Consultation Stage Impact Assessment:

Proposed amendments to the list of controlled drugs that physiotherapists can independently prescribe across the United Kingdom

Title: Consultation Stage Impact Assessment on proposed amendments to the list of controlled drugs that physiotherapists can independenty prescribe across the United Kingdom	**Impact Assessment (IA)**
IA No: 9548	**Date:** 10/07/2019
Publishing Approval Reference: PAR145	**Stage:** Consultation
Lead department or agency: NHS England	**Source of intervention:** Domestic
Other departments or agencies: Devolved administrations, professional bodies	**Type of measure:** Secondary Legislation
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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**
£21.2m	N/A	N/A	Not in Scope	Not a regulatory provision

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

Physiotherapists have been able to prescribe independently from a restricted list of controlled drugs since 2015. However, since this list was compiled in a consultation process in 2011, best practice in clinical prescribing has developed, and a number of additional controlled drugs are now suitable for patients in controlling pain and other symptoms. In addition, three drugs that physiotherapists could previously prescribe have since been classified as controlled drugs (tramadol hydrochloride, and more recently pregabalin and gabapentin). In order to align with current best clinical practice in patient care, amendments to legislation are required to update the restricted list of drugs physiotherapist independent prescribers can prescribe.

What are the policy objectives and the intended effects?

The objectives are to reduce delays in the provision of patient care, and thereby: a) reduce inefficient use of health professional time; b) improve patient experience; c) improve patient health.

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 – Enable physiotherapist independent prescribers to prescribe additional controlled drugs under the Misuse of Drugs Regulations (2001).

Will the policy be reviewed? It will 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	**Medium** 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 Policy Option 1 – Business as Usual

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019/20	PV 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'

In our main analysis, we assume that there are no costs associated with the business as usual option.

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 **Discount rate** 1.5/3.5

In our main analysis, we assume that there are no costs associated with the business as usual option.

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	**Net:** N/A	

Summary: Analysis & Evidence Policy Option 2 – Proposed Changes

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019/20	PV Base Year 2019/20	Time Period: 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: 19.7	**High:** 34.1	**Best Estimate:** 21.2

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			19.7
High			34.1
Best Estimate			**21.2**

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

Reduction in the number of consultations with doctors in primary and secondary care settings.
Reduced patient inconvenience having to re-arrange and attend an appointment with a GP.
Reduction in pain or other symptoms while waiting for the GP appointment.

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

Health benefits from more closely monitored courses of controlled drugs and long-term impacts of bringing forwards treatment and recovery.

Key assumptions/sensitivities/risks **Discount rate** 1.5/3.5

We have assumed that there is no inappropriate, unsafe or overprescribing of controlled drugs.
There is uncertainty around our estimates of efficiency savings.
We have discounted benefits to patient health and the NHS at 1.5% per annum, and all other benefits at 3.5% 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	**Net:** N/A	

Evidence Base (for summary sheets)

Narrative Summary
Problem under consideration

1. Since 2013, an advanced physiotherapist practitioner who has undergone additional Health and Care Professions Council (HCPC) approved training can practise as an independent prescriber. Further changes to legislation in 2015 allowed physiotherapist independent prescribers to be able to prescribe from a restricted list of seven controlled drugs. This list was determined based upon a consultation undertaken in 2011. However, clinical prescribing practices have developed since then, so that this list is no longer in line with best practice guidance.

2. In addition, physiotherapist independent prescribers are prevented from prescribing any medicines which have been scheduled as controlled drugs after the date of the consultation in 2011. An amendment to the Misuse of Drugs Regulations 2001 in 2014 to include tramadol hydrochloride as a schedule 3 controlled drug resulted in physiotherapist independent prescribers being unable to prescribe tramadol hydrochloride to their patients.

3. Furthermore, between November 2017 and January 2018, the Home Office consulted on proposals to schedule pregabalin and gabapentin as controlled drugs under the Misuse of Drugs Regulations 2001. This followed the recommendation to ministers by the Advisory Council on the Misuse of Drugs (ACMD)[1] that these two medicines should be placed in Schedule 3 of the Misuse of Drugs Regulations alongside their classification as Class C medicines under the Misuse of Drugs Act 1971. The consultation response[2] published in October 2018 indicated that both pregabalin and gabapentin would be listed in schedule 3 of the Misuse of Drugs Regulations without the application of safe custody requirements from April 2019. It is therefore being proposed that gabapentin and pregabalin are added to the proposed list of controlled drugs that podiatrists can independently prescribe so that they can continue to prescribe these medicines for their patients.

4. Currently, patients under the care of a physiotherapist who would potentially benefit from accessing these controlled drugs to relieve pain must make an additional appointment with another health professional, typically a GP.

Rationale for intervention

5. 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 professions are able to prescribe a wider range of medicines[3,4]. Currently, physiotherapist independent prescribers are sometimes in the position of not being able to provide medicines in line with best practice, even when they are the first to identify the need for a medicine within a clear and established pathway and can identify from patient records if the medicine would not be suitable for the patient. This leads to unnecessary consultations with other healthcare professionals which represents an inefficient use of public money and may delay access for patients who require their skills. It also inconveniences patients.

6. The delay in accessing medicines may result in unnecessary pain and suffering, as well as longer-term risks to effective recovery and rehabilitation. In some interventions, physiotherapists are placed in a position of advising a doctor, who may be less familiar with the patient's case.

[1] ACMD (2016) Correspondence: *advice on the anticonvulsant drugs pregabalin and gabapentin*

[2] Home Office (2018) *A consultation on proposals to schedule pregabalin and gabapentin under the Misuse of Drugs Regulations 2001: Government response to the consultation*

[3] Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs.*

[4] I5 Health (2015). *Non-Medical Prescribing (NMP) – An Economic Evaluation*

This practice was highlighted as a matter of concern within the Crown report (1999)[5], and most recently by the General Medical Council (GMC)[6].

Policy objective

7. The objectives of the proposed change are to reduce interruptions and delays in the provision of care, and thereby: a) reduce inefficient use of health professionals' time; b) improve patient experience; c) improve patient health outcomes.

Proposed policy change – amending the list of controlled drugs that physiotherapist independent prescribers can prescribe from

8. In 2015 NHS England commissioned a scoping project to look at the evidence for extending prescribing, and supply and administration of medicines responsibilities 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[7]. The resultant report recommended a review of the list of controlled drugs that physiotherapist independent prescribers can currently prescribe. The review was carried out to ensure physiotherapists can provide timely, evidence-based interventions and avoid unnecessary pressure on other services and professionals. The Chartered Society of Physiotherapy (CSP), the professional body representing physiotherapists across the UK, engaged with their members to determine what amendments to the list were required to provide optimal, evidence-based patient care. NHS England and the CSP also engaged with a number of stakeholders to ratify the list to and to determine any governance risks associated with their inclusion.

Description of options considered

Option 1 – Business as usual

9. The list of controlled drugs that physiotherapist independent prescribers can currently prescribe from is unchanged.

Option 2 - Enable physiotherapist independent prescribers to prescribe an additional four controlled drugs under the Human Medicines Regulations and the Misuse of Drugs Regulations

10. Currently, physiotherapist independent prescribers are unable to prescribe tramadol hydrochloride, codeine phosphate, pregabalin and gabapentin for their patients, leading to interruptions and delays in treatment when these medicines are required. The proposed change would add these four medicines to the list of controlled drugs which physiotherapist independent prescribers can prescribe from. This would improve the timeliness of treatment, which has the following intended benefits:

    a. **Efficient use of health professional time –** Currently, when one of these medicines is required there is a burden on the GP to have an appointment with an additional patient. Removing this burden by allowing physiotherapists to prescribe these medicines releases time for the GP that could be used for additional patient care.

    b. **Better patient experience** – Reducing delays in accessing the medicines required improves patient convenience and satisfaction. Patients would no longer have to wait for an additional appointment with a GP.

    c. **Improved patient health** – More timely access to treatment may reduce the risk of patients' conditions deteriorating and the severity of persistent pain. This change would

[5] Department of Health (1999). *Review of Prescribing, supply and administration of medicines (the Crown Report).*
6 Avery, T., Barber, N., Ghaleb, M. et al (2012). *Investigating the prevalence and causes of prescribing errors in general practice.*
7 NHS England (2014). *Five year forward view.*

also allow physiotherapists to amend the medicines prescribed in a timely fashion if they observe risk of dependence or evidence that the medicine is not suitable for the patient.

Costs

11. Amending the restricted list of controlled drugs physiotherapists can prescribe from will not lead to additional training costs. It is not anticipated that it will directly lead to an increase in the number of physiotherapists training to be independent prescribers, nor will it require current training courses to be extended.

Risks of prescribing errors

12. If physiotherapist independent prescribers are able to prescribe tramadol, codeine phosphate, gabapentin and pregabalin there is the potential that they will mistakenly prescribe 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[8]. Previous evaluations do not find any evidence of increased risk of medicines errors[3,4]. On balance, we conclude that there is unlikely to be an increase in the risk of inappropriate prescription of medicines. We discuss this further in paragraphs 32-35, and a table of potential risks and governance measures already in place to manage them can be found in section 4.6 of the full consultation guide.

Benefits

Method

13. In order to estimate the total benefits, we estimate the benefits per average affected appointment, and scale this up to the total number of appointments per year for the workforce where starting a course of either tramadol hydrochloride, codeine phosphate, pregabalin and gabapentin.

14. In our calculations of averages, we only include the cases where the process would be affected by the change.

15. After discussing with the leadership of CSP who consulted with a small number of practitioners, we have estimated the range of appointments involving either tramadol hydrochloride or codeine phosphate as between 40,500 and 202,500 per year, with a mid-estimate of 121,500 per year, the vast majority of which are likely to be codeine phosphate. They further advised that one third of these would involve a course of new treatment, i.e. a central estimate of 40,500 per year across the 880 physiotherapist independent prescribers[9].

16. The CSP have advised that gabapentin and pregabalin are currently used much less than codeine phosphate and tramadol hydrochloride and so we assume that 3,000 appointments a year involve gabapentin and pregabalin.

17. This equates to a central estimate of 43,500 consultations per year. We estimate costs in the range 20,000 to 70,000 consultations as lower and upper bound estimates. We assume that there are 46 working weeks a year and that the number of physiotherapist independent prescribers (and the resulting number of appointments) increases by 2% per year.

[8] 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

[9] Health and Care Professions Council (2019). Total number of independent and supplementary prescribers – January 2019.

Efficiency

18. If a GP appointment can be avoided there is an efficiency saving, as the GP can use that time to see other patients who would derive a health benefit from it. If the amendment helps improve access to GPs there is a potential health gain for patients. GP consultations last 9.2 minutes on average[10]. Based on a unit cost of £62.50 per hour for a GP (hourly equivalent of midpoint of GP salary according to PSSRU[10], and adjusted using an inflation rate of 2% to bring in line with 2019/20 prices) we estimate that this saving is £9.60 per affected appointment.

19. 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 a cost of £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 benefits. Assuming that all efficiency benefits are realised by NHS providers, we estimate efficiency benefits of £38.30 per affected appointment, or £1.7m annually.

Patient Experience

20. The CSP report that there is anecdotal evidence that most patients are disappointed to be informed they will have to make another appointment with a GP to access the medicines required. We consider the impact on patients to be an 'inconvenience cost' due to having to make additional appointments. We consider a rearranged appointment to take up an hour of patient time.

21. The Department of Transport published research in 2015 on the value of 'delayed travel time'. They estimate that for all modes/distances that travellers would be willing to pay (workers and non-workers) on average £11.21 in order to save one hour of travel time[11]. We consider this as the cost of wasted patient time, and an indication of patient dissatisfaction resulting from delays, although this is likely to underestimate the anxiety and inconvenience for patients.

22. Reduced wasted time resulting from the proposed changes has a benefit of £11.21 per affected appointment, or £0.5m annually.

Health Benefits

23. The GP Patient Survey tells us that just over 40% of all patients who accepted an appointment, got one on the same or next day, around a quarter for a 'few days later' and another quarter 'a week or more later'[12]. However, the survey cannot tell us how many of these waits are patient driven and how many are delays which inconvenience patients.

24. If a patient is in pain and requires a GP appointment to obtain a prescription, delays before the patient can access the pain relief they need could lead to a period of suffering and anxiety and quality of life loss for the patient.

25. Using the clinical scenarios from the NHS England full consultation guide we estimate a monetary value of this using EQ5D Crosswalk Index Calculator[13]. Patients with severe back pain or post-operative knee pain are the most likely to be affected (and may also have moderate mobility and self-care problems and slight 'usual activities' problems). If the medication they can obtain from the physiotherapist leaves them in severe pain their QALY score will be 0.38 on the EQ5D. If the 'best practice medicine' can reduce their pain from severe to moderate that will increase their QALY score to 0.59, a gain of around 20% of a QALY. We do not attempt to monetise long-term physical health benefits of bringing forward treatment and recovery.

26. If we assume that 50% of patients who experience delays in accessing the medicine experience this decrease in health over the course of 3 days, this results in an average gain of 0.0008

[10] Curtis, L. Burns, A. (2018). *Unit Costs of Health and Social Care 2018.* Personal Social Services Research Unit
[11] Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*
[12] NHS England (2018). GP Patient Survey 2018.
[13] EuroQol (2018). *EQ5D Crosswalk Index Value Calculator*

QALYs per affected appointment. Valuing a QALY at £60,000, this is a benefit of £49.30 per affected appointment. We do not, however, include it in the benefits for the high and central estimate of total benefits, using it only for the low-end estimate of consultations. The lower estimate of 20,000 affected appointments per year results in an annual benefit of £1.0m.

Total benefits

27. The undiscounted 10 year benefit is estimated to be £23.6m. Discounting benefits to health outcomes and to the NHS at 1.5% per annum and all other benefits at 3.5% per annum results in a present value benefit of £21.2m. A lower bound frequency estimate suggests a present value benefit of £19.7m, and the upper bound frequency estimate suggests a present value benefit of £34.1m.

28. Table 1, below summarises the high, best and low range estimates of total benefits broken down between the savings in professions' time, avoided inconvenience cost and possible health benefits.

Table 1: Summary of benefits

Range	Saved GP Time (Year 1)	Patient Satisfaction (Year 1)	Health Benefits (Year 1)	Total (10 year, discounted)
20,000 episodes per annum	£0.8m	£0.2m	£1.0m	£19.7m
43,500 episodes per annum	£1.7m	£0.5m		£21.2m
70,000 episodes per annum	£2.7m	£0.8m		£34.1m

Net Benefits

29. As there are no monetised costs attributed to the proposed changes, the net present value is the same as the total benefits. The lower bound estimate (based on 20,000 affected appointments per year and including the improved health outcomes is £19.7m, and the upper bound estimate (based on 70,000 affected appointments per year) is £34.1m. The central estimate based on 43,500 cases per year and no quantified health benefits is £21.2m. Table 2 below provides a summary over 10 years, with this table provided for lower and upper estimates in Annex A.

Table 2: Summary of 10 year costs and benefits, central estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	0.0	0.9	0.9
Year 2	0.0	0.9	0.9
Year 3	0.0	0.9	0.9
Year 4	0.0	1.0	1.0
Year 5	0.0	1.0	1.0
Year 6	0.0	1.0	1.0
Year 7	0.0	1.0	1.0
Year 8	0.0	1.0	1.0
Year 9	0.0	1.1	1.1
Year 10	0.0	1.1	1.1
Total (undiscounted)	*0.0*	*9.9*	*9.9*
Total (discounted)	*0.0*	*8.1*	*8.1*
Total with opportunity costs (undiscounted)	**0.0**	**23.6**	**23.6**
Total with opportunity costs (discounted)	**0.0**	**21.2**	**21.2**

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

30. There is not a significant amount of data available on the possible impacts of these changes, and so using estimates from the professional body, reality checked by the Chief Professions Officers' Medicines Mechanisms (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:

31. 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. greater compliance with medicines and care plans) could make this an under-estimate. The area of greatest uncertainty is in the total number of consultations that will be affected by the increased number of medicines available for patients. We have tried to account for this uncertainty by using a wide sensitivity analysis around the frequency of cases.

Risks of prescribing errors

32. In our main analysis, we have not attempted to quantify any risks of the potential harm to patients (health loss) that might occur if prescribing errors are 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[14], 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 1-2 times higher than the current error rate. This suggests that the conclusion that these changes would lead to net benefits may be sensitive to the theoretical risk of increased medicines error, however unlikely such an increase is.

    d. Note that this analysis is highly uncertain; it is not clear that the rate of prescription error used here is representative of physiotherapists' practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

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

[14] 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)]

a. Physiotherapists who would prescribe these drugs will be advanced physiotherapists already experienced in independent prescribing, and these drugs will need to form part of their assessed personal formularies. Independent academic evaluation of the impacts of extending prescribing to physiotherapists and podiatrists suggests that benefits are being realised with no observed increased risk of harm to patients[15].

b. If the physiotherapist has regular ongoing contact with the patient, more frequently than the GP does, they may have a better understanding of the patient's history and situation, and may therefore be in a better position to understand the patient's suitability for the medication.

c. The physiotherapist may also be in a better position to identify and respond to risks of dependency and adverse events related to these medicines. They would be in a position where they can amend the courses of these medicines that have been prescribed by other professionals to reduce risks, in a way that they are currently unable to do.

34. Although we think any increased risk in prescribing errors is unlikely, there are a number of processes in place that mitigate any risks.

    a. All physiotherapist independent prescribers are registered with the Health and Care Professions Council (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 minimum standards that the HCPC considers necessary to protect members of the public. Registrants must meet all these standards when they first register and complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet the standards relevant to their scope of practice to stay registered. Registrants must also ensure that they have appropriate indemnity in place to cover all of their work. This indemnity may be provided by an employer, a professional body or by private arrangement.

    b. Only advanced physiotherapists who are qualified independent prescribers will be able to prescribe from the list of controlled drugs. Physiotherapist independent prescribers must only prescribe medicines within their scope of practice and competence.

    c. Physiotherapist independent prescribers will be expected to include any additional controlled drugs in their personal formularies in order to demonstrate competence before prescribing them.

    d. The practice guidance for physiotherapist independent prescribers published by the professional body advises about adequate communication with other prescribers, duration of supply of controlled drugs and for patients to be seen by as few prescribers as possible.

    e. In line with national guidance monitoring of controlled drugs prescribing activity will already be in place in organisations.

    f. The practice guidance for physiotherapist prescribers states that all prescribers are required to engage with monitoring and audit activities, including liaison with the controlled drugs accountable officer.

Proposed implementation plan

35. A change in legislation is required to amend the list of controlled drugs that physiotherapist independent prescribers can prescribe.

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

[15] Carey, N., Stenner, K., Edwards, J. (2017). *Evaluation of Physiotherapist and Podiatrist Independent Prescribing, Mixing of Medicines and Prescribing of Controlled Drugs.*

37. 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 2012. Subject to the agreement of the proposed changes by Ministers; the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments.

38. 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.

39. 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

40. It is not anticipated that this change in legislation will have significant impacts on the private sector, other than the small (20%) proportion of the 880 physiotherapist independent prescribers who do private practice. Almost all benefits from the change would accrue to their patients and savings to the NHS and these are captured in the estimates above.

41. Because of the avoided inconvenience cost and possible health benefit of being given medicine in a timelier manner, physiotherapist independent prescribers might be able to charge higher consultation fees, post the change. But this effect, if it exists, is small and uncertain.

Annex A

Summary of 10 year costs and benefits, lower estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	0.0	0.7	0.7
Year 2	0.0	0.7	0.7
Year 3	0.0	0.7	0.7
Year 4	0.0	0.7	0.7
Year 5	0.0	0.7	0.7
Year 6	0.0	0.7	0.7
Year 7	0.0	0.7	0.7
Year 8	0.0	0.8	0.8
Year 9	0.0	0.8	0.8
Year 10	0.0	0.8	0.8
Total (undiscounted)	*0.0*	*7.3*	*7.3*
Total (discounted)	*0.0*	*6.0*	*6.0*
Total with opportunity costs (undiscounted)	**0.0**	**21.6**	**21.6**
Total with opportunity costs (discounted)	**0.0**	**19.7**	**19.7**

Summary of 10 year costs and benefits, upper estimate

	Cost (£m)	Benefit (£m)	Net benefit (£m)
Year 0	0.0	0.0	0.0
Year 1	0.0	1.5	1.5
Year 2	0.0	1.5	1.5
Year 3	0.0	1.5	1.5
Year 4	0.0	1.5	1.5
Year 5	0.0	1.6	1.6
Year 6	0.0	1.6	1.6
Year 7	0.0	1.6	1.6
Year 8	0.0	1.7	1.7
Year 9	0.0	1.7	1.7
Year 10	0.0	1.7	1.7
Total (undiscounted)	*0.0*	*15.9*	*15.9*
Total (discounted)	*0.0*	*13.1*	*13.1*
Total with opportunity costs (undiscounted)	**0.0**	**38.0**	**38.0**
Total with opportunity costs (discounted)	**0.0**	**34.1**	**34.1**