist to examine the patient and write up a prescription or
c) the patient will be required to leave without the fluoride treatment they need and they must return at a later date when the prescription is in place.

If dental hygienists and dental therapists were able to use exemptions to administer and supply these fluoride products at the point of contact it would ensure patients received timely treatment to protect their teeth from further decay whilst also effectively utilising the dental team.

[26] Health and Social Care Information Centre (2015) *Child Dental Health Survey 2013, England, Wales and Northern Ireland*

Scenario 2- local anaesthetic

Dental Caries (tooth decay) affects people of all ages and is the most common disease in young children. The most recent Child Dental Health Survey[27] undertaken in 2013 found that 47% of five-year-old children in England had evidence of dental caries. Although substantive improvements have been seen in the dental health of older children and adults (ADHS, 2009), no significant reduction in disease experience in young children has been observed for over twenty years.

The treatment for dental caries can be uncomfortable for patients of all ages; to aid patient compliance and complete what is necessary to help restore oral health, local and topical anaesthetics can be used. The type of local anaesthetic used can vary depending on the patient's medical and or social history. Changes in medical history such as hypertension and pregnancy can also affect the type of anaesthetic that is used. Currently such a change would necessitate:

- the patient to be seen again by the referring dentist to rewrite the PSD
- the dental hygienist or dental therapist needing to disturb the dentist during surgery to request the PSD
- possible delays to completion of treatment and to further appointments that day which puts extra pressure on the dental team whilst also being an inconvenience to the patient, especially if the dentist was not on the premises to issue a PSD

The use of exemptions would enable dental hygienists and dental therapists to administer the most appropriate and effective local anaesthetic for the patient without needing a PSD.

Scenario 3- nystatin

Certain situations or conditions can cause an imbalance in the normal bacteria in the mouth, particularly of Candida albicans which can lead to oral candidiasis (thrush). These situations include wearing dentures, following a course of antibiotics, using corticosteroid inhalers, having diabetes or anaemia, being in poor health, and smoking. Oral candidiasis is usually harmless and can be easily treated; however, it can be painful and reduce the ability to eat or drink, potentially causing further deterioration of health. Treatment can include using a medicine (miconazole oral gel) bought directly from a pharmacy (over the counter). However, this treatment is contra-indicated for patients taking statins and warfarin, medicines which are taken by a large number of elderly people living in care homes. Oral candidiasis can also be treated using nystatin oral suspension which is an antifungal preparation and is a prescription only medicine.

The community dental service provides dental care to patients with special or additional needs and dental hygienists and dental therapists carry out domiciliary visits, particularly into care homes to provide this care. Dental hygienists and dental therapists may identify oral candidiasis in patients who are unable to self-care or where the over the counter preparation is contra-indicated. Currently if there is no PGD or PSD in place, dental hygienists and dental therapists are unable to supply nystatin oral suspension to the patient and instead a doctor or dentist must examine the patient and prescribe the medication. This results in a delay in the patient receiving their treatment, increases the workload for the doctor or dentist and adds extra cost to the service.

With the use of exemptions, dental hygienists and dental therapists would be able to supply nystatin oral suspension. Benefits would include that the patient would receive timely treatment which would reduce their discomfort whilst also avoiding an additional visit by the dentist, which in turn optimises the use of the dental team and therefore the capacity of the dental practice.

[27] Health and Social Care Information Centre (2015) *Child Dental Health Survey 2013, England, Wales and Northern Ireland*

Scenario 4- minocycline

Implants are becoming increasingly common in the replacement of missing teeth. They are artificial titanium posts implanted into the bone of the jaw which act as a replacement for missing teeth and offer the patient a more "permanent" restoration of the missing tooth. Implants are not immune to disease and can be rejected by the body or fall out. Pain is not always a symptom of this condition so prompt action is important. Patients with dental implants need regular care and review appointments with the dental team.

If a patient presents with peri-implantitis (disease of the supporting structures of the implant) the guidance from the Association of Dental Implantology (ADI)[28] advises debridement (cleaning) of the implant surface, application of antibiotics directly to the affected area and if this does not resolve the problem then a referral to a specialist dentist is necessary. Peri-implantitis is a quickly progressing disease and treatment at the time of diagnosis is important. At present, a PSD for the necessary topical antibiotics is required from the patient's dentist; therefore, prompt treatment of the peri-implant disease is dependent on the availability of a dentist. If there is no dentist available, then this can result in the patient's treatment being delayed.

Exemptions for dental hygienists and dental therapists would allow for the use of this topical antibiotic to promptly stabilise the peri-implant disease until specialist intervention can be arranged, thus improving the chances of a successful outcome.

4.5 Management of potential risks associated with the proposal

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

There are a number of potential risks to the proposal to enable dental hygienists and dental therapists to supply and administer specific medicines under exemptions. The risks perceived are not unique to dental hygienists and dental therapists; they are similar to those for other professions that use exemptions to supply and administer medicines. As such, they can be mitigated against by the governance and patient safety measures described in section 5. The main potential risks perceived of the proposal, and a summary of the mitigating actions that can be taken are included in table 1 below.

[28] Ucer C, Wright S, Scher E, M, West N, Retzepi M, Simpson S; Slade K; Donos N (2012) *ADI guidelines on the management of peri-implant diseases*

Potential risk	Potential solution
Dental hygienists and dental therapists may supply or administer a medicine using exemptions without having successfully completed an approved training programme.	• Dental hygienists and dental therapists must only supply and administer medicines within their scope of practice and competence and the GDC has the powers to remove individuals from their register if they fall below the standards required. • The *Draft Practice Guidance* advises about training requirements prior to using exemptions. • The *Draft Outline Curriculum Framework* states the education competencies that will need to be met to fulfil the requirements for dental hygienists and dental therapists to use exemptions.
Exemptions programmes may be cost-prohibitive for dental hygienists and dental therapists or dental practices may not be able release dental hygienists and dental therapists to undertake the training due to lack of capacity. The impact being inconsistency in the provision of care provided because patients seeing these dental hygienists and dental therapists would not experience the benefits.	• Communication and engagement with relevant stakeholders regarding funding available to support implementation. • Training in the use of exemptions will initially be at a post-graduate level. In the future, the training is expected to be embedded within the undergraduate programmes for dental hygienists and dental therapists so that new members of the profession would be trained to use exemptions at the point of registration with the GDC. • Training programmes will be expected to contain a range of delivery methods, for example flexibility offered by blended learning.
Anti-microbial resistance may be affected from potential inappropriate supply and/or administration of the two antimicrobial medicines on the exemptions list.	• Dental hygienists and dental therapists will be further educated regarding antimicrobial resistance as part of training to use exemptions. • Antimicrobial stewardship forms part of the *Draft Practice Guidance*. The document strongly recommends ongoing training and supervision, adherence to local formularies and local and national guidelines. • Dental hygienists and dental therapists must ensure that they have all relevant information in relation to the safe supply and administration of any medicine for the individual patient, including antimicrobials. This may include obtaining additional information from the patient and their GP to ensure clinical appropriateness.

There may be an increase in the use of medicines with increased associated costs to the system.	• The list of proposed medicines for dental hygienists and dental therapists to administer or supply includes only those that would otherwise be prescribed by a dentist or already administered / supplied by dental hygienists and dental therapists using a PSD or PGD. • Being available under exemption for dental hygienists and dental therapists will not increase the prevalence of use, just the mechanism by which patients receive some medicines will change.

Table 1: Potential risks and governance measures to manage them

5 Governance and patient safety

5.1 Safe use of exemptions within medicines legislation

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*[29] contains full details of the considerations related to the safe supply and administration of the proposed medicines using exemptions by dental hygienists and dental therapists.

5.1.1 Profession-specific list

Registrants working under exemptions within the Human Medicines Regulations would only be permitted to supply and administer those medicines that pertain to their profession. For example - dental hygienists and dental therapists practising as such would only be permitted 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 or administer any other medicines without an additional mechanism such as a PGD or prescription being in place.

Dental hygienists and dental therapists trained to use exemptions would only be permitted to supply or administer the listed medicines that are within their scope of practice and competence. Furthermore, delegation of the supply or administration of a medicine using exemptions to another health professional is not permitted.

5.1.2 Local governance

Whilst registrants with the relevant qualification are legally permitted to supply or administer any of the approved medicines on their exemptions list provided they fall within their 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 hygienists and dental therapists to supply and administer only a number of the listed medicines. These restrictions would only apply to practice for that employer. Registrants must work to such locally-agreed protocols and procedures at all times in addition to the standards set by the regulator and any guidance provided by their professional body.

5.1.3 Professional accountability

When working under exemptions, dental hygienists and dental therapists would be professionally accountable for their decisions regarding the supply and administration of medicines using exemptions, including actions and omissions. They must work under their professional standards as directed by the regulator and professional bodies.

This also means that, although dental hygienists and dental therapists could supply or administer a medicine legally, they are not obliged to do so. This could be in relation to patient safety information about the medicine or a change to best practice guidelines which discourage the future use of the medicine. Dental hygienists and dental therapists should be aware of such changes and change practice accordingly.

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[29] British Association of Dental Therapists, British Society for Dental Hygiene and Therapy *Draft Practice Guidance for Dental Therapists and Dental Hygienists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*

5.1.4 Adverse drug reactions, interactions and errors

If an error in supply or administration occurs whilst using exemptions, dental hygienists and dental therapists must take immediate action to manage the effects on the patient, prevent potential side effects to the patient and must report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way, in order that anything learned from the incident is shared as appropriate.

If a patient experiences an adverse reaction to a medication: once the required treatment has been undertaken, this should be recorded in the patient's notes and, if indicated, the Medicines and Healthcare products Regulatory Agency should be notified via the Yellow Card Scheme[30]. Dental hygienists and dental therapists are expected to be able to recognise common side effects and adverse reactions to the medicines they administer, and to know when there is a potential risk of an interaction[31].

5.2 Eligibility to train to use exemptions within legislation

Eligible dental hygienists and dental therapists wishing to access exemptions in medicines legislation would be required to gain entry to and successfully complete an approved training programme before using exemptions. They would also be required to undertake appropriate steps to maintain their skills and competence in keeping with the GDC's *Standards for the Dental Team*[32].

It is proposed that all dental hygienists and dental therapists wishing to enter an exemptions training programme would need to meet the following requirements:

- be registered with the GDC as a dental hygienist and / or a dental therapist
- be practising in an environment where there is an identified need for the individual to regularly use exemptions in legislation
- be able to demonstrate that medicines and clinical governance arrangements are in place to support safe and effective use of exemptions
- 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
- be able to demonstrate how they reflect on their own performance and take responsibility for their own CPD
- 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.

[30] MHRA *Yellow Card Scheme*

[31] British Association of Dental Therapists, British Society for Dental Hygiene and Therapy *Draft Practice Guidance for Dental Therapists and Dental Hygienists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*

[32] General Dental Council (2013) *Standards for the Dental Team*

5.3 Education programme

A draft *Outline Curriculum Framework* [33] (OCF) to prepare dental hygienists and dental therapists to use exemptions has been developed by the professional bodies in conjunction with key stakeholders, including the GDC. The draft OCF is aimed at education providers intending to develop education programmes for dental hygienists and dental therapists interested in education programmes to fulfil the requirements to be qualified to use exemptions.

Training in the use of exemptions will initially be at a post-graduate level. Not all dental hygienists and dental therapists would be expected to train to use exemptions as they may not meet all the entry criteria listed above. In the future, it may be possible for the training to be embedded into the undergraduate training programmes for dental hygienists and dental therapists so that new members of the profession would be trained to use exemptions at the point of registration with the GDC. This is under active consideration by the GDC, as a key partner of this programme.

The Faculty of General Dental Practice (UK) (FGDP(UK)) will approve the education programmes for dental hygienists and dental therapists and will do this against the requirements of the OCF. The FGDP(UK) will also maintain a register of those dental hygienists and dental therapists who have successfully completed the education programme and are therefore qualified to use exemptions in their clinical roles. The register will be publicly available in order that patients and the public can readily seek assurance.

As a consultation partner, the GDC has undertaken to amend its scope of practice[34] document in due course to reflect the agreed arrangements that enable dental hygienists and dental therapists to use exemptions.

5.4 Communication of decisions to use exemptions

It is not expected that the communication of the proposed use of exemptions would require any change to the current communication processes undertaken by dental hygienists and dental therapists when administering or supplying medicines using PSDs or PGDs. If able to use exemptions, dental hygienists and dental therapists will have access to comprehensive dental records when administering or supplying medicines to patients. These include a full medical history taken from the patient and updated at each visit. They will also obtain additional information from the patient and other health professionals including their GP, as required. Dental hygienists and dental therapists must assure themselves that they have all relevant information in relation to the safe supply and administration of medicines for the individual patient and if there is any doubt, further information should be sought before making a decision whether to supply or administer medicines to the patient under exemptions.

Any medicines administered by dental hygienists and dental therapists for prevention or treatment purposes will be recorded within the patient's dental notes. This information would not routinely be communicated to the patient's GP but would be available to all the dental team. It is seldom necessary that information about medicines supplied in dental

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[33] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

[34] General Dental Council (2017) *Scope of Practice*

practice is communicated to the patient's GP but it is recorded within the patient's dental notes. Dental hygienists and dental therapists already undertake these processes when using PSDs and PGDs.

5.5 Antimicrobial resistance

Where supply or administration of antimicrobial medicines using exemptions is indicated, dental hygienists and dental therapists must take the requirements of antimicrobial stewardship into consideration. This is in line with national guidance[35] and to ensure the good infection prevention and prudent antimicrobial use that are essential to ensure safe and effective care[36]. Pending legislative change, when administering or supplying antimicrobials using exemptions, dental hygienists and dental therapists must work within local antimicrobial guidelines which take into consideration local resistance patterns. This may mean that one or more of the antimicrobials are not used in that locality, even though they are listed in legislation for use.

The two antimicrobials in the proposed list of medicines are indicated for use in dental care for very specific purposes and are already being administered and supplied by dental hygienists and dental therapists using other medicines mechanisms; therefore being available under an exemption for dental hygienists and dental therapists will not increase the prevalence of use, just the mechanism by which patients receive required antimicrobials will change.

Dental hygienists and dental therapists who will be required to administer or supply antimicrobials using exemptions will need to successfully complete an approved education programme on the safe use of exemptions, based on the draft *Outline Curriculum Framework*[37] which includes learning outcomes related to antimicrobial resistance. The draft *Practice Guidance*[38] developed by the professional bodies strongly recommends that dental hygienists and dental therapists administering or supplying antimicrobials undertake additional training about their role in antimicrobial stewardship. Resources[39] including the Dental Antimicrobial Stewardship Toolkit[40] are also 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.

5.6 Use of exemptions within legislation by private practitioners

Changes to legislation to permit dental hygienists and dental therapists to supply and administer medicines under exemptions within the Human Medicines Regulations would apply throughout the UK, in any setting in which dental hygienists and dental therapists work including the NHS, independent and voluntary sectors. Employers outside of the NHS have the same roles and responsibilities as those within the NHS and must implement the

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

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

[37] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

[38] British Association of Dental Therapists, British Society for Dental Hygiene and Therapy *Draft Practice Guidance for Dental Therapists and Dental Hygienists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*

[39] Faculty of General Dental Practice (UK)(2012) *Antimicrobial Prescribing for General Dental Practitioners*

[40] Public Health England (2016) *Dental antimicrobial stewardship: toolkit*

same standard of local governance arrangements related to the safe storage, supply and administration of medicines.

Dental hygienists and dental therapists working outside the NHS will still need to meet the same entry requirements of the education programmes, including demonstration that they have appropriate governance arrangements in place for their role as dental hygienists and dental therapists using exemptions. They must also comply with the same GDC standards and practice guidance as their NHS-employed colleagues and their practice is subject to the same level of scrutiny.

In addition to their registration as dental hygienists and / or dental therapists with the GDC, if dental hygienists and dental therapists work independently their practice or clinic must also be registered and regulated by one of the following, depending on the location of the practice:

- in England, the Care Quality Commission - the independent regulator of health and adult social care service providers in England
- in Wales, Healthcare Inspectorate Wales - the independent inspectorate and regulator of healthcare in Wales
- in Northern Ireland, the Regulation and Quality Improvement Authority - responsible for inspecting the availability and quality of health and social care services
- in Scotland, Care Inspectorate Scotland - responsible for regulating independent healthcare services.

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 is required 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 within England, Scotland and Wales have legal obligation under the Equality Act 2010[41], and are required to have due regard to the aims of the Public Sector Equality Duty[42] (PSED) set out at section 149 of the Equality Act 2010, in exercising their functions, such as when making decisions.

There are three aims to the PSED and public bodies must, in exercising their functions, have due regard to them all. They are the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it

The PSED covers the following protected characteristics:

- age
- disability
- gender reassignment
- pregnancy and maternity
- race (includes ethnic or national origins, colour or nationality)
- religion or belief (includes lack of belief)
- sex
- sexual orientation
- marriage and civil partnership (but only in regard to the first aim of the PSED- eliminating discrimination and harassment)

As this is a UK-wide consultation, due regard has also been given to the requirements of section 75(1) of the Northern Ireland Act 1998[43] which requires all public authorities in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status and sexual orientation
- men and women generally

[41] Equality Act 2010

[42] Public Sector Equality Duty 2011

[43] Northern Ireland Act 1998

- persons with a disability and persons without
- persons with dependants and persons without

Furthermore, section 75(2) of the 1998 Act requires public authorities without prejudice to their obligations under subsection (1) to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion and racial group.

6.2 Health inequality duties

Health inequalities have been defined as ‘differences in health status or in the distribution of health determinants between different population groups’ by the World Health Organisation. The National Health Service Act 2006 as amended by the Health and Social Care Act 2012[44] established specific legal duties on NHS England and NHS Improvement to ‘have regard’ to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way.

The Act does not define a list of groups impacted by the duties, any group experiencing health inequalities is covered. This means that NHS England and NHS Improvement must consider the whole of the population for which they are responsible, identify inequalities within that population group and have regard to the need to reduce inequalities when exercising their functions.

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.

[44] Health and Social Care Act 2012

7 Consultation format

7.1 Who can respond to this consultation?

Everyone is welcome to respond. We are keen 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 questionnaire
- requesting a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net

  Please complete this form and return it to:

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

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

This consultation remains open for eight weeks and will close on **10th December 2020**.

7.3 Alternative formats

- A patient and public summary version of this consultation guide is available; it can be made available in alternative formats such as large print and easy read, and may be available in alternative languages, upon request. Please contact england.cpomedicinesmech@nhs.net
- A paper copy of the patient and public summary consultation guide is available on 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 review, analyse and consider all responses received. 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 Ministers; the Medicines and Healthcare products Regulatory Agency will make the necessary amendments. The Human Medicines Regulations are co-signed by the Secretary of State and the Minister of Health in Northern Ireland and 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.

8 Appendices

8.1 Appendix A: Clinical indications for use of proposed medicines

Proposed list of medicines to be included within the list of exemptions to be used by dental hygienists and dental therapists	
Lidocaine with adrenaline	
Use	Clinical need for inclusion on exemption list
A type of local anaesthetic used to numb the mouth when the dental hygienist and dental therapist is: • cleaning above and below the gums when teeth are sensitive • cleaning around dental implants that might have a gum • removing decay or fillings from teeth • doing deep fillings that might involve the nerve in baby teeth • taking out baby teeth	• The first-choice local anaesthetic. It can be used on most patients but not all; for example, if they are taking certain medicines or have certain health conditions. • It can be used for injections in the upper or lower jaw. • It includes adrenaline which also helps to stop bleeding.
Articaine hydrochloride with adrenaline	
Use	Clinical need for inclusion on exemption list
A type of local anaesthetic which can be used for all patients aged over 3 years (see list of uses above).	Particularly good at giving anaesthesia when it's difficult to give an injection in the lower jaw called a "block". This is an injection that numbs half the lower lip and half the tongue and can be more difficult to give in some patients. This might be because they find it difficult to sit still or because they have an infection in one of their teeth.
Mepivacaine hydrochloride	
Use	Clinical need for inclusion on exemption list
A local anaesthetic used to provide pain relief for both simple and complex dental procedures in adults, adolescents and children 4 years of age or older (see list of uses above).	• Does not include adrenaline, so can be used if the patient has a certain heart conditions where adrenaline might lead to complications. • Good if patients have certain allergies for example latex allergy as the device it is in has latex-free plungers and seals. • Does not contain methylparaben as a preservative. This is useful in patients who are allergic to this ingredient.
Prilocaine with felypressin	
Use	Clinical need for inclusion on exemption list
A local anaesthetic used to provide pain relief (see list of uses above).	Does not include adrenaline, but does include felypressin which also helps to stop bleeding. Can be used in patients with certain heart conditions, where it is still important to reduce bleeding.
Lidocaine and prilocaine (periodontal gel)	
Use	Clinical need for inclusion on exemption list
A local anaesthetic gel which can be placed directly on the gums for adults during gum treatment which might otherwise be painful.	• Indicated for adults who require localised pain relief in the gums during treatment. • Soft tissue pain relief for those with a fear of injections.

Sodium fluoride varnish	
Use	Clinical need for inclusion on exemption list
• Indicated for use in all children and in adults with tooth decay. • A highly concentrated form of fluoride which is put onto the surfaces of teeth by the dental hygienist and dental therapist using a brush. It helps to prevent tooth decay. • Can also help to reverse very early decay and it can help sensitive teeth. • Can also be used for people who are at greater risk of getting tooth decay, for example people with dry mouths or children wearing braces.	As a topical treatment it has a number of practical advantages: • well accepted and considered to be safe • the application of fluoride varnish is simple so patients find it a pleasant procedure Recommended in the *Delivering Better Oral Health* toolkit[45] to help prevent decay.
Sodium fluoride toothpaste (0.619% (2800ppm))	
Use	Clinical need for inclusion on exemption list
Suitable for adults and children over 10 years of age who may be at risk of tooth decay. For example if they have: • active or a history of dental decay • high sugar diets • orthodontic appliances (braces)	Prevention of dental caries and treatment of early dental decay for adults and children over 10 years of age.
Sodium fluoride toothpaste (1.1% (5000ppm))	
Use	Clinical need for inclusion on exemption list
Suitable for adults and children over 16 years of age who may be at risk of tooth decay for example if they have: • active or a history of dental decay • exposed root surfaces • high sugar diets • orthodontic appliances (braces) • dry mouth	Prevention of dental caries and treatment of early dental decay for adults and children over 16 years.
Minocycline (periodontal gel)	
Use	Clinical need for inclusion on exemption list
• One of a group of antibiotics called tetracycline. • It can be used to help treat severe gum disease in adults, by placing it directly on the gums.	Can be used to treat: • moderate to severe gum disease affecting a small area of the mouth in adults • also indicated in the guidance for the treatment of an infection around an implant[46]
Nystatin oral suspension	
Use	Clinical need for inclusion on exemption list
Anti-fungal to treat oral thrush.	An antifungal medicine used for treatment of oral thrush in the mouth or soreness and cracking at the corners of the mouth.

[45] Public Health England. (2014) Delivering better oral health: an evidence-based toolkit for prevention
[46] Ucer C, Wright S, Scher E, M, West N, Retzepi M, Simpson S; Slade K; Donos N (2012) ADI guidelines on the management of peri-implant diseases

8.2 Appendix B: Contributors

8.2.1 Chief Professions Officers' Medicines Mechanisms Programme Board

Name	Organisation	Organisational Role
Professor Martin Stephens (Chair)	University of Portsmouth/NHS England and NHS Improvement	Visiting professor/Local Pharmacy Network Chair
Suzanne Rastrick (SRO)	NHS England and NHS Improvement	Chief Allied Health Professions Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief Allied Health Professions Officer
Fiona Carragher (until 31.12.18)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Angela Douglas (from 1.4.19)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Janet Clarke	NHS England and NHS Improvement	Deputy Chief Dental Officer
Dr Bruce Warner	NHS England and NHS Improvement	Deputy Chief Pharmaceutical Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19 - 30.9.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Claire Potter	Department of Health and Social Care	Medicines Regulation & Prescribing
Graham Prestwich	NHS England and NHS Improvement	Patient & Public Representative
Bill Davidson	NHS England and NHS Improvement	Patient & Public Representative
Anne Ryan	Medicines and Healthcare products Regulatory Agency	Policy Division
Katherine Gough	NHS Dorset CCG	Head of Medicines Management
Dr Joanne Fillingham	NHS Improvement	Clinical Director Allied Health Professions, Deputy Chief AHP Officer
Professor Iain Beith	Council of Deans for Health	Head of a multidisciplinary Health and Social Care School
Graham Mockler	Professional Standards Authority	Head of Accreditation
Samina Malik	Health Education England	Senior Education and Training Policy Manager
Jan Beattie	Scottish Government	Allied Health Professions Officer for Primary Care
Dr Rob Orford	Welsh Government	Chief Scientific Adviser (Health)
Dr Mark Timoney (until 7.12.18)	Northern Ireland Government	Chief Pharmaceutical Officer
Hazel Winning (from 1.1.19 – 1.9.19)	Northern Ireland Government	Lead Allied Health Professions Officer
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.2.2 Exemptions project working group

Name	Organisation	Role
Janet Clarke (Chair) (until 30.9.19)	NHS England and NHS Improvement	Deputy Chief Dental Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19)
Professor Nick Barker (from 15.10.19)	East Suffolk & North Essex NHS Foundation Trust	Project SRO
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Fiona Sandom	British Association of Dental Therapists	Past president and professional body representative
Michaela O'Neill	British Society of Dental Hygiene and Therapy	Past president and professional body representative
Janet Collins (until 6.7.18)	General Dental Council	Head of Standards
Hannah Winter (until October 2018)	General Dental Council	GDC Representative
Richard Drummond (from October 2018)	General Dental Council	Head of Public Policy
Christopher Walker	NHS England and NHS Improvement	Patient & Public Representative
Debs Smith (until 22.6.18)	NHS England and NHS Improvement	Patient & Public Representative
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.3 Appendix C: Role of the professional bodies

The British Society of Dental Hygiene and Therapy

The British Society of Dental Hygiene & Therapy, (BSDHT) - formerly the British Dental Hygienists' Association, - was set up in 1949. Nearly 70 years later, the BSDHT is a nationally recognised body that represents over 4000 members of the profession in the UK and internationally and is the UK's largest professional body for practising dental hygienists, dental therapists and students of the professions.

The mission of BSDHT is to:

- represent the interests of its members
- provide a consultative body for public and private organisations on all matters relating to dental hygiene and therapy
- influence positive change and provide information
- work with other professional and regulatory groups to provide the most up-to-date and accurate information to members as well as to the public

Having been instrumental in many of the developments in the profession over the years the Society continues to work for and on behalf of all members and their patients. The BSDHT website offers guidance and standards that the professions can reference and has a public-facing page.

The British Association of Dental Therapists

The British Association of Dental Therapists (BADT) represents dental therapists and dental hygienists in the UK and Northern Ireland and has approximately 500 members. The BADT was founded in 1962 with the first annual general meeting taking place on 2 March 1963 at New Cross School for Dental Auxiliaries.

Since that time the BADT has been working for dental hygienists and dental therapists in all areas of the profession, improving working conditions and pay, striving for good relationships, good practice, quality education courses and increasing recognition. The BADT website offers guidance and standards that the professions can reference.

8.4 Appendix D: Frequently asked questions.

1) Why are the proposed exemptions for dental hygienists and dental therapists needed?

There are many potential benefits for patients, commissioners and health care providers of the proposal. In some clinical pathways, the scope of the existing legislation fits well with the needs of patients and enables optimal care. For example, the use of PGDs works for some dental hygienists and dental therapists working in community services and secondary care, however they do not best support the needs of patients in general dental practice. Where patients require medicines outside those specified in PGDs, or when a PGD is not available, a prescriber (normally a dentist) would need to be involved in the diagnosis or treatment to write a PSD. The existing arrangements result in unnecessary delays and are costly to administer.

With the proposed exemptions, patient outcomes would improve through ensuring they receive the right treatment, from dental hygienists and dental therapists without delay. Patient experience would be enhanced through improved access to appointments, resulting in improved convenience and choice across the multi-disciplinary dental teams, especially in a time where there is an increasing demand for dental services.

2) Would *all* dental hygienists and dental therapists be able to use exemptions as proposed?

Not all dental hygienists and dental therapists would meet the entry requirements for training. Only dental hygienists and dental therapists who are currently registered with the GDC and who have an identified clinical need for exemptions within their practice will be eligible to train to use the proposed exemptions.

In the future, it may be possible for the training to be embedded in the undergraduate programme for dental hygienists and dental therapists so that new members of the profession would be trained to use exemptions as part of their degree. This is in line with the podiatry, optometry and midwifery professions.

3) What training would dental hygienists and dental therapists receive in order to be able to use exemptions as proposed?

Comprehensive education programmes would be put in place to ensure that dental hygienists and dental therapists are sufficiently competent, confident and educated to supply and administer medicines using exemptions. The British Society of Dental Hygiene & Therapy and the British Association of Dental Therapists have developed a draft *Outline Curriculum Framework*[47] for education programmes to prepare dental hygienists and dental therapists to use exemptions.

4) Who will approve the education programmes for dental hygienists and dental therapists?

Following conversations with The Faculty of General Dental Practice (UK), it has been agreed that, working closely with the General Dental Council, they are able to provide approval of education programmes and hold a register of dental hygienists and dental therapists who are qualified to use exemptions. Further conversations are being held with other organisations such as the Royal College of Surgeons (Edinburgh) and the University of Bangor and they may be considered as a contingency.

[47] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

5) How can we be assured that it would be safe to allow dental hygienists and dental therapists to supply and administer medicines under exemptions as proposed?

Patient safety remains of paramount importance to dental hygienists and dental therapists. They have a long history of supplying and administering medicines via PGDs and PSDs, and are therefore already experienced in supplying and administrating the proposed medicines albeit via a different mechanism.

If changes of legislation occur, the draft *Practice Guidance*[48] will be published and will provide best practice guidance and considerations. The document will apply to dental hygienists and dental therapists and their employers to enable safe use of exemptions to administer and supply the listed medicines.

Dental hygienists and dental therapists using the proposed exemptions would be accountable for their actions to both their employers and the GDC which includes adherence to standards and best practice guidance including the *Practice Guidance*.

Additionally, the draft *Outline Curriculum Framework*[49] (OCF) will inform the curriculum of education programmes which will prepare dental hygienists and dental therapists to use the proposed exemptions. The OCF contains required learning outcomes which, should the dental hygienists and dental therapist successfully complete the education programme, will enable them to demonstrate that they can use exemptions safely. Extending access to medicines administration and supply mechanisms has the potential to improve patient safety by reducing delays in care, improving compliance with medicines and supporting clearer lines of professional responsibility.

6) Would dental hygienists and dental therapists be able to supply and administer medicines to children using the proposed exemptions?

It is proposed that dental hygienists and dental therapists using exemptions will be able to supply and administer medicines to children if this falls within their scope of practice and competence. Dental hygienists and dental therapists already have experience in the supply and administration of medicines to children using PGDs and PSDs. In addition, local and national policies and procedures would need to be followed which address medicine management issues in paediatrics.

7) How do we ensure the proposed use of exemptions by dental hygienists and dental therapists would not increase antimicrobial resistance?

All healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of microbes. It is proposed that all dental hygienists and dental therapists supplying or administering medicines via exemptions will be required to work within their scope of practice and the *Antimicrobial Prescribing and*

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[48] British Association of Dental Therapists, British Society for Dental Hygiene and Therapy *Draft Practice Guidance for Dental Therapists and Dental Hygienists for the Supply and Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*

[49] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

Stewardship Competencies[50]. They would also be required to follow local policies for antimicrobial use. This is a specific competence included in the Draft OCF[51].

8) How do we ensure the proposed use of exemptions by dental hygienists and dental therapists would not contribute to oversupply of medication?

Medicines supply and administration is not an activity that occurs in isolation, dental hygienists and dental therapists using exemptions would communicate with other practitioners involved in the care of patients in order to ensure that medicines supply is not duplicated and is appropriate for the condition to be treated.

9) How would dental hygienists and dental therapists using exemptions maintain their competency in the proposed use of medicines?

Practising dental hygienists and dental therapists are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence[52]. To maintain registration with the GDC, dental hygienists and dental therapists must sign an annual professional declaration to confirm that they continue to meet the GDC's standards for continuing professional development.

Examples of CPD for dental hygienists and dental therapists include:

- peer review
- peer supervising and teaching
- attending regular meetings
- attending study days
- recording self-reflection
- presenting at conferences

Dental hygienists and dental therapists working within the NHS community service also require annual appraisals, of which medicines management will be a part.

10) Would dental hygienists and dental therapists working outside of the NHS be able to train to use exemptions as proposed?

Yes, provided they meet the entry requirements of the education programme, including demonstration that they have appropriate governance arrangements in place for their role as a dental hygienist and / or dental therapist using exemptions.

11) Would the proposed use of exemptions by dental hygienists and dental therapists mean that they would also be able to write prescriptions?

No, exemptions are not a prescribing mechanism. The exemptions will only allow dental hygienists and dental therapists to supply and administer the proposed medicines. Dental hygienists and dental therapists will not be able to write prescriptions for any medicines.

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[50] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies*

[51] British Association of Dental Therapists and the British Society of Dental Hygiene & Therapy *Draft Outline Curriculum Framework for Education Programmes to prepare Dental Hygienists and Dental Therapists to use exemptions*

[52] General Dental Council *The enhanced CPD guidance*

9 Glossary

Term	Explanation
Administration of medicines:	Process by which a medicine is introduced into, or applied onto, the patient’s body.
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 ministers on the safety, effectiveness and quality of medicinal products and on changes to medicines law.
Continuing professional development:	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.
Direct access:	Way of working in England where dental hygienists and dental therapists can see, examine and treat patients within their scope of practice without the patient having seen a dentist first.
Exemptions:	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).
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.

Term	Explanation
General Dental Council (GDC):	Responsible for the regulation of the UK dental team of approximately 40000 dentists and 60000 dental care professionals. The GDC maintains a register of dental professionals that are fit to practise in the UK, and is responsible for setting the standards that all dental hygienists and dental therapists must meet regarding their education, performance, conduct and ethics. It is mandatory that dental hygienists and dental therapists register with the GDC in order to practise.
General sales list (GSL) medicines:	Medicines that may be bought in specified packs from a wide range of lockable retail premises without a prescription.
Human Medicines Regulations 2012:	Set out a comprehensive process for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. They also set out which health professionals can prescribe medicines, and which can use PGDs and exemptions to supply and administer medicines.
Independent prescriber:	A practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about clinical management including the prescribing of medicines. Dentists are amongst the professional groups that prescribe in this way.
Licensed medicine:	A medicine must be granted a licence by the appropriate body before it can be widely used in the UK. A licence indicates all the proper checks have been carried out and the product works for the purpose for which it is intended.
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 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.

Term	Explanation
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 (P) medicine:	Pharmacy (P) medicines are available only from a pharmacist but without a prescription. A pharmacist must make or supervise the sale.
Prescription Only medicine (POM)	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 exemptions that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation.
Supply of medicines:	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.

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.

A patient and public summary of this consultation guide is available.