Consultation Stage Impact Assessment:

# 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

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| **Title:** Consultation Stage Impact Assessment on the proposed amendments to the list of medicines that paramedics are able to administer under exemptions within the Human Medicines Regulations 2012<br>**IA No:** 9549<br>**Publishing Approval Reference:** PAR145<br>**Lead department or agency:** NHS England<br>**Other departments or agencies:**<br>Devolved administrations, professional bodies | **Impact Assessment (IA)**<br>**Date:** 10/07/2019<br>**Stage:** Consultation<br>**Source of intervention:** Domestic<br>**Type of measure:** Secondary Legislation<br>**Contact for enquiries:** england.cpomedicinesmech@nhs.net |

## Summary: Intervention and Options

**RPC Opinion:** Not applicable

| Cost of Preferred (or more likely) Option | | | | |
|---|---|---|---|---|
| **Total Net Present Value** | **Business Net Present Value** | **Net cost to business per year** (EANDCB in 2014 prices) | **One-In, Three-Out** | **Business Impact Target Status** |
| £47.9m | N/A | N/A | Not in Scope | Not a regulatory provision |

**What is the problem under consideration? Why is government intervention necessary?**

Paramedics have been able to administer certain specified medicines to patients since 1997 under exemptions within medicines legislation. This list of medicines was last updated in 2011, and since then the role of paramedics has changed and medicines technology has evolved. In order to be in line with current best practice, it is proposed that the list of medicines paramedics can administer under exemptions be updated.

**What are the policy objectives and the intended effects?**

The objectives of amending the list of medicines that paramedics can administer under exemptions are twofold. The first is to reduce administrative resources associated with the development and maintenance of patient group directions for those medicines added to the exemptions list. The second is to reduce the risk of delays in the provision of patient care, and thereby: a) reduce inefficient use of NHS resources; b) improve patient experience; c) improve patient health outcomes.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

Option 1 – Business as usual/no change

Option 2 - Amend the list of medicines that paramedics can administer to patients under exemptions within medicines legislation.

**Will the policy be reviewed?** It will/will not be reviewed. **If applicable, set review date:** post-implementation

| | | | | |
|---|---|---|---|---|
| Does implementation go beyond minimum EU requirements? | | N/A | | |
| Are any of these organisations in scope? | **Micro** No | **Small** No | **Micro** No | **Large** No |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | **Traded:** 0 | **Non-traded:** 0 | |

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible SELECT SIGNATORY: ..... Date: .....

# Summary: Analysis & Evidence

Option 1 – Business as usual

**Description:**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2019/20 | NPV base Year 2019/20 | Time Period: 10 Years | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** | **High:** | **Best Estimate:** 0 |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | | | | |
| **High** | | | | |
| **Best Estimate** | | | | **0** |

**Description and scale of key monetised costs by 'main affected groups'**

None

**Other key non-monetised costs by 'main affected groups'**

None

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | | | | |
| **High** | | | | |
| **Best Estimate** | | | | **0** |

**Description and scale of key monetised benefits by 'main affected groups'**

None

**Other key non-monetised benefits by 'main affected groups'**

None

**Key assumptions/sensitivities/risks**

None

**Discount rate** 1.5/3.5

**BUSINESS ASSESSMENT (Option 1)**

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: N/A |
|---|---|---|---|
| **Costs:** N/A | **Benefits:** N/A | **Costs:** N/A | |

# Summary: Analysis & Evidence

Option 2 – Proposed changes

**Description:**

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2019/20 | NPV base Year 2019/20 | Time Period: 10 Years | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** Optional | **High:** Optional | **Best Estimate:** 47.9 |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | | | | |
| **High** | | | | |
| **Best Estimate** | | | | **0** |

**Description and scale of key monetised costs by 'main affected groups'**

None. The identified healthcare professionals already have the ability to administer medicines under exemptions within medicines legislation, and are trained to competently do so. The proposed amendments extends the list of medicines and is not anticipated that this change will directly lead to any additional training cost being incurred. It is not anticipated that this will lead to an increase in the amount of time paramedics spend treating patients.

**Other key non-monetised costs by 'main affected groups'**

None

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | | | | |
| **High** | | | | |
| **Best Estimate** | | | | **47.9** |

**Description and scale of key monetised benefits by 'main affected groups'**

Less administrative resource will be required to develop and maintain patient group directions for those medicines added to the list of exemptions.

**Other key non-monetised benefits by 'main affected groups'**

Improved operating efficiency from reducing the risk of delays and interruptions in care
Improved patient outcomes and patient experience as a result of being able to access appropriate medicines in a timely manner.
Improvements in standardisation of care across the UK.

**Key assumptions/sensitivities/risks** **Discount rate** 1.5

We have assumed that there is no change in risks of inappropriate administration of medicines.
We have discounted benefits to patient health and the NHS at 1.5% per annum.

**BUSINESS ASSESSMENT (Option 2)**

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: N/A |
|---|---|---|---|
| **Costs:** N/A | **Benefits:** N/A | **Costs:** N/A | |

# Evidence Base (for summary sheets)

**Narrative Summary**
**Problem under consideration**

1. The law designates some medicines as being available by prescription only, meaning they can only be given to a patient if they have been prescribed by a doctor or another prescriber. Since 1997, paramedics have been able to administer medicines under exemptions from these restrictions. The list of medicines this applies to is stated under Schedule 17 of the Human Medicines Regulations 2012. Paramedics can administer the medicines listed within schedule 17 for the immediate, necessary treatment of sick and injured persons without the requirement for a prescription, directions of a prescriber or a patient group direction (PGD). This list was last updated in 2011.

2. Since 2011, the role of paramedics and the medicines they use has changed. Currently, there are medicines that paramedics must administer routinely for emergency care, but they can only do this by using a PGD. In order to ensure that best-practice medicines can be administered in a timely manner, NHS ambulance services must make sure that as many paramedics as possible have signed the relevant PGDs. This requires significant administrative effort on the part of the ambulance service, and there remains a risk that some paramedics will not be able to administer the required medicines at the required time.

**Rationale for intervention**

3. There are restrictions within UK-wide medicines legislation as to who can supply, administer and prescribe medicines. Evidence suggests there are potential efficiency gains and improvements to patient experience and health outcomes if certain healthcare professionals are provided with extended responsibilities in relation to being able to supply, administer and/or prescribe medicines[1,2].Currently, each ambulance service needs to develop and maintain large numbers of PGDs, and have these signed by as many paramedics as possible. This requires significant administrative burden, taking up time and resources that could be used delivering patient care. There is also a risk that the need for PGDs results in unnecessary variation in the care provided given that some ambulance services do not have PGDs developed for controlled drugs.

4. There are also likely to be some cases where certain paramedics have not signed a PGD, and so are unable to supply and administer medicines using this mechanism. In these cases the paramedic will need to rely on other health professionals to administer medicines, either additional ambulance units or upon arrival at hospitals. This represents inefficient use of NHS resources, and the delays in treatment may lead to worse health outcomes and patient experience.

**Policy objective**

5. The objective of the proposed amendment to the list of medicines that paramedics can administer under exemptions are twofold. The first is to reduce administrative resources associated with the development and maintenance of PGDs for those medicines added to the exemptions list. The second is to reduce the risk of delays in the provision of patient care, and thereby: a) reduce inefficient use of NHS resources; b) improve patient experience; c) improve patient health outcomes.

[1] Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs.*
[2] I5 Health (2015). *Non-Medical Prescribing (NMP) – An Economic Evaluation*

**Proposed policy change – amending the list of medicines listed under Schedule 17 of the Human Medicines Regulation (2012) that paramedics can administer**

6. In 2015 NHS England commissioned a scoping project to look at the evidence for extending the responsibilities for prescribing, supply and administration of medicines to a number of health professions. Prioritisation was given to professions which demonstrated benefits to a wide patient population and changes that were aligned with the Five Year Forward View[3]. The resultant report recommended that in order to ensure that care is being delivered in line with current best practice, additional medicines should be added to the exemption list for administration by all paramedics. The College of Paramedics have proposed the following 6 medicines to be listed in legislation for paramedics to be able to administer:

    a. **Controlled drugs** – lorazepam and midazolam

    b. **Prescription only medicines** – flumazenil, dexamethasone, magnesium sulfate and tranexamic acid

**Description of options considered**

*Option 1 – Business as usual/no change*

7. Paramedics will continue to be able to administer these medicines under PGDs, if they are in place within the organisation they are working for.

*Option 2 – Amend the list of medicines that paramedics can administer to patients under exemptions within the Human Medicines Regulations*

8. Currently PGDs must be developed by each ambulance service and they must aim for PGDs to be signed by all relevant paramedics. If paramedics have not signed some PGDs, then patients who could benefit from these medicines may need to wait longer for best practice treatment. The proposed change would expand the list of medicines that paramedics can administer under exemptions. This would avoid the need for PGDs for these medicines, which has the following intended benefits:

    a. **Efficient use of NHS resources** – (i) *Administrative savings to the ambulance service* – PGDs are burdensome to create and review, they take time for the paramedics to read and sign and require administrative effort on the part of the ambulance service to maximise the number of paramedics who have signed – removing the need for them will save time and resources that can be used elsewhere; (ii) *Operating savings* – exemptions would reduce the possibility that a paramedic is unable to administer the required medicine in an emergency, as there would no longer be a risk that they have not signed the PGD. This should reduce the need to divert unnecessary additional resources towards these patients.

    b. **Better patient experience** – Reducing delays in the administration of best practice medicines is likely to improve convenience and satisfaction of patients and carers, and reduce stress and anxiety.

    c. **Improved patient health –** Timely administration of medicines reduces the risk of a patient's condition deteriorating.

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

## Costs

9. Amending the list of medicines that paramedics can administer under exemptions as proposed will not lead to additional training costs. The use of exemptions is currently embedded within all of the pre-registration paramedic education and training programmes; amending the list of medicines will not require any revisions to this training. Paramedics are expected to already be competent in the administration of any medicines they would be using under exemptions. The exemptions training curricula are approved by the Health and Care Professions Council (HCPC), therefore paramedics are qualified to use exemptions upon registration with the HCPC.

*Risks of inappropriate administration of medicines*

10. If paramedics are able to supply and administer additional medicines to a patient under exemptions as proposed, there is the potential that they will mistakenly supply or administer a medicine that is unsuitable for the patient. If this becomes more likely than in current practice, there will be an associated net health cost. There is little published information testing differences in inappropriate medicines usage or medicines error resulting from expansions in medicines responsibilities. The most extensive relevant study finds no difference between nurse prescribers and consultant doctors, and that nurses outperform junior doctors[4]. Previous evaluations do not find any evidence of increased risk of medicines errors[1,2]. On balance, we conclude that there is unlikely to be an increase in the risk of inappropriate administration and supply of medicines. We discuss this further in paragraphs 26-28, and a table of potential risks and governance measures already in place to manage them can be found in section 4.5 of the full consultation guide.

## Benefits

*Efficiency*

Administrative Efficiency

11. Paramedics are currently required to use PGDs to administer the medicines that are not currently available via an exemption. These are costly to produce and must be reviewed every two to three years. Mechanisms and processes to ensure that all staff are competent in the administration of the proposed medicines will remain, but these have a considerably smaller administrative burden. Based on an estimate of forty hours input by different professionals, including pharmacists, doctors and paramedics, we estimate the average cost of producing a routine PGD is £1,700. The cost of reviewing them every three years is £1,200.

12. Based on the advice of the College of Paramedics (COP), we estimate that each of the 13 ambulance services[5] in the UK has an average of 1 PGD for each of the 6 medicines (although some ambulance services will have multiple PGD documents for the same medicine, referring to separate groups of patients) – a total of 78 PGDs. NICE guidelines suggest that PGDs expire after a maximum of three years, after which a review is needed[6], and so we assume that each PGD is reviewed every 3 years. The total undiscounted cost over 10 years for reviewing PGDs that would be avoided as a result of the proposed change is estimated to be £0.3m.

13. We also assume that there is an administrative cost associated with reading and signing the PGDs. There are currently around 28,000 registered paramedics across the UK[7], the vast majority being in regular patient facing roles, which currently must read and sign PGDs. Those who are not in regular patient facing roles are expected to read and sign in order for them to be available for major incidents. Based on the advice of the COP, we estimate that this will require an average of 2 hours per paramedic per year, to cover all their PGDs, and we estimate the costs of backfill for this time (to capture either the financial cost of backfilling staff or the economic cost

[4] Ashcroft, D., Lewis, P., Tully, M. (2015). *Prevalence, Nature, Severity and Risk Factors for Prescribing Errors in Hospital Inpatients: Prospective Study in 20 UK Hospitals*. Drug Safety, 38:833-843
[5] This includes 10 ambulance trusts in England and the Welsh, Scottish and Northern Ireland Ambulance Services. It does not include the integrated Isle of Wight NHS trust.
[6] National Institute for Clinical Excellence (2017) *patient group directions: medicines practice guideline*
[7] Health and Care Professionals (2019). Registrants by Profession & route &-Gender

of reduced activity) based on a unit cost of £19.10 per hour (top of band 6 in Agenda for change pay bands[8,9]). The hourly cost of staff covering colleagues' absence is assumed to be the same as there are no (or marginal) capital or management costs associated with the additional cost of staff backfill. Assuming a 2% growth rate in the size of the profession, the total undiscounted cost over 10 years for reading and signing PGDs that would be avoided as a result of the proposed change is estimated to be £12.9m. This is likely to be an underestimate, as paramedics will need to re-sign all the required PGDs if they rotate between ambulance services as PGDs are not transferable across organisations.

14. We estimate that there is a further cost in "chasing up" signatures, as ambulance services try to get as many paramedics as possible to sign each PGD. We estimate that this requires 25% of one administrative staff member's time (costed at £27,200 per year – midpoint of band 5 in Agenda for Change pay bands[8]) in each ambulance service. The total undiscounted cost over 10 years for chasing up PGDs that would be avoided as a result of the proposed change is estimated to be £1.0m.

15. This results in a total undiscounted administrative cost over 10 years that would be avoided as a result of the proposed change of £14.2m.

Operating efficiency

16. Despite the cost and effort directed towards maximising the number of paramedics who sign PGDs, not everyone does. Where this is not the case, and a paramedic does not have a suitable PGD in place, there is a risk that they will not be able to perform best practice treatment. This could result in more complex handovers of unstable patients, longer lengths of stay and the possibility of requiring additional paramedics to be called-out for the same emergency. All of these consequences would require the use of unnecessary additional NHS resources that could be used more effectively elsewhere. Because these incidents are relatively rare, and their outcomes are very uncertain, we have not attempted to monetise the benefits from avoiding them.

*Patient Experience*

17. The clinical scenarios in the NHS England full consultation guide describe situations where emergency procedures are delayed because paramedics cannot administer the required medicines. This can lead to increased levels of distress for patients and their families. Again, these incidents are relatively rare, and their outcomes are very uncertain, so we have not attempted to monetise the benefits from avoiding them.

*Health Benefits*

18. Delays in treatment can also result in worse patient outcomes. We have not attempted to monetise the benefits from avoiding these delays, but in emergency situations they could be large.

*Total Benefits*

19. We have only monetised the most concrete and visible benefit, that of reduced administrative cost associated with the development and maintenance of PGDs. We estimate that this would result in a total undiscounted benefit over 10 years of £14.2m.

20. The Department of Health and Social Care (DHSC) estimates that even though the value of a Quality Adjusted Life Year (QALY) is close to £60,000, NHS funds can be used to generate QALYs at £15,000 per QALY at the margin, due to budget constraints on providers. As a result, releasing £1 of resources by making efficiency savings is estimated to produce £4 of health

[8] NHS Employers (2019). *Agenda for Change pay scales - Hourly 2019/20*

[9] Throughout the Impact Assessment the 2019/20 Agenda for Change (AfC) pay scales for England and Wales have been used. Pay rates in Scotland and in Northern Ireland are not identical to those in England and Wales, but differences are assumed to make a negligible difference to the overall net benefit. Furthermore, we expect similar differences in pay between the home nations for professions outside of the AfC, again we believe there will be no difference to overall net benefits.

benefits. Considering that all efficiency benefits are realised by NHS providers, we estimate total undiscounted benefits over 10 years of £56.9m. Discounting benefits to the NHS at 1.5% per annum gives a present value benefit of £47.9m

21. We believe the non-quantified benefits to patient outcomes and operating efficiency would make this benefit significantly higher.

**Net Benefits**

22. As there are no monetised costs attributed to the proposed changes, the net present value is the same as the total benefits estimated at £47.9m.

**Table 1 Summary of 10 year costs and benefits, central estimate**

| | Cost (£m) | Benefit (£m) | Net benefit (£m) |
|---|---|---|---|
| Year 0 | 0.0 | 1.2 | 1.2 |
| Year 1 | 0.0 | 1.2 | 1.2 |
| Year 2 | 0.0 | 1.2 | 1.2 |
| Year 3 | 0.0 | 1.2 | 1.2 |
| Year 4 | 0.0 | 1.3 | 1.3 |
| Year 5 | 0.0 | 1.3 | 1.3 |
| Year 6 | 0.0 | 1.3 | 1.3 |
| Year 7 | 0.0 | 1.3 | 1.3 |
| Year 8 | 0.0 | 1.4 | 1.4 |
| Year 9 | 0.0 | 1.4 | 1.4 |
| Year 10 | 0.0 | 1.4 | 1.4 |
| *Total (undiscounted)* | *0.0* | *14.2* | *14.2* |
| *Total (discounted)* | *0.0* | *11.9* | *11.9* |
| **Total with opportunity costs (undiscounted)** | **0.0** | **56.9** | **56.9** |
| **Total with opportunity costs (discounted)** | **0.0** | **47.9** | **47.9** |

**Rationale and evidence that justify the level of analysis used in the IA (proportionality approach)**

23. There is not a significant amount of data available on the possible impacts of these changes, and so using guidance from representatives of the COP, reality checked by the Chief Professions Officers' Medicines Mechanism (CPOMM) programme: lists project working group (which includes professional bodies and staff from NHS England) and interpreted cautiously by analysts is appropriate.

**Risks and assumptions:**

24. We believe our estimates of the monetised value of the benefits of this change are reasonable and that some of the non-monetised benefits (e.g. more immediate administration of best practice medicines in life threatening situations) will make this an under-estimate.

25. Because many of the benefits are not monetised, there are not significant risks of over-stating the estimates presented here.

*Risks of inappropriate administration of medicines*

26. In our main analysis, we have not attempted to quantify any risks of the potential harm to patients (health loss) that might occur if inappropriate administration of medicines was more likely as a result of the proposed changes. Although the evidence suggests this is unlikely, we have attempted to conduct a break-even analysis to understand the scale of this risk. We try to estimate how much the rate of medicines errors would need to increase to offset the benefits.

a. A medicine error is a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient. The frequencies of medication errors are not known with any precision either in general or in specific settings, but limited data below reveals they are quite common but that they do not always result in noticeable harm. A UK hospital study of 36,200 medication orders found that a prescribing error was identified in 1.5% of cases and 0.4% of errors were serious[10], and we take this 1.5% as the baseline medicines error rate.

b. We estimate the cost of a medicines error based on a study on the costs and benefits of reducing prescription errors. They identify six medicines where errors are clinically important, and estimate the QALY difference between prescriptions with and without errors using parameters from the literature. Using these estimates, and the relative frequency of these, we estimate that prescription errors cost an average of 0.08 QALYs. Although the medicines considered were chosen based on their known clinical effect, because the proposed changes are for controlled drugs we assume that this is representative of the 1.5% of expected errors. Valuing a QALY at £60,000, this suggests an economic cost per medicine error of £4,800.

c. Given this cost per medicines error, we estimate that the net benefits would be offset if the error rate were 5-6 times higher than the current rate. This suggests that the conclusion that these changes would lead to net benefits is probably not sensitive to the theoretical risk of increased medicines error.

d. Note that this analysis is highly uncertain; it is not clear that the rate of prescription error would be the same as the rate of administration error, and it is a simplification to assume that an error rate is attributable to a single professional or factor. It also uses a conservative estimate of the net benefits, and so probably over-estimates the risk.

27. The likelihood of any increased risk in inappropriate administration of medicines is considered to be low. This is for three main reasons:

    a. Paramedics will typically have considerable experience in administering any medicines that they will administer under exemptions in their current practice. This will entail an understanding of the risks of contraindication, allergies or previous adverse reactions to the medicine required.

    b. Paramedics will only administer medicines within their organisational and/or personal formularies, and will have continuing professional development and assessment to make sure their practice is in line with their competence."

    c. In the cases where paramedics are unable to administer best-practice medicines due to not having signed a PGD, the ability to use exemptions would decrease the risk that they use sub-optimal medicines. It would also increase the likelihood that the health professional who first comes into contact with the patient, and may be best informed about their condition, is the one who treats them.

28. Although we think any increased risk in inappropriate administration of medicines is unlikely, there are a number of processes in place that mitigate any risks.

    a. Training provided in paramedic qualification courses mitigates this risk, in particular training on: managing, ordering, receiving, preparing, administering and recording medicines in accordance with relevant legislation, policy and the Medicines and Healthcare Products Regulatory Agency (MHRA) requirements/regulations; knowledge of drug legislation including medicines management adhering to legal frameworks; recognising adverse drug reactions and managing them appropriately, including reporting where required.

[10] Dean B, Schachter M, Vincent C, Barber N. (2002) *Prescribing errors in hospital inpatients: their incidence and clinical significance*, Qual Saf Health Care, vol. 11 (pg. 340-4)]

b. Legislation states that all aspects of the storage, handling, administration and recording of controlled drugs are overseen by a controlled drugs accountable officer in each organisation where controlled drugs are used. In line with guidance relating to the safe use of medicines, if an error in administration occurs when using exemptions the individual must take immediate action to prevent potential side effects to the patient and must report the error as soon as possible according to local protocols. If a patient experiences an adverse reaction to a medication this should be recorded in the patient's notes and MHRA should be notified via the Yellow Card Scheme.
c. Moving to an exemption will remove the cost of producing multiple PGDs, but will still require clinical practice guidelines (treatment protocols).

d. Paramedics are required to only administer medicines within their scope of practice and competence and the HCPC as the regulator has the powers to remove individuals from their register if the person falls below the standards required.

**Proposed implementation plan**

29. A change in legislation is required to amend the list of exemptions for paramedics.

30. NHS England are consulting on the proposed changes until 10th December 2020.

31. Following the consultation, 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.

32. 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.

33. 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.

**Private sector impact**

34. It is not anticipated that this change in legislation will have an impact upon the private sector, amending the list of exemptions will not require additional training for paramedics.