Consultation Stage Impact Assessment:

Proposal for the supply and administration of medicines using patient group directions by biomedical scientists across the United Kingdom

Title: Consultation Stage Impact Assessment on the proposal for the supply and administration of medicines using patient group directions by biomedical scientists across the United Kingdom **IA No:** 9550 **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**
£91.4m	N/A	N/A	Not in Scope	Not a regulatory provision

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

Currently, biomedical scientists can only administer and supply medicines using patient specific directions. When a patient specific direction has not been produced, biomedical scientists 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 biomedical scientists 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	**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: 30.3	**High:** 213.7	**Best Estimate:** 91.4

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate				**30.8**

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				61.1
High				244.5
Best Estimate				**122.2**

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

Reduction in inefficient search time by biomedical scientists.
Reduction in number of consultations with other health professionals.
Improved patient experience.
Improved patient health.

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

None

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 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	

Biomedical Scientist Impact Assessment
Evidence Base (for summary sheets)

Narrative Summary
Problem under consideration

1. Biomedical scientists 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 biomedical scientists increasingly involves them working in multidisciplinary teams, providing point of care diagnostic and clinical support to doctors. This means they are sometimes in the position of being able to clearly identify required diagnostic and treatment procedures. Currently, they are unable to directly administer and supply medicines in these situations without acquiring a PSD from a prescriber, typically a doctor. Given the difficulty of anticipating the need for medicines for particular patients, biomedical scientists 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 provided with extended responsibilities in relation to being able to supply, administer and/or prescribe medicines[1,2]. Currently, biomedical scientists 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 diagnostic or 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 investigations and/or treatment. In some interventions, biomedical scientists 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 procedures 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 professional time; b) improve patient experience; c) improve patient health outcomes.

Policy Change – enabling biomedical scientists 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 biomedical scientists be able to administer and supply medicines using

[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.*

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

Option 2 - Allow biomedical scientists to administer and supply medicines using Patient Group Directions

8. Currently, biomedical scientists 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 biomedical scientists 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 usually a burden on the biomedical scientist 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 biomedical scientist 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 another appointment.

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

Costs

Patient Group Direction costs

9. There will be an additional cost of developing and approving PGDs for biomedical scientists. Based on an estimate of forty hours' input by different professional and administrative staff, including pharmacists, doctors and biomedical scientists, 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 Institute of Biomedical Science, the professional body representing biomedical scientists, estimates that there will be a demand for the development and approval of 5-10 PGDs for biomedical scientists at each of 180 health organisations across the UK[6]. We use the midpoint of this range to estimate that 1,350 PGDs will be produced over the first three years (450 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 £6.1m.

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 estimate that this will require an average of 2 hours per trained biomedical scientist per year, to

[6] This is an estimate based on 152 acute 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*

cover all their PGDs, and we estimate the costs of backfill of this time (to capture either the financial cost of backfilling staff or the economic cost of reduced appointments) based on a unit cost of £20.80 per hour (midpoint of band 7 in Agenda for Change pay bands[8,9]). The total undiscounted cost over 10 years for reading and signing PGDs is estimated to be £1.0m. This is likely to be an underestimate, as Biomedical Scientists will need to re-sign all the required PGDs if they rotate between NHS trusts as PGDs are not transferable across organisations.

12. This results in a total undiscounted administrative cost over 10 years of £7.1m.

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 biomedical scientists. This will take 90 minutes and, as above, we estimate the costs of backfill for those being trained based on a unit cost of £20.80 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 body estimates that 10% of the profession will be trained within the first three years (approximately 800 of the 23,300 biomedical scientists[11] in each of the first three 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 £0.1m.

14. The profession have also advised that biomedical scientists are not likely to be currently supplying and administering medicines, and so those who train to use PGDs will likely undergo additional competency training, which may include topics such as pharmacology, drug interactions, contraindications, handling medicines and injections. Any additional training required would be locally determined based on the needs of biomedical scientists in that organisation and the PGDs that they will use, but we estimate that on average this will require two days of training. We consider the net cost to be two days of backfilling biomedical scientist time (£330), and we assume that the training would be delivered to 5 biomedical scientists at a time by a professional in a medicines management role (estimated to also be paid at the mid-point of band 7 in Agenda for Change pay bands[8]). This gives an average unit cost per professional being trained of £400. The total undiscounted cost over 10 years is estimated to be £1.1m.

Total Costs

15. This results in a total undiscounted training cost over 10 years of £1.2m, and including the PGD costs gives an estimated total undiscounted 10 year cost of £8.3m.

16. 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, 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 £33.1m. Discounting costs to the NHS at 1.5% per annum results in a discounted present value cost of £30.8m.

Risks of inappropriate administration of medicines

17. If biomedical scientists 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

[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

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 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.

19. Three clinical scenarios (based upon typical situations where PGDs would allow biomedical scientists to provide timely diagnostic investigations and/or treatment to patients) have been used to illustrate how efficiency savings for the NHS, improved patient satisfaction and health benefits for patients can arise. These clinical scenarios are taken from the NHS England full consultation guide. We acknowledge that these clinical scenarios will not capture all of the possible effects, but believe that they are relatively representative of the nature of the cases that are affected.

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. Table 1 expresses estimated consequences of the inability to use PGDs. These assumptions are provided by the Institute of Biomedical Science.

Table 1 Parameter Estimates of Benefits from Biomedical Scientist Profession

Estimate Number of patients (week/month)	**Scenario 2 - Acute, Bleeding Disorder clinic**	**Scenario 3 – Community Hospital**	**Scenario 4 – tests to Virology lab**
Net time saved by biomedical scientist with PGD in place (per patient)	15 minutes	20 minutes	30 minutes
Time saved by other Healthcare professionals with biomedical scientist PGD in place	20 minutes	60 minutes	30 minutes consultant 30 minutes nurse/GP
Inconvenience to patient	Rearranged appointment – 60 minutes	Rearranged appointment – 60 minutes	0 minutes
Reduction in risk to patient	Small reduction in risk due to timely diagnosis	Reduced chance of life-threatening bleed	Small – ensures patient has received medication at the earliest opportunity. Reduced risk of foetal complications

[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

Relative frequency of scenario	*30%*	*65%*	*5%*

21. The professional body has advised that approximately one case is affected by the inability to use PGDs every two weeks for each trained biomedical scientist. Sensitivity analysis on the changes to the frequency of affected assessments is discussed in paragraph 29-30.

Efficiency

22. There are two sources of efficiency benefits. The first represents the savings to the biomedical scientist's time from not having to find a prescriber (valued again at £20.80). Based on the parameters in table 1, and using the unit costs of the biomedical scientist, this gives an average estimated benefit of £11.44 per affected case.

23. The second represents the time savings for other professionals, such as doctors, who no longer have to see these patients just to write a PSD. Using the assumptions in table 1 and unit costs of £62.50 per hour for a GP (hourly equivalent of midpoint of GP salary according to PSSRU), £54.10 per hour for a consultant doctor (the hourly equivalent of the midpoint of consultant salaries according to NHS Health Careers[13]) and £15.40 per hour for a nurse (top of band 5, Agenda for Change[8]). The unit costs for GPs and consultant doctors have been adjusted using an inflation rate of 2% per year to bring them in line with 2019/20 prices. We estimate that this results in an average efficiency benefit of £37.50 per affected case.

24. The total efficiency benefit per affected appointment is therefore estimated to be £48.90. DHSC estimates that even though the value of a 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 £195.60 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 consider a rearranged appointment to take up an hour of patient time, and as this is the outcomes of scenarios 2 and 3, the average patient time that is taken up by delays per affected case is estimated to be 57 minutes.

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 £10.60 per affected case.

Health Benefits

28. The health impacts in scenarios 2 and 3 of having to wait between 3 and 7 days for appropriate treatment are captured by the impact on Quality Adjusted Life Years of an increase in anxiety from 'slight' to 'moderate'. According to the EQ5D Crosswalk Index Value Calculator, this would reduce the patients QALY by 12%[15], and we conservatively assume that this lasts for three days. This reduction is valued using the £60,000 value of a QALY used by DHSC and based on DfT research, to result in an estimated health benefit per affected case of £41.40.

[13] NHS Health Careers (2018). *Pay for doctors*.
[14] Department of Transport (2015). *Provision of market research for value of travel time savings and reliability*
[15] EuroQol (2018). *EQ5D Crosswalk Index Value Calculator*

Total benefits

29. We scale up the impacts on the average affected case based on the estimate that there are two affected cases per professional per month, and assuming there are 46 working weeks per year. We also consider a lower bound of one affected case per month, and an upper bound of one affected case per week.

30. The undiscounted 10 year benefit is estimated to be £134.6m. Discounting benefits to patient health 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 £122.2m. A lower bound frequency estimate suggests a present value benefit of £61.1m, and the upper bound frequency estimate suggests a present value benefit of £244.5m.

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 £91.4m, with a lower and upper estimates of £30.3m and £213.7m. 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	1.1	1.3	0.1
Year 2	1.2	2.6	1.4
Year 3	1.2	4.0	2.7
Year 4	0.7	4.1	3.4
Year 5	0.7	4.1	3.5
Year 6	0.7	4.2	3.5
Year 7	0.7	4.3	3.6
Year 8	0.7	4.4	3.7
Year 9	0.7	4.5	3.8
Year 10	0.7	4.6	3.9
Total (undiscounted)	*8.3*	*38.0*	*29.7*
Total (discounted)	*7.7*	*34.7*	*27.0*
Total with opportunity costs (undiscounted)	**33.1**	**134.6**	**101.5**
Total with opportunity costs (discounted)	**30.8**	**122.2**	**91.4**

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

32. The clinical scenarios used to illustrate the potential benefits are based upon typical real life situations where biomedical scientists could use PGDs to improve patient care. 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: PGD project working group (which includes professional bodies, regulators 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 the extent to which the clinical scenarios used here are representative of the typical cases that biomedical scientists face, 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.

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[16], 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 10-11 times higher than the current error rate. This suggests that the conclusion that these changes would lead to net benefits is not sensitive to the theoretical risk of increased inappropriate supply or administration of medicines.

    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 a biomedical scientist'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 biomedical scientist 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 biomedical scientist 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] biomedical scientists 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:

[16] 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. All biomedical scientists 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. Once registered, biomedical scientists 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[17].

d. The HCPC regulatory processes for biomedical scientists, 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 biomedical scientists to administer and supply medicines using PGDs.

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.

[17] 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	1.1	0.6	-0.5
Year 2	1.2	1.3	0.1
Year 3	1.2	2.0	0.8
Year 4	0.7	2.0	1.4
Year 5	0.7	2.1	1.4
Year 6	0.7	2.1	1.4
Year 7	0.7	2.2	1.5
Year 8	0.7	2.2	1.5
Year 9	0.7	2.2	1.6
Year 10	0.7	2.3	1.6
Total (undiscounted)	*8.3*	*19.0*	*10.7*
Total (discounted)	*7.7*	*17.3*	*9.6*
Total with opportunity costs (undiscounted)	**33.1**	**67.3**	**34.2**
Total with opportunity costs (discounted)	**30.8**	**61.1**	**30.3**

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	1.1	2.5	1.4
Year 2	1.2	5.2	4.0
Year 3	1.2	8.0	6.7
Year 4	0.7	8.1	7.4
Year 5	0.7	8.3	7.6
Year 6	0.7	8.4	7.8
Year 7	0.7	8.6	7.9
Year 8	0.7	8.8	8.1
Year 9	0.7	9.0	8.3
Year 10	0.7	9.1	8.5
Total (undiscounted)	*8.3*	*76.0*	*67.7*
Total (discounted)	*7.7*	*69.3*	*61.6*
Total with opportunity costs (undiscounted)	**33.1**	**269.2**	**236.1**
Total with opportunity costs (discounted)	**30.8**	**244.5**	**213.7**