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Patient and public summary of:

Consultation on proposed amendments to the list of medicines that paramedics are able to administer under exemptions within the Human Medicines Regulations 2012 across the United Kingdom

October 2020

This is a summary of the full consultation guide '*Consultation on proposed amendments to the list of medicines that paramedics are able to administer under exemptions within the Human Medicines Regulations 2012 across the United Kingdom'.*

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

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

Equality and Health Inequalities Statement

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

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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1 Introduction to the consultation

1.1 What are we consulting on?

In collaboration with the Scottish, Welsh and Northern Ireland governments, we are consulting on proposed changes to add to the list of medicines that registered paramedics are currently able to administer directly to patients under exemptions within the Human Medicines Regulations 2012.

The six additional medicines being proposed are:

Controlled drugs:

- lorazepam (by injection)
- midazolam (by injection)

Prescription only medicines (POMs):

- dexamethasone
- magnesium sulfate
- tranexamic acid
- flumazenil

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

Paramedics have been able to use exemptions to administer medicines directly to patients since 1992. Exemptions permit certain medicines listed in legislation to be sold, supplied and/or administered to patients by certain health professional groups without using a patient specific direction (PSD) or patient group direction (PGD). See appendix D in the full consultation guide for the current list of medicines.

There are two options for consideration in this consultation:

Option 1: no change

Option 2: addition of six medicines to the existing list of medicines that paramedics are able to currently administer directly to patients under exemptions within the Human Medicines Regulations 2012.

The proposed changes require amendment to both the Human Medicines Regulations and the Misuse of Drugs Regulations 2001. The Human Medicines Regulations apply UK-wide so subject to the agreement of Ministers, changes to them will apply across the four countries. The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

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

1.2 Why are the proposed changes being considered?

Paramedics have been able to supply and administer medicines to their patients for many years, through the use of:

- patient specific directions (PSD) since 1968
- exemptions since 1992
- patient group directions (PGDs) since 2000

More recently, paramedics working at an advanced level have also been able to prescribe medicines for their patients, using:

- supplementary prescribing since 2018
- independent prescribing since 2018

Section 4.2 of this guide contains more information about these mechanisms.

Although, current ways of supplying and administering medicines have improved patient care, there could be greater benefit to patients if more medicines were to be added to the list that paramedics can administer under exemptions as proposed. This would also be an important part of developing the paramedic role in caring for patients in emergency situations.

Further information on the benefits of this proposal, and potential risks and measures in place to manage the risks are presented in section 4.3 and section 4.5 of the full consultation guide respectively.

1.3 Supporting documents

The following documents provide additional information about the proposal:

- The *Consultation Stage Impact Assessment* which focuses on what impact the proposed policy change is likely to have and highlights the costs, benefits and risks of the proposed changes.
- The *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions within the Human Medicines Regulations 2012* describes how paramedics should administer medicines to patients safely.

1.4 What you will be asked about

The consultation questions ask:

- what you think about the proposal and whether you have additional information on any aspects not already considered as to why the proposal SHOULD or SHOULD NOT go forward
- what you think about the Consultation Stage Impact Assessment which accompanies the proposal
- whether the proposal will have a positive or negative impact on people who are affected by equality and health inequality issues
- about yourself or your organisation so that the views of different groups can be better understood.

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

You can find a glossary of terms used in this document in section 8 of this guide.

2 Background

A scoping project was undertaken in 2015 by NHS England and looked at the need for some regulated health professions to supply and administer medicines to their patients. The report of the project made a number of recommendations, including that patients could benefit if additions were made to the list of medicines that can be administered by paramedics in emergency situations under exemptions in medicines legislation.

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

We are leading consultations on proposals to change the medicines responsibilities for eight health professions, as follows:

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

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

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

3 The paramedic profession

All paramedics must be registered with the Health and Care Professions Council (HCPC), the regulatory body which sets the standards that all paramedics are expected to meet. They must successfully complete an HCPC-approved pre-registration programme of education in order to become registered. The education programmes include information about the use of exemptions and prepare paramedics to administer medicines using exemptions as soon as they are registered. Once registered, paramedics must show that they are completing regular education, and that they continue to practise both safely and effectively within their scope of practice, in order to maintain their registration. There are currently 29,760[1] paramedics registered with the HCPC in the UK.

Paramedics are trained in all aspects of emergency care, ranging from acute problems such as cardiac arrest, strokes, spinal injuries and major trauma, to urgent problems such as minor illness and injury, including flare ups of long term conditions, falls and fractures.

[1] Health and Care Professions Council *registrants by profession & route & gender* September 2020

Paramedics make full assessments of patients and make decisions about the care that they need. They treat, refer or discharge patients there and then; and for those patients needing to go to hospital they continue treatment and care until arrival at an Emergency Department.

Paramedics can also administer medicines on their own initiative in emergency situations. Exemptions in medicines legislation can be and are used by paramedics from entry level to consultant level, most commonly to deliver immediate care such as pain relief and medicines for the treatment of emergencies.

Paramedics may work partly or completely in independent practice. No matter where they work, they must always meet the same high standard as set by the HCPC. Likewise, their employers must use the same standard or systems and checks to ensure patient safety is maintained.

The professional body representing paramedics across the United Kingdom is the College of Paramedics.

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 increase the number of medicines that paramedics can administer using exemptions. This is because current legislation enables paramedics to administer certain medicines to patients in the course of their professional practice. However, if patients need further medicines, they need to be referred to prescribers, usually doctors, to prescribe the medicine, or a paramedic must use a patient group direction (PGD) where available.

Two options have been considered.

Option 1- no change
There would be no change to legislation; paramedics would continue to use PSDs and PGDs to administer those medicines which are not included in the current list of exemptions.

Benefits
For some patients, the existing legislation works well, e.g. for those patients whose medicines needs can be met by the current list of exemptions.

Limitations
Existing arrangements may not best support the needs of all patients, particularly those who need a different medicine than currently available on the paramedics' exemptions list. More detail on the impact of this option and the limitations of the current mechanisms available to paramedics can be found in section 4.2 of this guide.

Option 2: addition of six medicines to the list of medicines that paramedics can already administer under exemptions

Benefits
The proposed amendments to the paramedic exemptions list should ensure that patients receive timely access to medication, by enabling paramedics to administer medicines indicated by best clinical evidence from a comprehensive exemptions list without delay.

Limitations
The proposed additions to the list of medicines that paramedics could administer may mean that a small number of patients may still need input from additional health professionals to access medicines outside of those that paramedics are permitted to administer. This would most likely be because they need medicines for a medical condition that is outside of the current scope of practice of a paramedic.

4.2 Limitations of the current use of medicines mechanisms by paramedics

Paramedics are currently able to use exemptions to administer medicines to patients, and patient specific directions (PSDs) and patient group directions (PGDs) to administer or supply medicines to their patients. Some advanced paramedic practitioners can also prescribe medicines as independent prescribers.

4.2.1 Supply and administration mechanisms

4.2.1.1 Exemptions
Exemptions allow certain medicines listed in legislation to be administered to patients by paramedics without using a prescription or patient group direction (PGD).

The way that paramedics work has changed considerably since 2011 when the list of medicines that paramedics can currently administer under exemptions was last updated. In response to changes to the ways that urgent and emergency care is being given, guidelines relating to paramedic practice have been updated and new guidance published. This means that some of the medicines that paramedics need to administer to patients are not on their current list of exemptions. As a result, paramedics must either ask a prescriber to prescribe the medicine or ask for a PGD to be written by the organisation in which they work. This can lead to differences across the UK in the way that the medicines are administered to patients by paramedics. If the proposed medicines were to be included in the list of exemptions then all paramedics can administer the medicines wherever they treat patients.

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

4.2.1.3 Patient group directions (PGDs)

PGDs are written instructions for medicines to be supplied and/or administered by groups of health professionals to groups of patients. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor. They are NOT a form of prescribing[2].

PGDs are very effective for supplying courses of medicines by specialist and advanced paramedics in urgent and emergency care roles, and the administration of medicines by a small number of specialist and advanced paramedics in critical care roles. However, the responsibility for writing and authorising the large number of PGDs needed, and making sure that every paramedic who needs to use them has read and signed them is a huge workload for ambulance organisations.

4.2.2 Prescribing mechanisms

4.2.2.1 Independent prescribing

Since April 2018 advanced paramedics can train to become independent prescribers. Only advanced practitioner paramedics can undertake the training and therefore exemptions will remain the main mechanism used by all paramedics to administer medicines.

More detailed information about how paramedics currently provide patients with medicines can be found in section 4.2 in the full consultation guide.

4.3 Benefits of the proposal

The proposed addition of medicines to the list of exemptions that all paramedics need to be able to administer would lead to the same standard of patient care anywhere in the UK. This would be because the need for the writing and implementing of some PGDs by a large number of organisations would not be needed. Paramedics would be able to work for more than one organisation without confusion about what medicines they can administer to patients.

Standardising the care that patients receive across the UK would mean that patients get maximum benefit from their medicines regardless of where they are treated. The paramedic that treats them is responsible for the care given and will be able to provide the right treatment at the right time and in the right place.

Examples of how some of the medicines might be administered under exemptions by paramedics can be found in section 4.3 of the full consultation guide.

4.4 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 with the enhanced responsibilities. Identification of the risks informs the development of governance and safety measures that are necessary to maintain patient safety.

[2] NICE (2017) *Patient group directions: medicines practice guideline*

There are a number of potential risks to the proposal to enable paramedics to be able to administer additional medicines to their patients using exemptions. The risks perceived are not new to paramedics using exemptions; as such, they are managed by the governance and safety processes detailed in section 5 below that are already in place in organisations which employ paramedics.

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

5 Governance and patient safety

As all registered paramedics can already administer certain listed medicines under exemptions, the following governance and safety considerations reflect current practice.

5.1 Safe use of exemptions within medicines legislation

Paramedics working under exemptions within the Human Medicines Regulations must only administer those medicines that are listed in legislation for use by their profession. They may not supply and administer any other medicines without either a PGD or PSD being in place. Paramedics must only administer the medicines that they have the knowledge and skills for. National and local policies may limit the proposed list of medicines even further.

Paramedics are also allowed to keep a stock of the medicines listed in legislation as exemptions. They keep these safe by following national and local guidance and will continue to follow the guidance when storing the additional medicines.

5.1.1 Engagement with the controlled drugs accountable officer (CDAO)

What CDAOs must do and the requirement for organisations to appoint them is stated in law[3] [4] [5]. The CDAO is usually the chief pharmacist or another senior person in the organisation and is accountable for everything that happens with controlled drugs- for example how they are ordered, stored, prescribed and administered to patients. CDAOs have the same responsibilities in all organisations where controlled drugs are kept or used including organisations outside of the NHS.

The CDAO has a responsibility to ensure that the organisation has a controlled drugs policy and a set of procedures detailing how to look after controlled drugs properly. Regular checks are also required to make sure they are followed by everyone who works in the organisation. When administering controlled drugs under exemptions, paramedics must comply with these policies and procedures in order to keep their patients safe.

[3] The Controlled Drugs (Supervision of Management and Use) Regulations 2013
[4] The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)
[5] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

5.2 Communication of decisions to administer medicines using exemptions

When medicines are being administered, good communication is important for two main reasons- firstly so that the paramedic has enough information to make the correct decision about medicines for the patient, and secondly so that other health professionals know about what medicines the patient has already been given.

Medicines administered by paramedics under exemptions are almost always part of ongoing care for the patient, for example, where a patient receives intravenous pain relief before reaching hospital, or on arrival at an emergency department. Paramedics are trained to effectively hand over patients, in both written and verbal ways, to the team taking over the patient's care.

Before administering medicines to a patient, paramedics must satisfy themselves that they have undertaken a full assessment, including what medicines the patient is currently taking, which leads to a diagnosis. Where possible, this should include access to the patient's medical record and may involve talking to carers, especially if the patient has additional needs.

6 Equality and health inequality considerations

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

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

6.1 Public sector equality duty

Public bodies across England, Scotland and Wales have legal obligations under the Equality Act 2010[6], and are specifically required to consider the aims of the Public Sector Equality Duty[7], as set out at section 149 of the Equality Act 2010 when making decisions. This means that NHS England and NHS Improvement should understand the potential effect of the proposal on people with characteristics that have been given protection under the Equality Act 2010, especially in relation to their health outcomes and the experiences of patients, communities and the workforce. This will help us to consider whether the policy or practice will be effective for all people.

[6] Equality Act 2010
[7] Public Sector Equality Duty 2011

As this consultation is UK-wide, appropriate consideration has also been given to the requirements of the Northern Ireland Act 1998[8].

6.2 Health inequality duties

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

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

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

7 Consultation format

7.1 Who can respond to this consultation?

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

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

7.2 How to respond

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

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

  Please complete this form and return it to:

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

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

[8] Northern Ireland Act 1998

7.3 Alternative formats

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

7.4 Engagement events

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

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

7.5 How your responses will be used

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

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

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

7.6 Next steps

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

As this proposal is in relation to controlled drugs, changes to the Misuse of Drugs Regulations are also required. The proposed changes to medicines legislation and the findings of the consultation will be presented to the Advisory Council on the Misuse of

Drugs who makes recommendations to Ministers regarding changes to the Misuse of Drugs Regulations. Subject to the agreement of Ministers, the Home Office will then make the necessary amendments.

The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

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 and the Misuse of Drugs Regulations could come into force in 2021.

8 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 the government on the safety, effectiveness and quality of medicinal products, and on changes to medicines law.
Continuing professional development (CPD):	Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively.
Controlled drugs:	Controlled drugs are medicines that are classified in the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused. Strict laws exist to prevent them being misused, being obtained illegally or causing harm.
Controlled Drugs Accountable Officer (CDAO):	Person responsible for all aspects of controlled drugs management within their organisation. The roles and responsibilities of CDAOs, and the requirement to appoint them, are governed by legislation[9] [10] [11].
Department of Health and Social Care (DHSC):	The central government department with responsibility for leading the nation's health and social care system to help people live more independent, healthier lives for longer.
Exemptions:	Permit certain medicines listed in legislation to be sold, supplied and/or administered to patients by certain health professional groups without using a prescription or PGD.
Health and Care Professions Council (HCPC):	The regulator of 16 different health and care professions including paramedics. It maintains a register of health and care professionals that are fit to practise in the UK and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals.
Independent prescriber:	A practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for

[9] The Controlled Drugs (Supervision of Management and Use) Regulations 2013
[10] The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)
[11] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Term	Explanation
	decisions about clinical management, including the prescribing of medicines.
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 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 groups of patients. They contain information about which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor.
Patient specific direction (PSD):	A prescriber's written instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.
Prescription only medicine:	Medicines that normally need to be prescribed by a doctor or another prescriber before they can be administered or supplied to a patient. 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 processes undertaken, in response to formal orders, to issue medicines directly to the patient to take away. Patients then administer the medicine to themselves or allow others to help them.

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