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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 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 paramedics to administer additional medicines under exemptions within legislation.

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).

This UK-wide consultation is being led by NHS England and NHS Improvement on behalf of the four nations and relates to proposed amendments to legislation to enable registered paramedics to administer additional medicines directly to patients in the course of their professional practice under exemptions within legislation, namely:

Controlled drugs:

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

Prescription only medicines (POMs):

- dexamethasone
- magnesium sulfate
- tranexamic acid
- flumazenil

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 administer directly to patients

The proposed changes require amendment to both the Human Medicines Regulations 2001 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 throughout the UK, in any setting in which paramedics work including the NHS, independent and voluntary sectors.

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

A glossary of terms used in this guide can be found in section 9

1.2 Why are the proposed changes being considered?

All of the proposed medicines are currently being administered by paramedics using other mechanisms such as PGDs. The inclusion of additional medicines to the list of exemptions within the Human Medicines Regulations for paramedics to administer to their patients is an important part of developing the paramedic role in delivering frontline care and patient-centred services and supports the achievement of a number of current ambitions across the UK.

Further information about the benefits of this proposal is presented in section 4.3. Further information on the clinical use of the medicines listed above can be found in section 4.4 and appendix A. 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 College of Paramedics, the professional body that represents paramedics in the UK has also collaborated in the development of this consultation guide and the supporting documents that accompany it.

In February 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:

- *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*[1]
- *Consultation Stage Impact Assessment.*

1.4.1 Practice guidance

The *Practice Guidance* has been developed and published by the College of Paramedics. The document provides information about the behaviours, actions, knowledge and skills which should underpin the decision-making and actions of paramedics when administering the listed medicines under exemptions.

[1] College of Paramedics *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions*

1.4.2 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
Should amendments to legislation be made to enable paramedics to administer additional specifically listed medicines to their patients using exemptions?

Question 2
Do you have any additional information on any aspects not already considered as to why the proposal to amend the list of medicines that paramedics are able to administer under exemptions SHOULD go forward?

Question 3
Do you have any additional information on any aspects not already considered as to why the proposal to amend the list of medicines that paramedics are able to administer under exemptions SHOULD NOT go forward?

Question 4
To what extent do you agree or disagree with each of the proposed medicines that paramedics would be able to administer to their patients under exemptions within the Human Medicines Regulations?

Question 5
Does the '*Consultation Stage Impact Assessment'* give a realistic indication of the likely costs, benefits and risks of the proposal?

Question 6
Do you think that this proposal could impact (positively or negatively) on any of the protected characteristics covered by the Public Sector Equality Duty under the Equality Act 2010 section 149 or by section 75 of the Northern Ireland Act 1998?

Question 7
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[2] 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[3] 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*[4], *Health and Social Care Delivery Plan 2016*[5] and *Realising Realistic Medicine 2015/16*[6]

In Wales: supports the achievement of ambitions set out in *Taking Wales Forward 2016-2021*[7], *Prosperity for All: the national strategy*[8] and *A Healthier Wales: our Plan for Health and Social Care*[9]

In Northern Ireland: supports the delivery of *Health and Wellbeing 2026: Delivering Together*[10] and the *Medicines Optimisation Quality Framework*[11]

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

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

regulated health professionals. The resultant report 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 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 proposals which include changes to medicines responsibilities for eight 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 in emergency situations 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, and 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 paramedic profession

3.1 The role of the paramedic

Paramedics are statutory regulated health professionals. There are currently 29,760[12] paramedics registered with Health and Care Professions Council (HCPC) in the UK. The term 'paramedic' is a protected title by law.

Paramedics are autonomous, first contact practitioners, who work in a range of settings including responding to 999 calls, and 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 exacerbations of long term conditions, falls and fractures. Paramedics undertake full clinical assessments and make decisions regarding the care patients require. A paramedic's scope of practice involves the immediate treatment and stabilisation of patients at the patient's side. The majority of paramedics work in pre-hospital / out of hospital settings, and care and treat, refer or discharge patients at the scene; and for those patients needing hospital care they continue treatment and care while transporting patients to hospital. Paramedics are trained to resuscitate and/or stabilise patients, utilising sophisticated techniques and equipment.

Paramedics can also administer medicines on their own initiative in emergency situations or certain identified clinical situations. Exemptions in medicines legislation are used by paramedics across all levels of practice, most commonly to deliver immediate treatment to patients with urgent, emergency and critical care needs, such as pain relief and resuscitation.

Paramedics who have developed their skills beyond the entry level of their profession, by undertaking additional higher or post-graduate education, take on specialist or advanced paramedic roles. All education undertaken to become a specialist or advanced paramedic is done so at higher education institutions at diploma, degree (BSc) or masters (MSc) level.

3.2 The professional body

The College of Paramedics is the professional body representing paramedics and the ambulance profession in the UK. The role of the professional body is summarised in appendix C for information.

3.3 Professional regulation

The purpose of professional regulation is to protect the public. All paramedics must be registered with the HCPC. The HCPC sets the standards that all registrants have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the standards that the HCPC considers necessary for safe, effective practice Registrants must meet all these standards and meet the standards relevant to their scope of practice to stay registered. They must complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet these standards. Registrants must also ensure that they have appropriate indemnity in place to

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

cover all of their work. This indemnity may be provided through an employer, a professional body or by private arrangement.

3.4 How paramedics are trained

There are currently 69 HCPC approved pre-registration paramedic programmes in England, 3 in Wales, 1 in Northern Ireland, and 2 programmes in Scotland. The majority of pre-registration programmes are now delivered through a formal partnership between ambulance trusts and a university and the remainder by NHS ambulance organisations training centres. Student paramedics learn about the specific diseases, medicines and legal mechanisms associated with paramedic practice throughout their training, and experience the use of medicines in practice during educational placements in clinical settings.

The use of exemptions is embedded within all of the pre-registration paramedic education and training, the curricula provided by education providers are approved by the HCPC and therefore paramedics are qualified to use exemptions upon registration with the HCPC. All programmes include training and education content relating to the use of medicines used under exemptions and using other mechanisms such as PGDs where the medicine is required in paramedic practice.

3.5 Continuing professional development (CPD)

Once registered, paramedics must undertake CPD and demonstrate that they continue to practise both safely and effectively within their scope of practice, in order to maintain their registration. For the duration of their career, registrants are required to maintain a continuous, up-to-date and accurate record of their CPD activities, which must demonstrate a mixture of learning activities relevant to current or future practice. Their CPD activities must contribute to both the quality of their practice and service delivery, and benefit service users.

When the members of a profession within its remit renew their registration, the HCPC audits the CPD activities of 2.5% of registrants chosen at random from that profession. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. A failure to submit or to meet the standards required leads to administrative removal from the register. Additionally, every paramedic working in the NHS must undertake an annual professional development review with their manager or other designated person as a local governance arrangement to ensure competence is maintained.

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 also 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 be able to administer only certain medicines to patients in the course of their professional practice. Consequently, if patients need further medicines to be administered to them, they need to be referred to prescribers, usually doctors, to prescribe the medicine or write a patient specific direction (PSD) or paramedics must use patient group directions (PGDs) where they are available.

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

Option 1- no change
There would be no change to legislation; paramedics would continue to use PSDs and PGDs to supply and 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 who receive the medicines they need from paramedics to enable optimal care.

Limitations
Existing arrangements may not best support the needs of all patients, particularly those who need a different medicine than anticipated because initial treatment has been ineffective, or whose medical condition is complicated by the environment they are in. The full impact of this option and the limitations of the current mechanisms available to paramedics are outlined in section 4.2.

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

Benefits
The proposed additions 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 to see additional health professionals to access medicines outside of those that paramedics are permitted to administer. This is most likely to be because they need medicines for a medical condition that is outside of the usual scope of practice of a paramedic.

In summary, there are two options for consideration in this consultation:

- **Option 1**: no change
- **Option 2**: addition of further medicines to the list of medicines that paramedics can already administer under exemptions

4.2 Limitations of the current use of medicines mechanisms by paramedics

4.2.1 Patient specific directions (PSDs)

Paramedics can administer medicines to named patients using patient specific directions (PSDs). A PSD is a written instruction to supply or administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine[13]. The PSD then enables a paramedic 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
- they can be restrictive when access to a prescriber is problematic for instance, when in remote situations, where a GP may not always be immediately available or where a doctor is not part of the patient pathway

4.2.2 Patient group directions (PGDs)

Since 2000, paramedics 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 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[14].

PGDs are very effective for administration and supply of medicines by specialist and advanced paramedics in urgent care roles, and the administration of medicines by a small number of specialist and advanced paramedics in critical care roles. The responsibility and accountability for PGDs is shared across several stakeholders, such as medical directors and chief pharmacists, and the logistics of producing large libraries of PGDs available to every paramedic in an entire workforce, and repeated for every ambulance trust, is extremely labour intensive.

4.2.3 Exemptions from medicines legislation

The law defines some medicines as prescription only medicines, which normally need to be prescribed by a doctor or another prescriber before they can be administered or supplied to

[13] Specialist Pharmacy Service (2018) *Questions about patient specific directions*
[14] NICE (2017) *Patient group directions: medicines practice guideline*

a patient. However, there are a range of exemptions from these restrictions which allow certain groups of health professionals – for example, midwives, chiropodists / podiatrists, optometrists, paramedics and orthoptists – to supply and/or administer particular medicines direct to patients.

Paramedics have been able to use exemptions since 1992 and the list of medicines in Schedule 17 of the Human Medicines Regulation was last updated in 2011 (see appendix D). Paramedics can administer the medicines listed within schedule 17 for the immediate, necessary treatment of sick or injured persons without the requirement for a prescription, directions of a prescriber or a PGD. Legislation also allows registered paramedics to obtain stocks of these medicines as well as pharmacy medicines for administration in the course of a business operated by them.

Paramedic practice, the roles of paramedics and models of service delivery have evolved considerably since 2011 when the list of medicines that paramedics can administer under exemptions was last reviewed. To meet the changing needs of the healthcare system in relation to urgent and unscheduled care, advancing medicines technology, and in light of new research and best practice findings, guidelines relating to paramedic practice have been refreshed and new guidance published. Although paramedics are able to supply and administer medicines using PGDs, parenteral medicines which are indicated in national guidelines for use in acute/emergency situations, such as head injury, are better administered under an exemption which enables all paramedics who are eligible to use exemptions to access the indicated medicines as long as this falls within their scope of practice and competence, thus standardising paramedic practice across the UK.

Furthermore, the use of exemptions for the medicines indicated within national guidelines and in line with the evidence-base, allows service providers to apply UK-wide consistency with their formulary and medicines governance arrangements. Consequently, the proposal seeks to amend the list of medicines that paramedics are able to administer under exemptions in line with current practice and published national guidelines.

4.2.4 Independent prescribing

Amendments to legislation in April 2018 have enabled advanced practitioner paramedics to undertake additional training to become independent prescribers. Only advanced practitioner paramedics are eligible to undertake the training and therefore exemptions will remain the main mechanism used by all paramedics to administer medicines.

4.3 Benefits of adding to the list of medicines that paramedics can administer using exemptions

Although the current use of mechanisms by paramedics for the administration of medicines to patients has benefits for patient care, the impact of the addition of the proposed medicines to the list that paramedics can administer using exemptions is anticipated to further benefit patients, commissioners and providers.

4.3.1 Standardisation of practice

Addition of the proposed medicines to the list of existing medicines available for administration by paramedics under exemptions should reduce variation and increase

standardisation of practice. The proposed medicines are those that are well established in the clinical evidence base, and are already proven in practice via another legal mechanism (usually a PGD). Importantly, medicines listed for use under exemptions are those that all grades of paramedic need to be able to administer. The proposal would prevent the need for the development of multiple PGDs by a large number of ambulance trusts, therefore reducing variation and duplication of effort within the NHS.

Therefore the proposal supports standardisation of care across the UK, by ensuring the same standard of governance and safety. The proposal also facilitates the transferability of the paramedic between ambulance trusts whilst maintaining the same standard of practice.

4.3.2 Improved outcomes

If an urgent, emergency or critical illness or injury arises, the public, especially vulnerable older people, expect access to a service that will provide them with the right care, where and when they need it. 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.

The proposed amendment will help maximise patient outcomes regardless of where they are being treated by a paramedic, recognising that paramedics now work in other settings as well as the ambulance service. This will be because it will be the responsibility of organisations to agree the inclusion of the medicines into local formularies based on clinical evidence, without the regional differences caused by availability of PGDs.

4.3.3 Clearer lines of clinical responsibility and accountability

Medicines which appear in common practice guidance, such as the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines[15], often have to be accompanied by the development of PGDs in each Trust, and signed by 800+ paramedics every two to three years. These medicines are indicated for use by paramedics at all clinical levels from graduate level onwards. Grouping these common medicines in to a single mechanism ensures that the paramedics themselves have clearer lines of accountability for the medicines they administer in practice.

4.3.4 Increasing capacity

The workload of development, implementation and maintenance of PGDs is time consuming to ambulance organisations but they are currently absorbing this administrative burden. The proposed additions to the current list of exemptions by paramedics would reduce the workload as all paramedics would be able to administer the additional medicines without the need for PGDs, therefore releasing capacity for ambulance services.

4.3.5 Service redesign

The proposed changes allow paramedics to provide further support to local service commissioners and providers to develop the paramedic workforce and enhance local services to meet the needs of patients in the most cost-effective way. Service redesign may be realised through paramedics accessing care pathways more quickly, and by ensuring

[15] Joint Royal Colleges Ambulance Liaison Committee (JRCALC) (2016) *UK Ambulance Services Clinical Practice Guidelines*

patient outcomes are optimised by providing the correct medicines as early as possible in their episode of care.

4.3.6 Medicines optimisation

Medicines optimisation looks at how patients can get the best use from their medicines over a period of time. It may involve stopping some medicines as well as starting others, and considers opportunities for lifestyle changes and nonmedical therapies to reduce the need for medicines. Administration of a medicine using exemptions in legislation by paramedics could enable patients to get the best use of their medicines, in line with the principles of medicines optimisation[16].

- The proposed medicines to be listed as exemptions in the Human Medicines Regulations are used as part of evidence-based emergency clinical care.
- The proposed medicines are for administration only during acute episodes of care and therefore prevent ongoing oversupply leading to confusion and risk of error.

4.4 Use in clinical practice

The scenarios below are illustrative examples to demonstrate how paramedics might use some of the proposed medicines within clinical practice and the benefits to be gained from this proposal.

[16] Royal Pharmaceutical Society (2013) *Medicines Optimisation: Helping patients to make the most of medicines- good practice guidance for healthcare professionals in England*

Scenario 1- magnesium sulfate

Asthma attacks lead to around 1500 deaths each year in the UK; it is the most severe of these that can be treated successfully with magnesium sulfate. This is a licensed medicine that is used for a purpose outside of the manufacturer's license specifications; however, there is robust evidence and national guidance[17] [18] which clearly indicates its use for this condition.

Patients with acute severe asthma are often successfully treated using salbutamol and ipratropium, but some do not respond to this therapy and may deteriorate further. In these cases, being able to escalate treatment rapidly without needing to wait for a prescriber is essential to prevent delay. A single dose of magnesium sulfate administered intravenously may be considered for patients with acute severe asthma (PEF <50% best or predicted) who have not had a good initial response to inhaled bronchodilator therapy[19].

Currently, paramedics cannot use this medicine unless a PGD is in place. The relatively rare presentations of truly life-threatening asthma may be seen as a barrier to the significant resource requirement to produce PGDs for many hundreds of paramedics in an ambulance trust. Where a paramedic is working in an emergency department, they would need to refer to a prescriber to arrange for this medicine to be prescribed and administered.

If magnesium sulfate were included in the list of exemptions for paramedics to administer, the treatment could be administered when indicated without delay. The evidence suggests that intravenous magnesium sulfate is safe, can resolve symptoms, and can reduce risk of need for admission to intensive care[20]. It may also reduce hospital admissions in adults with acute asthma who have had little or no response to standard treatment. Adding this medicine to mainstream practice will provide the opportunity to benefit patients who are at risk of a poor outcome where treatment is delayed.

Scenario 2- lorazepam

Paramedics are commonly called to attend children who suffer convulsions. These are usually associated with a sudden rise in temperature, often due to a minor illness, and are self-limiting. Where the child has epilepsy or other diseases causing fits, extended fitting (status epilepticus) is a possible and very serious complication[21].

Paramedics can currently administer lorazepam using a PGD to children over 28 days old who are suffering a seizure (generalised fitting, either continuous or repeated) for 30 minutes or more in duration, and where buccal midazolam is not available and/or the child has not responded to other therapies prior to the arrival of the paramedic. Caution is given where the child's parents have administered another benzodiazepine rectally or orally.

A second dose of lorazepam may be given if the fitting continues prior to conveyance to hospital, and if the PGD includes provision for this. If a second dose is given, conveyance should not be delayed or an enhanced care team should be requested to scene. The child should be stabilised and prepared for rapid transfer to the nearest suitable hospital able to provide the next emergency treatment and/or inpatient care.

Currently, paramedics can only administer one benzodiazepine (diazepam) under exemption, and others can only be provided if a PGD is in place. This can create variation in practice and can delay the correct care at the point of need. If paramedics were able to administer lorazepam using exemptions, rapid management can be initiated as early as possible anywhere the UK, to prevent the sudden deterioration that children sometimes experience, and can promote better outcomes for patients.

[17] Rowe BH, Bretzlaff J, Bourdon C, Bota G, Blitz S, Camargo Jr CA. (2000). *Magnesium sulfate for treating exacerbations of acute asthma in the emergency department.*

[18] British Thoracic Society & Scottish Intercollegiate Guidelines Network (2016) *British guideline on the management of asthma*.

[19] British Thoracic Society & Scottish Intercollegiate Guidelines Network (2016) *British guideline on the management of asthma*.

[20] Rowe BH, Bretzlaff J, Bourdon C, Bota G, Blitz S, Camargo Jr CA. (2000). *Magnesium sulfate for treating exacerbations of acute asthma in the emergency department.*

[21] National Institute for Health and Clinical Excellence. (2016). *Epilepsies: diagnosis and management*

Scenario 3- midazolam and flumazenil

Paramedics commonly attend incidents where patients have received traumatic injuries, including head injuries. Where a patient's head injury affects their level of consciousness, this can also affect their ability to breathe effectively. There are occasions where the treatment of the patient's overall condition becomes extremely challenging due to the agitation associated with a head injury, and exacerbated by the worsening levels of oxygen in the bloodstream. In this situation, administering midazolam to sedate the patient maximises the effectiveness of the patient's ability to breathe[22].

Patients who have been given midazolam as part of the overall approach to managing their injuries must be monitored throughout. Rarely, the sedative effect of midazolam can cause unwanted respiratory suppression and the patient would require reversal of the sedation by the use of flumazenil. This scenario was described by the National Patient Safety Agency (NPSA) in a Rapid Response Review[23] which recommended that flumazenil was available where midazolam is used. Flumazenil is rarely used by paramedics but must be available.

If midazolam is added to the exemptions list then it is advisable that flumazenil is also added to ensure all paramedics who have access to midazolam under exemptions also have access to flumazenil. Furthermore, this will further reduce the administrative burden associated with PGDs as suitably skilled paramedics who currently use a PGD for midazolam to sedate patients also require a PGD for flumazenil.

In cases where midazolam is used, every effort should be made to either rapidly convey the patient to a Major Trauma Centre, or where this is difficult, consider requesting an enhanced care team to scene to deliver pre-hospital anaesthesia, or convey the patient to a local Trauma Unit for stabilisation.

Scenario 4- tranexamic acid

Trauma is a major cause of death in adults in the UK, and tranexamic acid (TXA) has become a useful medicine used extensively to very good effect by paramedics at all levels of practice. TXA is indicated in patients with time-critical injuries where significant internal haemorrhage is suspected or external haemorrhage is identified[24]. TXA is commonly given by paramedics using PGDs[25]. Enabling paramedics to administer TXA under exemption would not change the indications for use, and organisations would continue to use the published practice guidance.

Each UK ambulance trust employs around 800-1000 paramedics, each of which has to sign the PGD document every two to three years. For medicines which are used by every paramedic, the logistics required to sign the PGD can be challenging and can lead to regional variation. Using an exemption does not reduce the safety or scrutiny relating to the use of the medicine but does reduce significantly the resource burden on the trusts. The clinical benefits of TXA are well recognised, and therefore the benefit to patients of this medicine being added to the list of medicines within exemptions and hence removing the need for a PGD, is enabling all trained paramedics to be able to administer it within clinical practice guidance.

[22] AACE (Association of Ambulance Chief Executives) (2016). *JRCALC (Joint Royal Colleges Ambulance Liaison Committee) Clinical Practice Guidelines*. Bridgwater: Class Professional. 239

[23] NPSA (2008) Rapid Response Review: *Reducing risk of overdose with midazolam injection in adults*

[24] CRASH-2 Collaborators. (2011). *The importance of early treatment with tranexamic acid in bleeding trauma patients: an exploratory analysis of the CRASH-2 randomised controlled trial*. The Lancet. 377, p1096-1101.

[25] AACE (Association of Ambulance Chief Executives) (2017). *JRCALC (Joint Royal Colleges Ambulance Liaison Committee) Supplementary Guidelines*. Bridgwater: Class Professional. 194

4.6 Management of potential risks associated with the proposal

Whenever there is an 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 paramedics to administer additional medicines to their patients using exemptions. The risks perceived are not new to paramedics using exemptions; as such, they are mitigated against by the governance and safety processes detailed in section 5 that are already in place in organisations which employ paramedics. The main potential risks perceived of the proposal and a summary of the mitigating actions are included in table 1 below.

Table 1: Potential risks and governance measures already in place to manage them

Potential unintended consequences	Potential solution
Paramedics may administer one of the additional medicines under exemptions without having the required skills and knowledge about the medicine therefore resulting in an increased risk of error.	• Paramedics are required to only administer medicines within their scope of practice and competence and the HCPC has the powers to remove individuals from their register if the person falls below the standards required. • They must undertake CPD and experience to demonstrate to the HCPC that they are capable of working safely and effectively within their scope of practice. • Local governance arrangements already in place related to assurance and maintenance of competence will encompass the proposed changes to the medicines listed.
Ambulance organisations may decide not to include the additional medicines in the local formulary therefore patients seeing paramedics will not benefit from the change to legislation.	• The proposed medicines are currently used as part of emergency clinical care which is based on best-practice evidence and clinical guidelines and therefore it is unlikely that organisations would not include them in the local formulary as this will help them reduce the administrative burden associated with PGDs for these medicines. • NHS England and NHS Improvement, NHS Scotland, NHS Wales and the Department of Health in Northern Ireland, together with professional bodies and key stakeholders, will raise awareness of any changes in legislation, in order to inform

	local decision-making to promote consistency.
Paramedics may administer lorazepam to a benzodiazepine-naïve patient and the patient may suffer a reaction as a consequence	• Paramedics already administer lorazepam using PGDs. They administer a one off dose for an acute situation, which reduces the chance of side effects occurring. They will take a careful medication history prior to administration in order to prevent drug interactions. • Paramedics are required to only administer medicines within their scope of practice and competence and the HCPC has the powers to remove individuals from their register if the person falls below the standards required. • Paramedics have the necessary skills such as airway management and fluid support if an adverse reaction were to occur.
There may be an increase in the use of medicines with increased associated costs to the system	• The proposed list of additional medicines for paramedics to administer using the exemption mechanism includes only those that would otherwise be supplied or administered using a PGD or PSD from a prescriber.

5 Governance and patient safety

The following governance and patient safety measures are already in place in organisations which employ paramedics. Paramedics must be already compliant with the measures in place and the policies of the employing organisation, as well as the relevant HCPC standards.

5.1 Safe use of exemptions within medicines legislation

The *Practice Guidance*[26] contains full details of the considerations related to the safe administration of the proposed medicines using exemptions by paramedics.

5.1.1 Profession-specific list

Registrants working under exemptions within the Human Medicines Regulations would only be permitted to administer those medicines that pertain to their profession. For example - a paramedic would only be permitted to administer medicines under exemptions that are listed in legislation as exempt for paramedics and may not administer any other medicines without an additional mechanism such as a PGD or prescription being in place. Furthermore, paramedics working under exemptions must only administer the listed medicines that are within their scope of practice and competence. Delegation of the administration of a medicine using exemptions to another health professional is not permitted.

5.1.2 Storage of medicines

Registered paramedics are also permitted to keep stocks of the medicines currently listed as exemptions in legislation. Access to stocks is through a body permitted to receive wholesale supplies of medicines, usually an ambulance trust[27]. Possession of controlled drugs by paramedics under certain conditions is covered by a Home Office License Group Authority[28] or, in Northern Ireland, a licence issued by the Department of Health. Measures for safe storage are already in place for the existing list of medicines including the storage and safe custody requirements for controlled drugs as detailed in the *Misuse of Drugs (Safe Custody) Regulations 1973*[29] and the *Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973*[30].

5.1.3 Local governance procedures

All registered paramedics are legally able to use medicines exemptions, and employers are required to demonstrate good governance arrangements as part of their medicines management / optimisation processes. Arrangements include:

- Each employing organisation should provide their staff with a scope of practice and local formulary approved for use.
- Provision by employing organisations of ongoing refresher training for medicines.
- Paramedics must undertake CPD activities, which should include learning and reflecting on medicines and their use.

[26] College of Paramedics *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions*
[27] MHRA (2014) *Rules for the sale, supply and administration of medicines for specific healthcare professionals*
[28] Royal Pharmaceutical Society (2016) *medicines ethics and practice: the professional guide for pharmacists*
[29] The Misuse of Drugs (Safe Custody) Regulations 1973
[30] The Misuse of Drugs (Safe Custody) (Northern Ireland) Regulations 1973

- Whilst registrants are legally permitted to 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 such as a local medicines formulary which restrict paramedics to administer only some of the listed medicines. These restrictions would only apply to practice for that employer.
- Registrants must always work to such locally agreed written protocols and procedures in addition to the standards set by the regulator and any guidance provided by their professional body.

5.1.4 Engagement with controlled drugs accountable officer (CDAO)

All aspects of controlled drugs management are overseen by a CDAO in each organisation who is accountable for the governance where controlled drugs are used including monitoring all controlled drug prescribing within their area. The CDAO is usually the chief pharmacist or other senior person in the organisation; the roles and responsibilities and the requirement to appoint a CDAO are governed by legislation[31] [32] [33]. The responsibilities of the CDAO include:

- ensuring that the organisation has a controlled drugs policy that includes use of exemptions
- ensuring that the organisation has a set of standard operating procedures covering all aspects of controlled drug handling and use including exemptions
- ensuring that processes for monitoring compliance are in place
- being a member of local intelligence networks which share concerns and oversee management of controlled drugs

All paramedics, regardless of setting, must know who the local CDAO is and comply with any local monitoring and/or inspection requests that the CDAO may make.

5.1.5 Professional accountability

Paramedics must ensure they provide evidence-based care within their scope of practice and competence. When working under exemptions they will be professionally accountable for their decisions regarding the administration of medicines using exemptions, including actions and omissions. For example, the legislation does not define the appropriate use of medicines on exemptions lists and therefore they can be used ‘off-license’ (where a medicine is sold, supplied or administered outside the marketing authorisation). However, the paramedic must be satisfied that there is sufficient evidence and / or experience of using the medicine to demonstrate its safety and efficacy. Patients should also be advised of the 'off-license' use, consent obtained and recorded. Paramedics must also have due regard to patient safety information and should be aware and change practice accordingly, which may include not using a medicine even though it can legally be administered under exemptions.

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

5.1.6 Adverse drug reactions (ADRs), interactions and errors

In line with guidance relating to the safe use of medicines, if an error in administration occurs whilst using exemptions the paramedic 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[34].

Paramedics 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[35]. Organisations should ensure that untoward incidents involving medicines are included within their mainstream approach to learning from events and errors. Employers should promote a continual improvement approach and culture, particularly where the origin of any investigation relates to medicines.

5.2 Communication of decisions to administer medicines using exemptions

Medicines administered by paramedics under exemptions are almost always associated with ongoing care for the patient, for example, where a patient receives intravenous analgesia in the pre-hospital environment, or on arrival at an emergency department. Structured and effective clinical communication is a vital aspect of safe healthcare practice, and passing on information, both written and verbal, to the team taking over the patient's care is vital. Paramedics are trained to effectively hand over patients across the various settings in which they work.

Before administering medicines to a patient, paramedics must satisfy themselves that they have undertaken a full assessment of the patient, including a thorough history and physical assessment which leads to a point of diagnosis. This should, where possible, include accessing a full clinical record including medication and allergy history. This process may involve carers, especially if the patient has additional needs.

Documentation of any medicines administration must be recorded in clinical records at the time of treatment at the patient's side. Only in exceptional, unforeseen circumstances should documentation be delayed, and this would be considered a rare event which may require formal incident reporting/investigation. For example, were the ambulance to be involved in a road accident on route to hospital and the paramedic injured, a delay in the record would occur until the paramedic was well enough to complete this or report to a manager. Records must include the details of the medicines given, and include salient information to facilitate track-and-trace and adequate availability to audit. This should accompany relevant details of the consultation with the patient.

[34] MHRA *Yellow Card Scheme*

[35] College of Paramedics (2018) *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions*

Where controlled drugs are administered, depending on the levels of control needed, communication of transfer between storage places (for example ambulance bases to vehicle), administration and stock levels may also be recorded in a controlled drugs register. This process is already in place in ambulance trusts as morphine sulfate is on the current list of exemptions for administration by paramedics. Organisations may include controlled drugs from other schedules in this requirement as a local agreement.

5.3 Use of exemptions within legislation by private practitioners

Paramedics predominantly work in the NHS, with the vast majority being employed within ambulance services. Paramedics may also be employed by the private sector and commissioned or contracted by an NHS organisation to deliver NHS services. A number of paramedics provide services for voluntary or independent organisations, whilst others work in a completely private capacity. It is unclear how many paramedics work in the private, independent and voluntary sectors due to a lack of robust data, although it has been previously estimated to be around 16%.

Changes to legislation to permit paramedics to administer additional medicines under exemptions within the Human Medicines Regulations would apply throughout the UK, in any setting in which paramedics work including the independent and voluntary sectors. Paramedics undertaking private practice are able to utilise exemptions in the course of their work and within their scope of practice and competence. Paramedic medicines exemptions listed in Schedule 17 of the Human Medicines Regulations include some controlled drugs. Where controlled drugs are included in private practice, the additional safeguards must be observed to the same standards as required in NHS settings.

Employers outside the NHS have the same roles and responsibilities as those within the NHS to implement the same standard of local governance arrangements related to the safe storage, supply and administration of medicines, including controlled drugs. The requirement for good medicines governance is unchanged in private practice and paramedics operating in this way must follow all required safe custody and governance processes. All registered paramedics, regardless of their work setting are subject to the HCPC standards of proficiency, conduct, performance, character and health.

In summary: paramedics must be already compliant with the measures in place in the employing organisation as described above when administering medicines under exemptions. Should legislation be amended, paramedics will be required to continue to be compliant with the same measures when administering the proposed additional medicines.

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[36], and are required to have due regard to the aims of the Public Sector Equality Duty[37] (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[38] 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

[36] Equality Act 2010
[37] Public Sector Equality Duty 2011
[38] Northern Ireland Act 1998

- men and women generally
- 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[39] 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.

[39] Health and Social Care Act 2012

7 Consultation format

7.1 Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients/patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, dentists, doctors, pharmacists, paramedics, other 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 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 and NHS Improvement will be data controller for any personal data you provide as part of your response to the consultation. NHS England and NHS Improvement have 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. We 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 (MHRA) 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.

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 Appendices

8.1 Appendix A: Clinical indications for use of proposed medicines

Proposed medicines to be added to the existing list of exemptions in medicines legislation	
Lorazepam	
Indications for use by paramedics	Example of clinical need
Lorazepam is a benzodiazepine (a medicine which can sedate and have a hypnotic effect). Paramedics use this medicine in clinical practice for the following conditions: • conscious sedation for procedures • status epilepticus- an epileptic fit which does not stop without treatment • febrile convulsions-fits caused by a raised body temperature, usually as a result of an infection • fits caused by poisoning	**Status epilepticus** Status epilepticus is the term used to describe patients who have a fit which does not stop on its own, or after being given medicines. Fits which continue too long are dangerous to patients for a number of reasons, including causing inadequate breathing, physical injuries and potential brain damage.
Midazolam	
Indications for use by paramedics	Example of clinical need
Midazolam is also a benzodiazepine (a medicine which can sedate and have a hypnotic effect) and has many uses in paramedic practice, including: • status epilepticus- an epileptic fit which does not stop without treatment • febrile convulsions- fits caused by a raised body temperature, usually as a result of an infection • conscious sedation for procedures • confusion and restlessness in palliative care (along with other medicines) • convulsions in palliative care	**Conscious sedation** Conscious sedation is used for procedures where the intention is to keep the patient awake and / or aware but more relaxed. Patients who suffer head injuries and who become 'agitated' (the injury to their brain causes changes to their behaviour) may not breathe effectively, and may require sedation to allow the paramedic to support their breathing and provide additional oxygen.
Flumazenil	
Indications for use by paramedics	Example of clinical need
Flumazenil is a medicine used to reverse the sedative effects of benzodiazepines, such as lorazepam and midazolam.	The sedative effect of drugs such as lorazepam and midazolam (benzodiazepines) may be dangerous if too much of the medicine is given, or the patient is more sensitive to its effects. Flumazenil reverses the sedative effect and returns the patient to their previous state of consciousness prior to the benzodiazepine being given. It is important to have this medicine available if paramedics are treating patients needing sedation.

Dexamethasone	
Indications for use by paramedics	Example of clinical need
Dexamethasone is a corticosteroid which is used to reduce swelling. It is used by paramedics to treat: • mild croup (using oral medicines) • severe croup • relieving nausea and vomiting symptoms where patients are receiving palliative care	**Severe croup** Croup is inflammation of the throat and airway in children, associated with infection and causes breathing difficulties. Severe croup needs to be treated in hospital. Paramedics would not use this when working in the ambulance service, this medicine would be used mainly by those working in hospital settings.
Magnesium sulfate	
Indications for use by paramedics	Example of clinical need
Magnesium sulfate is available over the counter in a weak form to be taken by mouth, better known as Epsom Salts. In its stronger form it is a prescription only medicine and is used via injection; it is useful to help treat acute severe asthma attacks.	**Acute severe asthma** Asthma is a common illness which affects around 5.4m people in the UK. Severe asthma attacks kill around 1000 people per year in the UK, and patients can get worse very quickly before reaching hospital. Using this medicine sooner by paramedics can help reduce deaths in patients with this condition. Magnesium sulfate works by reducing the inflammation (swelling) in the airways in the lung that is affected by the asthma attack.
Tranexamic acid	
Indications for use by paramedics	Example of clinical need
Tranexamic acid (TXA) is used to treat areas of bleeding-both internal and external - caused by trauma such as car accidents. The medicine is used by paramedics to: • control excessive nosebleeds that don't stop on their own • prevention and treatment of significant bleeding following trauma	**Prevention and treatment of significant haemorrhage following trauma** Patients can suffer internal bleeding (bleeding which does not appear outside the body as it does with laceration) when they are involved in car accidents or falls from height. Internal bleeding needs to be stopped, but usually cannot be compressed in the same way a cut can be. TXA is a medicine that helps the body to maintain the clots it forms early on in bleeding. Without it, when the first clots break down, there may not be enough of the right ingredients present in the blood to form the longer lasting clots, and this means the patient keeps bleeding.

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 (until 30.9.19)	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)
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 Lists project working group

Name	Organisation	Role
Dr Bruce Warner (Chair)	NHS England and NHS Improvement	Deputy Chief Pharmaceutical Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief AHP 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)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Pip White	The Chartered Society of Physiotherapy	Professional Adviser
Dave Baker	The Chartered Society of Physiotherapy	MSK Practitioner and Independent Prescriber
Professor Alan Borthwick	College of Podiatry	Professional Adviser
James Coughtrey	College of Podiatry	Professional Adviser
Martin Harvey	Institute of Chiropodists and Podiatrists	Professional Adviser
Jill Burnett-Hurst	Institute of Chiropodists and Podiatrists	Professional Adviser
Andy Collen (until September 2018)	College of Paramedics	Professional Adviser
David Rovardi (from September 2018)	College of Paramedics	Professional Adviser
Richard Fitzgerald	NHS England and NHS Improvement	Patient & Public Representative
Rebecca Harmston	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 body

The College of Paramedics is the recognised professional body for paramedics and the ambulance profession in the UK. It represents its members in all matters affecting their professional practice and supports them to achieve the highest standards of patient care by providing advice to members and to those who are considering joining the ambulance professions.

The College further represents the interests of paramedics and ambulance clinicians by providing a contact point for the media, through membership of appropriate committees and advisory groups, by developing professional standards guidance, and by responding to consultation documents and requests for advice from government, and other professional and registrant bodies.

Membership is open to UK paramedics registered with the HCPC, those who are interested in the sector or those studying for a qualification leading to eligibility to apply for registration with the HCPC.

8.4 Appendix D: Current exemptions list for use by paramedics

The current list in Schedule 17 (part 3) of the Human Medicines Regulations includes the following medicines, specifically for parenteral administration.

The administration shall be only for the immediate, necessary treatment of sick or injured persons and in the case of prescription only medicine containing heparin sodium shall be only for the purpose of cannula flushing.

(a) diazepam 5 mg per ml emulsion for injection

(b) succinylated modified fluid gelatin 4 per cent intravenous infusion

(c) medicines containing the substance ergometrine maleate 500 microgram per ml with oxytocin 5 units per ml, but no other active ingredient

(d) prescription only medicines containing one or more of the following substances, but no other active ingredient:

(i) adrenaline acid tartrate
(ii) adrenaline hydrochloride
(iii) amiodarone
(iv) anhydrous glucose
(v) benzylpenicillin
(vi) compound sodium lactate intravenous infusion (Hartmann's solution)
(vii) ergometrine maleate
(viii) furosemide
(ix) glucose
(x) heparin sodium
(xi) lidocaine hydrochloride
(xii) metoclopramide
(xiii) morphine sulfate
(xiv) nalbuphine hydrochloride
(xv) naloxone hydrochloride
(xvi) ondansetron
(xvii) paracetamol
(xviii) reteplase
(xix) sodium chloride
(xx) streptokinase
(xxi) tenecteplase.

8.5 Appendix E: Frequently asked questions.

1) Why is the list of medicines available under exemptions for paramedics being proposed for amendment?

Healthcare practice continually evolves and improves, usually based on advances in medical sciences which introduce new medicines and techniques into patient care. Paramedics, like all health professionals, seek to use the most up to date ways of treating patients, and therefore the medicines needed to treat patients in an emergency changes over time. Updating the list with the proposed medicines should support paramedics to provide the very best care for patients with the conditions these medicines can treat.

Usually, when a new medicine is made available, employers provide a PGD for paramedics to use, but PGDs create challenges to employers such as ambulance services who may have many hundreds of paramedics, all of which have to sign the PGD document. Using exemptions would provide the same level of safety and governance and would be suitable for medicines given as a single or repeat dose in an emergency.

2) Why does the consultation only refer to schedule 17 exemptions and not schedule 19?

The medicines listed in schedule 19[40] of the Human Medicines Regulations are for parenteral administration in an emergency by any competent person; however, they do not permit possession of the medicines. Schedule 17 includes specified professions or roles and in some instances, specific circumstances in which the medicines can be used. Schedule 17 also permits the designated health professional to hold stocks of the medicines listed.

3) Do *all* paramedics use exemptions, and would the additional medicines proposed also be used by all paramedics?

Yes. All paramedics are permitted to use exemptions from the point of registration with the HCPC within their scope of practice and competence. The proposed additional medicines would also be available to all paramedics to use within their scope of practice and competence.

4) What training do paramedics receive in order to be able to use exemptions?

Paramedics can use exemptions from the point of initial registration, and therefore receive extensive training in their pre-registration training to ensure that they understand the pharmacology, use and place in treatment pathways for all the medicines listed. The College of Paramedics produces curriculum guidelines for universities to develop their training courses, and these include the competencies necessary regarding medicines. The legal mechanisms, such as exemptions and PGDs, are covered in undergraduate course content; student paramedics also witness the use of medicines during their extensive periods in practice placement (the time they spend during their training with a qualified paramedic on operational duty within an ambulance service).

[40] Human Medicines Regulations 2012- schedule 19

5) What assurances are there that it would be safe to allow paramedics to administer the proposed additional medicines under exemptions?

Patient safety remains of paramount importance. Paramedics have used exemptions to administer medicines for many years, as well as the other legal mechanisms available to them, such as PGDs and PSDs. Paramedics using exemptions are professionally responsible for their own actions, and it is an ongoing requirement as a registrant to practice in a safe and competent way.

In response, to the proposal to add to the list of exemptions, and to improve general safety in practice, the College of Paramedics has published a *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions within the Human Medicines Regulations 2012*[41]. This document facilitates access to best practice information, advice and guidance for paramedics in the use of exemptions and enable safe patient care.

Extending access to medicines supply and administration mechanisms has the potential to improve patient safety by reducing delays in care and supporting clear lines of professional responsibility.

6) Will paramedics using exemptions be able to sell or supply, as well as administer medicines?

The legislation does not permit paramedics to sell or supply any of the medicines listed as exemptions in the Human Medicines Regulations

7) Why do paramedics need to have an updated list of medicines that they can administer using exemptions now that they can train to become independent prescribers?

Only advanced paramedics are eligible to train to become independent prescribers. All registered paramedics can administer the listed medicines using exemptions in legislation so this mechanism will continue to be used widely.

8) How do paramedics communicate their decisions to other practitioners involved in a patient's care, will the additional exempt medicines proposed affect this?

The settings in which exemptions are used by paramedics are usually emergency situations, and therefore most patients are taken to hospital for ongoing care, and a comprehensive handover is given to the clinical team responsible for the ongoing care of the patient.

In some situations, patients may be definitively treated (for example, resolving situations where patients with diabetes become hypoglycaemic [low blood glucose] using intravenous glucose). In these situations, patients are rarely "discharged" from the paramedic's care; instead they are referred back to their GP or diabetes nurse specialist. The paramedic is responsible for ensuring all medicines administered are documented, and any onward referral includes this information.

Where exemptions are used within a static care setting, such as an emergency department or GP practice, the medicines used will be documented in the patient's notes, and will be included in any discharge summaries or onward referral letters (where relevant).

[41] College of Paramedics *Practice Guidance for Paramedics for the Administration of Medicines under Exemptions*

9) How do paramedics using exemptions maintain their competency in the use of medicines?

As HCPC registrants, paramedics are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. Every two years, a paramedic must sign a professional declaration upon registration/renewal of registration to confirm that they continue to meet the HCPC standards for continuing professional development and to maintain their professional registration. Further detail can be found in section 3.5.

Employers are required to provide opportunities to learn about medicines as part of mandatory training. In England, the Care Quality Commission inspects the policies and behaviours relating to the use of medicines in ambulance trusts; there is a similar process in each of the devolved administrations.

10) Are paramedics working outside the NHS able to use exemptions?

Yes, provided they can demonstrate that they have same standard of governance arrangements in place as when practising within the NHS, that they meet the regulatory requirements and that their organisation meets the same requirements as an NHS organisation. Further detail can be found in section 5.3.

11) How are paramedics annotated to indicate that they are qualified to use exemptions?

Paramedics, unlike many other registered health professions, do not have a specific annotation on their HCPC register entry to use exemptions. This is because the use of exemptions is granted at the point of initial registration, rather than following completion of a post-graduate training programme.

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 (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 prescription only medicines that are controlled by the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused, and placed in one of the schedules of the Misuse of Drugs regulations. Strict legal controls apply to controlled drugs to prevent them being misused, being obtained illegally or causing harm The measures include how controlled drugs can be stored, administered, supplied and recorded.
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[42] [43] [44].
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.
Formulary:	A medicines formulary is a list of approved medicines. It may be agreed locally and is used alongside other resources to promote safe and appropriate use of medicines for patients.
Health and Care Professions Council:	The regulator of 16 different health and care professions including the allied health professions. It maintains a

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

Term	Explanation
	register of health and care professionals that are fit to practice in the UK and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals.
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.
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 for.
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.
Misuse of Drugs Act 1971:	The main purpose of the Misuse of Drugs Act as the primary legislation is to prevent the misuse of controlled drugs and achieves this by imposing a complete ban on the possession, supply, manufacture, import and export of controlled drugs except as allowed by regulations or by license from the Secretary of State. The scope of this legislation is UK-wide.
Misuse of Drugs Regulations:	The Misuse of Drugs Regulations 2001 set out those exceptions to the Act in England, Scotland and Wales. As this is a UK-wide consultation, reference to the Misuse of Drugs Regulations 2001 should also be read as the Misuse of Drugs Regulations (Northern Ireland) 2002.
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 o.

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