Consultation Stage Impact Assessment:

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

Title: Consultation Stage Impact Assessment on proposed amendments to the list of controlled drugs that podiatrists can independently prescribe across the United Kingdom **IA No:** 9547 **Publishing Approval Reference:** PAR145 **Lead department or agency:** NHS England **Other departments or agencies:** Devolved administrations, professional bodies	**Impact Assessment (IA)** **Date:** 10/07/2019 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **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**
£37.2m	N/A	N/A	Not in Scope	Not a regulatory provision

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

Podiatrists 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 podiatrists 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 podiatrist 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 podiatrist 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

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'

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	**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: 23.8	**High:** 55.8	**Best Estimate:** 37.2

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				23.8
High				55.8
Best Estimate				**37.2**

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-arange and attend appointments with other health professionals.
Reduction in pain or other symptoms while waiting for treatment.

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 change in 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 podiatrist 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 podiatrist independent prescribers to be able to prescribe from a restricted list of four 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.

2. In addition, podiatrist 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 podiatrist independent prescribers being unable to prescribe tramadol hydrochloride for 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. This followed the recommendation to ministers by the Advisory Council on the Misuse of Drugs (ACMD) 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[1] published in October 2018 indicated that both pregabalin and gabapentin will 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 to their patients.

4. Currently, patients under the care of a podiatrist 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[2,3]. Currently, podiatrist 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 the patient.

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, podiatrists are placed in a position of advising a doctor, who may be less familiar with the patient's case. This practice was highlighted as a matter of concern within the Crown report (1999)[4], and most recently by the General Medical Council (GMC)[5].

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

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

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

[4] Department of Health (1999). *Review of Prescribing, supply and administration of medicines (the Crown Report).*

[5] Avery, T., Barber, N., Ghaleb, M. et al (2012). *Investigating the prevalence and causes of prescribing errors in general practice.*

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.

Policy Change – amending the list of controlled drugs that podiatrist 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[6]. The resultant report recommended a review of the list of controlled drugs that podiatrist independent prescribers can prescribe. The review was carried out to ensure podiatrists can provide timely, evidence-based interventions and avoid unnecessary pressure on other services and professionals. The College of Podiatry (COP) and the Institute of Chiropodists and Podiatrists (IOCP), the professional bodies representing podiatrists 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 also engaged with a number of stakeholders to ratify the list 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 podiatrist independent prescribers can currently prescribe from is unchanged.

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

10. Currently, podiatrist independent prescribers are unable to prescribe tramadol hydrochloride and morphine sulfate for their patients, leading to interruptions and delays in treatment. Following the scheduling of these medicines from April 2019 they are now also unable to prescribe pregabalin and gabapentin. The proposed change would add tramadol hydrochloride, morphine sulfate, pregabalin and gabapentin, to the list of controlled drugs which podiatrist 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 or other health professional to have an appointment with an additional patient. Removing this burden by allowing the podiatrist to prescribe these medicines releases time for the GP or other health professional 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 other health professionals.

    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 also allow podiatrists 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.

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

Costs

11. Amending the restricted list of controlled drugs podiatrists 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 podiatrists training to be independent prescribers, nor will it require current training courses to be extended.

Risks of prescribing errors

12. If podiatrist independent prescribers were able to prescribe the proposed controlled drugs, 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[7]. Previous evaluations do not find any evidence of increased risk of medicines errors[2,3.] 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 42 - 44, 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, morphine sulfate, 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 the COP and the IOCP who consulted with a small number of practitioners, the profession has estimated the range of appointments involving a course of new treatment of tramadol hydrochloride or morphine sulfate as between 23,500 and 31,500 per year.

16. In addition, the COP and IOCP have advised that gabapentin and pregabalin are currently used much less than morphine sulfate and tramadol hydrochloride, and so we assume that 1,000 appointments a year involve gabapentin and pregabalin. Therefore, across the 340 podiatrist independent prescribers[8], the profession believes that the total number of consultations per year requiring a scheduled drug is between 24,500 and 32,500.

17. As there is a small range between the lower and upper bounds of affected appointments provided by the profession, the sensitivity analysis (see Table 1) will use 15,000 affected appointments as a conservative lower bound, 30,000 as the central estimate, and an upper bound estimate of 45,000 affected appointments. For the main analysis we will use the central estimate of 30,000 affected appointments per year. We assume that there are 46 working weeks a year and the number of podiatrist independent prescribers (and the resulting number of appointments) increases by 2% per year.

18. The profession also advised that some of these (30%) would involve a short delay in the appointment as the podiatrist searched successfully for an alternative prescriber. The majority however, (65%) would require the patient to attend a new appointment with his or her GP and a small minority (5%) who were attending for surgery would also have to make a GP appointment and re-arrange the operation.

[7] 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

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

19. For ease of reading, the cohorts described from paragraph 20 will be categorised as: *minor* for the patients who experienced a short delay, *major* for the patients who only require an additional GP appointment, and *severe* for patients who require both an additional GP appointment and a re-arranged operation.

Efficiency

Search costs

20. For the affected appointments which have minor delays that can be resolved on site, there are search costs for the podiatrists and interruption costs for the prescribers. For this cohort of affected appointments, a podiatrist would spend approximately 10 minutes searching for another prescriber.

21. Multiplying the unit cost of a podiatrist independent prescriber (£26.00 – top of Band 8 A in Agenda for Change pay bands[9,10]) by the time taken-up by the delay, we estimate a cost of £4.30 per appointment affected with a minor delay. Weighting this based on the frequency of minor delays (30%), we estimate that avoiding search time saves £1.30 per average affected appointment.

Other health professionals' time

22. For minor delays, we assume a hospital medical prescriber, with a unit cost of £54.10 (the hourly equivalent of the midpoint of consultant salaries according to NHS Health Careers[11], and adjusted using an inflation rate of 2% to bring in line with 2019/20 prices), spends 5 minutes assessing the patient before providing the prescription. Calculating in the same way as above, we estimate that avoiding this cost saves £4.50.

23. In an estimated 70% (GP appointments as part of both major and severe delays) of affected appointments a GP appointment can be avoided and this represents a much bigger potential efficiency saving. GP consultations last 9.2 minutes on average[12]. Based on a unit cost of £62.50 per hour for a GP (hourly equivalent of midpoint of GP salary according to PSSRU[12], 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.

24. We assume for severe delays there is an additional estimated cost of an unplanned cancelled operation at half the average cost of a day case[13]. After adjusting for an inflation rate of 2% to bring the price in line with 2019/20 pricing this amounts to £385.00.

25. We calculate the weighted average across the three kinds of delays, to estimate that avoiding inefficient use of other health professionals' time saves £27.40 per affected appointment.

Total Efficiency

26. The total efficiency savings which could be generated is estimated to be an average of £28.70 per affected appointment.

27. 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

[9] NHS Employers (2019). *Agenda for Change pay scales - Hourly (2019/20)*
[10] 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.
[11] NHS Health Careers (2018). *Pay for doctors*.
[12] Curtis, L. Burns, A. (2018). *Unit Costs of Health and Social Care 2018*. Personal Social Services Research Unit
[13] NHS Improvement (2018). *National schedule of reference costs (2017/18)*

health benefits. Assuming that all efficiency benefits are realised by NHS providers, we estimate efficiency benefits of £114.60 per affected appointment, or £3.4m annually.

Patient Experience

28. The COP and IOCP report that there is anecdotal evidence which suggests that most patients are disappointed to be informed that they will have to make another appointment with a GP to access the medicines required.

29. We assume that rearranging an appointment takes up an hour of patient time, and that where a patient has had to have an operation re-scheduled there is an additional 3 hours lost patient time. Together, this results in an average wasted patient time of 51 minutes per affected appointment.

30. 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[14]. 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.

31. Reduced wasted time resulting from the proposed changes has a benefit of £9.50 per affected appointment, or £0.3m annually.

Health Benefits

32. 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'[15]. However, the survey cannot tell us how many of these waits are patient driven and how many are delays which inconvenience patients.

33. 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.

34. Using the clinical scenarios from the NHS England full consultation guide we estimate a monetary value of this using EQ5D Crosswalk Index Calculator[16]. Patients with post-operative 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 podiatrist 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.

35. If we assume that 50% of patients who experience major or severe delays experience this decrease in health, this results in an average gain of 0.0006 QALYs per affected appointment. Valuing a QALY at £60,000, this is a benefit of £34.50 per affected appointment. We do not, however, include it in the benefits for the high and mid-range estimates of total benefits, using it only for the low-end estimate of consultations. The lower estimate of 15,000 affected appointments per year results in an annual benefit of £0.5m.

Total Benefits

36. The undiscounted 10 year benefit is estimated to be £40.8m. 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 £37.2m. A lower bound frequency estimate suggests a present value benefit of £23.8m, and the upper bound frequency estimate suggests a present value benefit of £55.8m.

[14] Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*
[15] NHS England (2018). GP Patient Survey 2018.
[16] EuroQol (2018).*EQ5D Crosswalk Index Value Calculator*

37. Table 1, below summarises the high, central 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 health professional time (Year 1)	Patient Satisfaction (Year 1)	Health Benefits (Year 1)	Total (10 year, discounted)
15,000 episodes per annum	£1.7m	£0.1m	£0.5m	£23.8m
30,000 episodes per annum	£3.4m	£0.3m		£37.2m
45,000 episodes per annum	£5.2m	£0.4m		£55.8m

Net Benefits

38. 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 15,000 affected appointments per year and including the improved health outcomes) is £23.8m, and the upper bound estimate (based on 45,000 affected appointments per year) is £55.8m. The central estimate based on 30,000 cases per year and no quantified health benefits is £37.2m. 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	1.1	1.1
Year 2	0.0	1.2	1.2
Year 3	0.0	1.2	1.2
Year 4	0.0	1.2	1.2
Year 5	0.0	1.2	1.2
Year 6	0.0	1.3	1.3
Year 7	0.0	1.3	1.3
Year 8	0.0	1.3	1.3
Year 9	0.0	1.3	1.3
Year 10	0.0	1.4	1.4
Total (undiscounted)	*0.0*	*12.5*	*12.5*
Total (discounted)	*0.0*	*10.3*	*10.3*
Total with opportunity costs (undiscounted)	**0.0**	**40.8**	**40.8**
Total with opportunity costs (discounted)	**0.0**	**37.2**	**37.2**

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

39. 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 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:

40. 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 plan) could make this an under-estimate.

41. 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

42. 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[17], 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 2-3 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 podiatrists' practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

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

    a. Podiatrists who would prescribe these drugs will be advanced podiatrists 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[18].

    b. If the podiatrist has regular ongoing contact with the patient, more frequently than other health professionals, they may have a better understanding of the patient's history and

[17] 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)]

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

situation, and may therefore be in a better position to understand the patient's suitability for the medication.

c. The podiatrist 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.

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

a. All podiatrist 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 podiatrists who are qualified independent prescribers will be able to prescribe from the list of controlled drugs. Podiatrist independent prescribers must only prescribe medicines within their scope of practice and competence.

c. Podiatrist 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 podiatrist 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 podiatrist independent 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

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

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

47. 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.

48. 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.

49. 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

50. It is not anticipated that this change in legislation will have significant impacts on the private sector. All benefits from the change would accrue to their patients and savings to the NHS and these are captured in the estimates above.

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	0.8	0.8
Year 6	0.0	0.8	0.8
Year 7	0.0	0.8	0.8
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*	*7.7*	*7.7*
Total (discounted)	*0.0*	*6.3*	*6.3*
Total with opportunity costs (undiscounted)	**0.0**	**26.1**	**26.1**
Total with opportunity costs (discounted)	**0.0**	**23.8**	**23.8**

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	1.7	1.7
Year 2	0.0	1.8	1.8
Year 3	0.0	1.8	1.8
Year 4	0.0	1.8	1.8
Year 5	0.0	1.9	1.9
Year 6	0.0	1.9	1.9
Year 7	0.0	1.9	1.9
Year 8	0.0	2.0	2.0
Year 9	0.0	2.0	2.0
Year 10	0.0	2.1	2.1
Total (undiscounted)	*0.0*	*18.8*	*18.8*
Total (discounted)	*0.0*	*15.5*	*15.5*
Total with opportunity costs (undiscounted)	**0.0**	**61.2**	**61.2**
Total with opportunity costs (discounted)	**0.0**	**55.8**	**55.8**