Consultation Stage Impact Assessment:

Proposal for the supply and administration of medicines using patient group directions by operating department practitioners across the United Kingdom

Title: Consultation Stage Impact Assessment on the proposal for the supply and administration of medicines using patient group directions by operating department practitioners across the United Kingdom **IA No:** 9551 **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**
£466.9m	N/A	N/A	Not in Scope	Not a regulatory provision

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

Currently, operating department practitioners can only administer and supply medicines using patient specific directions. When a patient specific direction has not been produced, operating department practitioners are unable to supply and administer required medicines, even though they may be the first to identify the need for a medicine within a clear and established treatment pathway. 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.

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 operating department practitioners to supply and administer medicines using patient group directions under the Human Medicines Regulations 2012

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'

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	**Net:** 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: 59.5	**High:** 772.4	**Best Estimate:** 466.9

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			
High			
Best Estimate			**42.4**

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

Administration cost of developing and reviewing patient group directions, borne largely by NHS organisations.
Training costs, borne largely by NHS organisations.

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			101.9
High			814.8
Best Estimate			**509.3**

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

Reduction in inefficient search time by operating department practitioners.
Reduction in number of consultations with other health professionals.
Improved patient experience.

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

Health benefits associated with more timely access to medicines.

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

We have assumed that there is no change in risks of inappropriate administration of medicines.
There is uncertainty around our estimates of efficiency savings.
We have discounted benefits to 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	

Operating Department Practitioner Impact Assessment Evidence Base (for summary sheets)

Narrative Summary
Problem under consideration

1. Operating Department Practitioners (ODPs) are currently able to administer and supply medicines under patient specific directions (PSDs). This is a written instruction to administer or supply a medicine to a named patient who has been assessed by an authorised prescriber.

2. The work of ODPs is to predominantly provide perioperative care to patients, but in recent times this has extended beyond the operating department as ODPs are increasingly using their transferable knowledge and skills in other hospital departments. Currently they are unable to directly administer and supply medicines without acquiring a PSD from a prescriber, typically a doctor. Given the difficulty of anticipating the need for medicines for particular patients, ODPs often do not have the required PSDs, and so are not able to supply and administer 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 professions are able to supply, administer and/or prescribe a wider range of medicines[1,2]. Currently, ODPs are commonly unable to supply or administer medicines, even when they are the first to identify the need for a medicine within a clear and established treatment 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.

4. The delay in accessing medicines may increase health risks for patients if it prevents them having timely access to treatment. In some interventions, ODPs are placed in a position of advising an independent prescriber, who may be less familiar with the patient's case or the medicines required, to effectively carry out the care required. This practice was highlighted as a matter of concern within the Crown report (1999)[3], and most recently by the General Medical Council (GMC)[4].

Policy objective

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

Policy Change – enabling Operating Department Practitioners to supply and administer medicines using patient group directions

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 where changes were aligned with the Five Year Forward View[5]. The resultant report recommended that ODPs be able to administer and supply medicines using PGDs to

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

provide timely, evidence-based interventions and avoid unnecessary pressure on other services and professionals.

Description of options considered

Option 1 – Business as usual/no change

7. ODPs continue being only able to administer medicines under PSDs. They will only be able to administer medicines for named patients if there is a written instruction to do so from an authorised prescriber.

Option 2 - Allow Operating Department Practitioners to administer and supply medicines using Patient Group Directions

8. Currently, ODPs are unable to administer a required medicine when a PSD is not in place, and must rely on another professional, typically a doctor, which is likely to cause a delay. The proposed change would allow ODPs to use PGDs, which would give them the ability to administer and supply specific medicines to pre-defined groups of patients without the need for a PSD. This would improve the timeliness of diagnostic and treatment procedures, which has the following intended benefits:

    a. **Efficient use of health professional time –** Currently, when a medicine is required there is often a burden on the ODP who has to seek out and organise a PSD, and a doctor who has to see the patient and provide this. Removing this burden by allowing the ODP to supply/administer the medicine using a PGD releases time that could be used for 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 health professionals during this time, or arrange, travel to and attend additional appointments.

    c. **Improved patient health** – More timely access to treatment may reduce the risk of patients' conditions deteriorating. It may also reduce the risk that ODPs are put in a position of advising an independent prescriber on what medicines are required.

Costs

Patient Group Direction costs

9. There will be an additional cost of developing and approving PGDs for ODPs. Based on an estimate of forty hours' input by different professional and administrative staff, including pharmacists, doctors and ODPs, we estimate the average cost of producing a routine PGD is £1,700. The cost of reviewing them is estimated to be £1,200.

10. The College of Operating Department Practitioners (CODP) and the Association for Perioperative Practice (AfPP), the professional bodies representing ODPs, estimate that there will be demand for the development of 10 PGDs for ODPs at each of approximately 215 health organisations across the UK[6]. We estimate that around 2,150 PGDs will be produced over the first three years (roughly 720 in each). NICE guidelines suggest that PGDs expire after a maximum of three years, after which a review is needed[7], and so we assume that each PGD is reviewed every 3 years. The total undiscounted cost over 10 years for producing and reviewing PGDs is estimated to be £9.7m.

11. We also assume that there is an administrative cost associated with reading and signing the PGDs once they are created. Based on the advice of professions that currently use PGDs, we

[6] This is an estimate based on 152 acute trusts and 35 community trusts in England, 16 regional health boards in Scotland, 5 NHS trusts in Northern Ireland and 7 Local Health Boards in Wales.
[7] National Institute for Clinical Excellence (2017) *patient group directions: medicines practice guideline*

estimate that this will require an average of 2 hours per trained ODP 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 of reduced activity) based on a unit cost of £15.40 per hour (Band 5/band 6 in Agenda for Change pay bands[8,9]). The total undiscounted cost over 10 years for reading and signing PGDs is estimated to be £1.6m. This is likely to be an underestimate, as ODPs will need to re-sign all the required PGDs if they move between NHS trusts as PGDs are not transferable across organisations.

12. This results in a total undiscounted administrative cost over 10 years of £11.3m. This is likely an overestimate as PGDs currently used by nurses could be modified to include ODPs.

Training costs

13. In line with NICE Guidance[7], additional on-line training (most likely using the programme available from the Centre for Postgraduate Pharmacy Education[10]) will be required in the use of PGDs for ODPs. This will take 90 minutes, and as above we estimate the costs of backfill for those being trained based on a unit cost of £15.40 per hour. 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. The professional bodies estimate that 40% of the profession will be trained within the first five years (approximately 1,200 of the 13,800 ODPs[11] in each of the first five years), and we assume that this proportion remains constant as the profession grows at 2% per annum. The total undiscounted cost over 10 years is estimated to be £0.2m.

14. ODPs are likely to be already administering required medicines using PSDs, and so more additional training in general medicines management or pharmacology is unlikely to be needed.

Total costs

15. This results in a total undiscounted training cost over 10 years of £0.2m and including the PGD costs gives an estimated total undiscounted 10 year cost of £11.5m.

16. Department of Health and Social Care (DHSC) estimates that even though the value of a 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, diverting £1 of resources towards PGD production and training has an opportunity cost of £4 lost health benefits. Taking account of this relationship, and assuming that all costs are borne by NHS providers, we estimate that the opportunity cost of training and PGD production undiscounted over 10 years is £45.8m. Discounting costs to the NHS at 1.5% per annum results in a discounted present value cost of £42.4m.

Risks of inappropriate administration of medicines

17. If ODPs are able to supply and administer medicines to a patient through PGDs, 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[12]. 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

[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.
[10] Centre for Postgraduate Pharmacy Education *PGD e-learning package*
[11] Health and Care Professionals (2019). Registrants by Profession & route &-Gender
[12] 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

risk of inappropriate administration and supply of medicines. We discuss this further in paragraphs 34-36, 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

Method

18. We estimate the benefits per average affected case, and scale this up to the total number of cases per year for the workforce which would have the relevant PGDs in order to estimate the total benefits. In our calculations of averages, we only include the cases where the process would be affected by the change. Here we have used a combination of the expertise of senior members of the CODP and the AfPP, plus responses from a small number of ODPs consulted by the AfPP to inform the evidence base.

19. Responses from consulted ODPs seemed to be unrepresentative of the entire profession. For example, one respondent worked in the community where a lack of PGDs would have had a very significant impact to the patient as the assessment would have to be rearranged in the majority of cases due to the lack of another prescriber. Therefore a significant amount of interpretation was needed. We weighted responses from the consulted ODPs as being representative of 25% of those trained and the remaining 75% was based on estimates from senior members of the CODP and AfPP.

20. These have been used to estimate the expected benefits of the policy, which are to: a) reduce inefficient use of health professionals' time; b) improve patient experience; c) improve patient outcomes.

21. Using the responses from the consulted ODPs and the estimates from the CODP and the AfPP, we estimate that 7.5 (25%) of the 30 cases that ODPs have per week are affected by delays through being unable to supply and administer the medicines their patients need. Sensitivity analysis on the changes to the frequency of affected assessments is discussed in paragraph 29.

Efficiency

22. There are two sources of efficiency benefits. The first represents the savings to the ODP's time (valued at £15.40 per hour) from not having to find a prescriber. Of the 7.5 delayed cases per week, responses suggest that 5.9 resulted in a minor (5 minute average) delay, 0.8 resulted in a major (30 minute average) delay, and 0.8 resulted in a severe delay (30+ minute average). We assume that these delays represent inefficient search time by the ODP. Assuming a minor delay takes-up an average of 5 minutes of ODP time, and both a major delay and severe delay take-up an average of 30 minutes of ODP time, we estimate that when the required mechanism is not in place, the average ODP time that is taken up by delays is 10.3 minutes per affected assessment, which could be saved under the proposed change. Using the unit costs of the ODP, this gives an average estimated benefit of £2.60 per affected case.

23. The second represents the savings to other health professionals' time. Currently, in order for the patient to receive the required medicines the ODP would usually have to locate a doctor who would provide the ODP with a PSD so that they can administer the medicine. We assume a doctor would take 5 mins to provide a PSD for the ODP and that the time it takes for the ODP to administer the medicine does not change. Using a unit cost of £54.10 for a doctor (the hourly equivalent of the midpoint of consultant salaries according to NHS Health Careers[13], and adjusted using an inflation rate of 2% to bring in line with 2019/20 prices), saving this time has an average estimated benefit of £4.50 per affected case.

24. The total efficiency benefit per affected assessment is therefore estimated to be £7.10. DHSC estimates that even though the value of a 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

[13] NHS Health Careers (2018). *Pay for doctors*.

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 £28.60 per affected case.

Patient Experience

25. We consider the impact on patients to be an 'inconvenience cost' due to delay or having to make additional appointments. We assume that a minor delay takes up an average of 5 minutes of patient time, a major delay takes up an average of 30 minutes of patient time, and severe delays an average of 60 minutes. We estimate that when the required mechanism is not in place, the average wasted patient time is 13.5 minutes per affected case.

26. 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.

27. Reduced wasted time resulting from the proposed changes has a benefit of £2.50 per affected case.

Health Benefits

28. ODPs work predominantly to provide care to perioperative patients, and therefore a delay in the administration of a medicine may cause patients a short amount of stress/anxiety in these instances. However, ODPs have extended into other areas of care, for example in the emergency department where ODPs assess, triage, and deliver care to patients particularly in trauma and resuscitation. Therefore, there is a risk of an escalation of conditions without timely access to medicines. These effects are not quantified, as effects are highly uncertain and there is insufficient data.

Total benefits

29. We scale up the impacts on the average affected case based on the estimate that there are 7.5 affected cases (25%) per professional per week, and assuming there are 46 working weeks per year. We also consider a lower bound of 1.5 affected cases per week (5%), and an upper bound of 12 affected cases a week (40% of assessments).

30. The undiscounted 10 year benefit is estimated to be £565.5m. Discounting benefits to patient health and the NHS at 1.5% per annum and all other benefits at 3.5% per annum results in a present value benefit of £509.3m. A lower bound frequency estimate suggests a present value benefit of £101.9m, and the upper bound frequency estimate suggests a present value benefit of £814.8m.

Net Benefits

31. Net benefits are the difference between the total benefits and the total costs. The net present value is the discounted net benefit, and is estimated to be £466.9m, with a lower and upper bound of £59.5m and £772.4m. Table 1 below provides a summary over 10 years, with this table provided for lower and upper estimates in Annex A.

[14] Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*

Table 1 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	1.3	4.7	3.4
Year 2	1.3	9.6	8.3
Year 3	1.4	14.8	13.4
Year 4	1.0	17.6	16.5
Year 5	1.1	20.5	19.4
Year 6	1.1	20.9	19.8
Year 7	1.1	21.3	20.2
Year 8	1.1	21.7	20.7
Year 9	1.1	22.2	21.1
Year 10	1.1	22.6	21.5
Total (undiscounted)	*11.5*	*175.8*	*164.4*
Total (discounted)	*10.6*	*159.9*	*149.3*
Total with opportunity costs (undiscounted)	**45.8**	**565.5**	**519.7**
Total with opportunity costs (discounted)	**42.4**	**509.3**	**466.9**

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

32. There is not a significant amount of data available on the possible impacts of these changes, and so using responses for a small number of ODPs from the AfPP, reality checked by the Chief Professions Officers' Medicines Mechanism (CPOMM) programme: PGD project working group (which includes professional bodies and staff from NHS England) and interpreted cautiously by analysts is appropriate.

Risks and assumptions

33. We believe our estimates of the monetised value of the benefits of this change are reasonable. The areas of greatest uncertainty are how we have weighted the cases reported by the ODPs consulted, and the frequency of these cases. We have tried to account for these uncertainties by including a wide sensitivity analysis around the frequency of cases. There is also some uncertainty about how patients would receive medicines when a PSD is not available. Although it is not recommended, it is possible that nurses (who can already use PGDs) would administer the medicine when doctors cannot be located. If this were to be the typical consequence, our estimate of the net present value in the central scenario would fall by almost two-thirds to £168.7m.

Risks of inappropriate administration of medicines

34. 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 is 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[15], 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. Given that the medicines considered were chosen based on the known clinical effect, we assume that this represents the 0.4% of serious errors, and assume that the rest of the errors have no effect. This results in a QALY cost per error of 0.02. Valuing a QALY at £60,000, this suggests an economic cost per medicine error of £1,280.

c. Given this cost per medicines error, we estimate that the net benefits would be offset if the error rate was 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.

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 or supply error, the estimated costs are not likely to be representative of an ODP's practice, and it is a simplification to assume that an error rate is attributable to a single professional or factor.

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

a. PGDs offer well-defined, specific instructions on how to administer medicines, which have been created with safety in mind and rely on significant input from senior pharmacists. This reduces risks of selecting the wrong medicines.

b. The ODP will have access to the patient's notes, and so would be in a position to understand if they have any contraindication, allergies or previous adverse reactions to the medicine required.

c. The ODP may have a better understanding of the patient's history and situation than an independent prescriber who has not previously met the patient and may therefore be in a better position to understand the patient's suitability for the medication.

d. In line with NICE guidance[7] ODPs would have local competency assessment on PGD administration every two years.

36. 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. All ODPs 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.

[15] 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. Once registered, ODPs must undertake continuing professional development (CPD) and demonstrate that they continue to practise both safely and effectively within their changing scope of practice, in order to retain their registration.

c. When the members of a profession renew their registration, the HCPC randomly audits the CPD of 2.5% of professionals. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. A failure to submit or complete successfully an audit may lead to removal from the register[16].

d. The HCPC regulatory processes for ODPs, as outlined above, will support the profession in mitigating the risk of supply or administration errors.

Proposed implementation plan

37. A change in legislation is required to allow ODPs to administer and supply medicines under PGD.

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

39. 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.

Private sector impact

40. It is not anticipated that this change in legislation will have an impact upon the private sector. There is no obligation for private sector providers or individuals not working for the NHS to take up the option to train to do this.

[16] HCPC (2017) *Continuing professional development and your registration*

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	1.3	0.9	-0.3
Year 2	1.3	1.9	0.6
Year 3	1.4	3.0	1.6
Year 4	1.0	3.5	2.5
Year 5	1.1	4.1	3.0
Year 6	1.1	4.2	3.1
Year 7	1.1	4.3	3.2
Year 8	1.1	4.3	3.3
Year 9	1.1	4.4	3.4
Year 10	1.1	4.5	3.4
Total (undiscounted)	*11.5*	*35.2*	*23.7*
Total (discounted)	*10.6*	*32.0*	*21.4*
Total with opportunity costs (undiscounted)	**45.8**	**113.1**	**67.3**
Total with opportunity costs (discounted)	**42.4**	**101.9**	**59.5**

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	1.3	7.6	6.3
Year 2	1.3	15.4	14.1
Year 3	1.4	23.6	22.2
Year 4	1.0	28.1	27.1
Year 5	1.1	32.8	31.7
Year 6	1.1	33.4	32.4
Year 7	1.1	34.1	33.0
Year 8	1.1	34.8	33.7
Year 9	1.1	35.5	34.4
Year 10	1.1	36.2	35.1
Total (undiscounted)	*11.5*	*281.3*	*269.9*
Total (discounted)	*10.6*	*255.8*	*245.2*
Total with opportunity costs (undiscounted)	**45.8**	**904.8**	**859.0**
Total with opportunity costs (discounted)	**42.4**	**814.8**	**772.4**