Title: Impact assessment: Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters. **IA No:** DH5189 **Lead department or agency:** Department of Health **Other departments or agencies:** Medicines and Healthcare products Regulatory Agency, Devolved Administrations, NHS England	**Impact Assessment (IA)** **Date: October 2015** **Stage: Final** **Source of intervention:** Domestic **Type of measure:** Other **Contact for enquiries:** John Roberts – 0207 972 5922

Summary: Intervention and Options

RPC Opinion: Fit for purpose

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
£0m	£0m	£0m	Yes	ZNC

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

The system for regulating registered pharmacies is currently in transition. The General Pharmaceutical Council (GPhC) is responsible for developing standards for registered pharmacies. Current legislation would require that these standards are developed as a set of rigid rules that stipulate in detail the requirements for registered pharmacies. These prescriptive rules would aim to guarantee that pharmacy owners comply with the minimum standards for the consumer to receive an acceptable quality of service. The problem is that, due to their detailed, prescriptive nature, this system of rules would increase costs to business and divert resources into activities that may be unnecessary to assure the standards of registered pharmacies.

What are the policy objectives and the intended effects?

The objective of the policy is to develop options which appropriately assure standards of pharmacies, while avoiding the imposition of additional and unnecessary costs for business and the regulators.

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

Policy Options:

1. Do nothing.
2. Amend the current legislation concerning registered pharmacy standards, and information gathering and publication.
3. Issue guidance on registered pharmacy standards and information obligations without amending legislation

Policy Option 2 is the preferred option as it meets the objectives in line with the rebalancing agenda, whilst expected to have a non-negative impact on costs. In particular, Option 1 implies higher transition costs compared to option 2. These refer to the costs to business and for the regulators. Option 3 would require rules-based standards to be developed under current legislation, resulting in an expected increase in costs for business. The consultation responses provided further support for the logic and analysis behind this.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 3 years after enactment

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** Yes	**< 20** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	

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 Minister: Alistair Burt Date: 15/01/16

Summary: Analysis & Evidence

Policy Option 1

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years N/A	Net Benefit (Present Value (PV)) (£m)		
			Low: N/A	**High:** N/A	**Best Estimate:** <£0

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

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

N/A

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

The analysis quantifies, but does not monetise the benefits. In particular, transition costs to businesses and to the regulators are expected to be higher compared with Option 2. Ongoing costs are also expected to arise, which are expected to be higher than those for Option 2.

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

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

N/A

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

N/A

Key assumptions/sensitivities/risks

N/A

Discount rate (%)

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: >£0	**Benefits:**	**Net: <£0**	No	

Summary: Analysis & Evidence

Policy Option 2

Description: Amend the current legislation concerning registered pharmacy standards, and information gathering and publication.

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	**PV Base Year** 2014	**Time Period Years** 10	**Net Benefit (Present Value (PV)) (£m)**		
			Low: Optional	**High:** Optional	**Best Estimate:** >£0m

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

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

None.

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

Initially, the analysis quantified, but does not monetise the benefits. Transition costs to business and to regulators are expected to be lower under Option 2, compared with Options 1and 3. This is because of the stage which the development of prototype pharmacy standards has reached. Whilst ongoing costs are expected to arise, the analysis suggests that these will be lower for business compared with Options 1 and 3. Through the consultation, we obtained further evidence supporting the initial analysis.

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

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

None

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

N/A

Key assumptions/sensitivities/risks

N/A

Discount rate (%) N/A

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**In scope of OIOO?**	**Measure qualifies as**
Costs: £0m	**Benefits:**	**Net:** >£0m	Yes	ZNC

Summary: Analysis & Evidence

Policy Option 3

Description: Issue guidance on registered pharmacy standards and information obligations without amending legislation

FULL ECONOMIC ASSESSMENT

Price Base Year 2014	PV Base Year 2014	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** £0m

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

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

None.

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

This Option cannot override the current legislative requirements (so in effect, is the same as Option 1). Rules-based pharmacy standards would need to be developed by the regulators and increased costs will result for them as well as business.

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

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

None.

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

In Northern Ireland, pharmacy standards already exist as guidance.

Key assumptions/sensitivities/risks

Discount rate (%) N/A

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: £0m	**Benefits:** £0m	**Net:** £0m	No	N/A

Rebalancing Medicines Legislation and Pharmacy Regulation –

Overarching background to a series of three Impact Assessments

Purpose and rationale

1. The Rebalancing Medicines Legislation and Pharmacy Regulation programme was set up by the Department of Health (DH - England) – on behalf of all UK Health Ministries.
2. Its purpose is to examine the respective scope of current UK legislation and regulation, and the relationship between them, in order to:
    - ensure these are optimally designed to provide safety for the users of pharmacy services;
    - facilitate, and reduce the barriers to, the development of professional practice; and
    - promote innovation and a systematic approach to quality in pharmacy.
3. There are other sanctions and penalties in UK medicines legislation which are not the subject of this Impact Assessment. Responsibility for reviewing such offences lies with the Medicines and Healthcare products Regulatory Agency (MHRA).
4. Government intervention is necessary in order to make changes to the legislative frameworks involved to achieve these objectives.
5. These changes cannot be delivered through conventional market mechanisms (price, exchange, permits, quotas) or some other mechanism that does not involve legislation.

Establishment of a Programme Board

6. A Programme Board was established in May 2013, chaired by Ken Jarrold, CBE, to consider how best to deliver the objectives. Its role is to:
    - advise Ministers and the devolved administrations (Scotland, Wales and Northern Ireland) on the development of policy within the terms of reference set for the board. The full terms of reference for the Board are available at: (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/193999/TERMS_OF_REFERENCE.pdf ; and
    - oversee the implementation of policy outcomes agreed by Ministers and the devolved administrations.

7. The Board's work includes to:

"(i) build on and propose amendments to legislation, as required, to deliver a modern approach to regulation which maintains patient and public safety, whilst supporting professional and quality systems development, including learning from dispensing errors made in registered pharmacies;

(ii) examine the legislative and regulatory framework for pharmacy premises to make recommendations that strengthen the professional regulatory framework as required, with a view to mitigating identified risks while ensuring

- the effectiveness of components of the system which support patient safety, such as the role of superintendent and the responsible pharmacist
- the legislative and regulatory framework for pharmacy premises supports the development and maintenance of a quality systems approach to pharmacy practice;

(iii) build on these foundations to address in parallel medicines and professional regulatory matters (e.g. supervision), which are considered to restrict full use of the skills of registered pharmacists and registered pharmacy technicians, impede the deployment of modern

technologies and put disproportionate or unnecessary obstacles in the way of new models of service delivery by and/or involving pharmacy

(iv) set out the principles underlying policy recommendations about the future scope of pharmacy regulation, ensuring that these are in line with the principles of good regulation."

The elements of the Board's programme

8. The Rebalancing programme comprises a number of linked, but distinct, elements with complementary but differing, objectives.

9. In summary, these are:

   a. Dispensing Errors: to review the criminal offences under the Medicines Act 1968 ("the Act") that could be used to prosecute a dispensing error by a regulated pharmacy professional operating from regulated pharmacy premises. The threat of such criminal sanctions is widely believed to hinder the reporting of errors and therefore wider learning. There is evidence that improving the rate of reporting and learning from such errors supports better patient safety.

   b. Superintendent Pharmacists and Responsible Pharmacists: The board was asked to examine the legislative and regulatory framework in terms of the effectiveness of components of the system, which support patient safety, not only in relation to responsible pharmacists, but also the role of and superintendent pharmacists, in order to provide greater clarity on role, accountability and competence. The Board has also examined the scope for reducing (or removing) the detail within the regulations and proposals for this area of the board's work are being prepared for public consultation later this year.

   c. Hospital Pharmacies: The Board is also considering the legislative requirements for hospital pharmacies (whether publicly or privately funded) under the Act. The supply of medicines by hospital pharmacies does not, for the most part, require the registration of the hospital pharmacy's premises with the General Pharmaceutical Council (GPhC) or PSNI, although regulated activities at those pharmacies may, in England, be subject to alternative licensing arrangements by the Care Quality Commission. Nonetheless, all hospital pharmacy professionals are subject to professional standards and regulation in the normal way. The Board's work is designed to underpin high quality hospital pharmacy services and enable a defence to criminal sanction for dispensing errors for pharmacy professionals in hospitals and other pharmacy services .

   d. Pharmacy Supervision: Building on the elements above, the Board has been asked to develop proposals regarding the requirements, under the Human Medicines Regulations 2012, for pharmacy professionals to supervise individual transactions in pharmacies which involve the supply of prescription only or pharmacy medicines. The aim is to identify and review all legislative requirements which may:

      - restrict the full use of the skills and expertise of registered pharmacists and registered pharmacy technicians;
      - impede the deployment of modern technologies; or
      - put unnecessary obstacles in the way of developing new models of pharmacy services and pharmaceutical care.

Registered pharmacy standards

10. In tandem with these elements, the GPhC, which administers the professional and premises registration requirements under the Pharmacy Order 2010 for England, Wales and Scotland, wishes to move to a system whereby pharmacy owners meet agreed requirements for pharmacy premises through registration standards that are set in a code of practice, rather than legislative rules. The PSNI (the equivalent body for Northern Ireland), which currently has standards for registered pharmacies but no statutory basis for them, supports this approach. New specifically modelled powers to draw up codes of practice would facilitate the regulators to implement a pharmacy inspection regime based on the outcomes achieved at the premises. The GPhC has also requested express powers to enable the publication of inspection reports. The Government supports these

aims. The Board has incorporated these proposals as part of the Rebalancing programme and supports them.

Organisation of the overall programme

11. To ensure this overall programme is manageable,:

Dispensing errors – where three reform options are considered and

proposals in respect of standards for registered pharmacies, where two reform options are considered, are being taken forward in the first phase. Elements 9b and 9c will follow in the next phase with pharmacy supervision in the final phase.

Impact Assessment 3: Registered pharmacy standards and related matters

The following options have been identified. They are not mutually exclusive.

Option 1 - Do nothing

Option 1 is the default "do nothing" option. No changes to the existing legislative framework occur. Whilst no new cost commitments arise, maintaining the current legislation will result in additional costs for business and for the regulators because the pharmacy standards development process would have to start afresh to comply with the Pharmacy Order 2010 and related legislation to set standards out in rules. As, in addition, no benefits have been identified from this Option, it is not considered further apart from the analysis of costs associated with this Option at paragraphs 52 – 58 below.

Option 2 - Amend the current legislation concerning registered pharmacy standards, and information gathering and publication.

Option 2 is to amend the relevant provisions in the Medicines Act 1968, the Pharmacy (Northern Ireland) Order 1976 and the Pharmacy Order 2010 relating to registered pharmacy standards, and the Pharmacy Order 2010 in relation to information obligations.

Option 3 - Issue guidance on registered pharmacy standards and information obligations without amending legislation

Option 3 is to issue revised guidance on registered pharmacy standards and information obligations without amending legislation.

The benefits of Options 2 and 3 are considered later in this IA.

Background and objectives

12. The pharmacy regulator, the General Pharmaceutical Council (GPhC), which administers the professional and premises registration requirements under the Pharmacy Order 2010 for England, Wales and Scotland, wishes to move to a system whereby pharmacy owners meet agreed requirements for pharmacy premises through registration standards set out in codes of practice, rather than legislative rules. This change has inevitable consequences for the way in which the standards are enforced.
13. The questions of what should be included in registered pharmacy standards, what status they should have, and how they should be enforced, have arisen in the context of the work that the GPhC has already undertaken, in consultation with key stakeholders, to develop prototype standards for registered pharmacies. As a result of that work, the GPhC is seeking to introduce both a new approach to standards for pharmacy owners, and a new inspection model that would support that approach.
14. In summary, the objective is to move away from a regime and mentality which relies on boxes being ticked (or not ticked – and, if not, to be in breach of the rules) to one where the owner demonstrates that operational practice supports and enables staff to deliver services safely and effectively. Under the new approach, rather than setting a strict list of "do's" and "don'ts", the premises standards for pharmacy owners would be outcomes-based, focussing on the achievement of results for patients. Such outcomes-based standards would then be supported by guidance on specific issues.

What this inspection model means in practice

15. The GPhC's new pharmacy inspection model is being rolled-out on a prototype basis through a phased approach to modernising pharmacy regulation. GPhC inspectors have begun inspecting pharmacies against the standards agreed by the GPhC Council and issuing reports to pharmacy owners and superintendent pharmacists detailing the GPhC's judgment of how well their pharmacy is meeting the standards. Action plans will be required and monitored where necessary improvements are identified by the inspectors.

16. During implementation, GPhC inspectors are continuing to work closely with the NHS, other regulators and relevant public authorities to share information where appropriate. Where pharmacy inspections raise serious concerns, the GPhC has the option of Fitness to Practise action against individual pharmacists or pharmacy technicians (including interim orders when these are needed to protect the public), and of setting conditions to secure safe and effective practice at particular pharmacies. The GPhC is also continuing a communications programme, to raise awareness of the registered pharmacy standards amongst owners and professionals. However, robust data on costings which would help inform the costs and benefits to business from this prototype model have not yet been collected.

Why Government intervention is necessary

17. The Health Departments for England, Wales and Scotland wish to amend the Pharmacy Order 2010 to support completion of the implementation of the GPhC's new outcomes-based approach to the inspection and regulation of pharmacies. This involves removing the requirement for registered pharmacy standards to be in rules.

18. Once the standards for registered pharmacies are no longer in rules, the current arrangements for enforcing them set out in the Pharmacy Order 2010 will no longer be fit for purpose. Consideration therefore needs to be given to revising those arrangements in ways that make best use of the GPhC's existing procedures, whilst at the same time ensuring that enforcement arrangements are in place that are both effective and proportionate within a system of registration standards.

19. Rolling out the new inspection model has also identified other specific drawbacks with the current enforcement regime that the responsible Health Departments wish to correct.

20. In particular, the absence of an express power to publish inspection reports, and the absence of any enforcement arrangements relating to the rule-making powers for the supply of information by pharmacy owners, compromise the proper functioning of an enforcement system. The opportunity to amend the Pharmacy Order 2010 would also enable the provisions relating to notification of the death of a registered pharmacist or registered pharmacy technician in Great Britain to be corrected.

The current position in Northern Ireland

21. The work of the GPhC on creating a new inspection model is supported in principle by the Pharmaceutical Society of Northern Ireland (PSNI). However, PSNI is operating from a different legislative base and starting point. It needs to take a different route to achieving outcomes-based standards with effective and proportionate enforcement arrangements.

22. At the moment, the PSNI publishes non-statutory registered pharmacy standards, albeit based on a traditional "do's" and "don'ts" model. The PSNI wishes to move to a statutory code of practice, the content of which will be less prescriptive and more outcomes-based. Enforcement again would be on the basis of making best use of existing procedures.

What the proposals would comprise

23. The legislative powers to create standards for registered pharmacies through codes of practice produced by the GPhC and the PSNI would be the same. Both bodies, within the limits imposed by the statutory framework, would, however, be free to take their own decisions as regards the actual content of their codes of practice.

24. The proposals for England, Wales and Scotland to a large extent reflect the changes to the provisions currently in articles 7 to 14 of the Pharmacy Order 2010, and section 80 of the Medicines Act 1968, that were proposed by the Law Commission in their report: "*Regulation of Health Care Professionals: Regulation of Social Care Professionals in England*" (Cm 8839: SG/2014/26), published in April 2014.

25. Recommendation 98 of that report indicated that the Law Commission recommended retaining the premises regulation provisions of the Pharmacy Order 2010 with some minor amendments.

26. Paragraph 11.16 of the report stated:

> *"...We propose some minor changes to the [General Pharmaceutical] Council's powers to regulate premises. In broad terms, the intention is to remove the duty to set standards in rules, and turn them into code of practice style obligations, and enforce them via the disciplinary procedures set out in section 80 of the Medicines Act 1968. The changes have been developed with the agreement of the General Pharmaceutical Council and the Government.*

28. Although there is no parliamentary time available to progress the Law Commission's proposed Regulation of Health and Social Care Professions Etc. Bill immediately, ministers are considering options in order to progress the proposals. The PSNI powers to create premises standards through codes of practice in the proposed article 5A of the Pharmacy (Northern Ireland) Order 1976 also follow the model included in the Law Commission Bill.

Option 1 – do nothing

29. Given the need to amend legislation to support the work of the GPhC, this option carries no benefits and it does not deliver the policy objectives. It would also have the significant drawback of requiring the GPhC to unpick the work it has already done in developing its new prototype inspection model incurring costs which may be significant for the regulator. A major rewriting of the GPhC's standards for registered pharmacies would be required for them to be incorporated in rules, which by their nature have to be precise and unambiguously worded. This would cause pharmacy businesses extra costs in adopting a new regime which would be less conducive to supporting different pharmacy business models and evolving pharmacy practice, in response to patient and public need. A description of these costs, whilst not monetised, is set out in the Economic Analysis at paragraphs 44 *et seq*. An analysis of the specific costs associated with Option 1 is at paragraphs 52 – 58. This option is not considered further than this.

Option 2 – amend the current legislation

30. This would involve a series of changes to the Medicines Act 1968, the Pharmacy (Northern Ireland) Order 1976 and the Pharmacy Order 2010 which would enable the standards system currently in prototype to be fully implemented. These are explained in detail in **Table 1** below (pages 19 *et seq*). The effect of these changes would be to deliver the objectives above.

Benefits

31. The principal benefits are that this delivers a unified coherent system for standards for both the GPhC and the PSNI, which removes the need for a separate, rules-based regime in England, Wales and Scotland. Whilst it is difficult to put a value on such benefits and they have not been monetised in the Economic Analysis, our discussions with pharmacy owners indicate they would support this move. It would mean only one enforcement regime needs to be followed. Under the existing regime in England, Wales and Scotland, different enforcement arrangements and outcomes can arise depending on whether the regulatory Fitness to Practice Committee route, criminal sanctions or the regulatory Registration Appeals Committee route is followed.

32. An outcomes based system would be less onerous and cumbersome for business generally, providing a "lighter-touch" approach than the existing, prescriptive requirements.

33. Overall, we believe the benefits are positive, as borne out by the Economic Analysis at paragraphs 44 *et seq*, but because they cannot yet be monetised, it is difficult to quantify them.

Costs

34. From regular meetings with business (which is also fully represented on the Rebalancing Programme Board), no familiarisation costs have been identified so far, since standards already exist under the new prototype inspection regime being rolled out by the GPhC – and also exist on a non-statutory basis by the PSNI. Business would need to familiarise itself with the changes that do take place, but again, no significant costs have been identified nor thought likely to arise. Responses tyo the consultation also encourage this view. More information is given in the Economic Analysis section.

35. Any costs that do arise are, at this stage, very unlikely to create additional cost pressures for businesses or on individual pharmacists or pharmacy technicians. Rather, they would be absorbed as part of the costs pharmacy businesses habitually incur in order to keep up to date with regard to

pharmacy law and practice. This was also the conclusion from responses to the consultation, and meetings held with the regulators and a number of representatives of business to test this view further.

36. Pharmacy professionals, as part of their normal expected standards of professional behaviour, are also already required to keep up to date about changes to the law and practice of pharmacy that directly affect them. Similarly, pharmacy owners, in order to operate their businesses within an area of law and practice where constant change is inevitable, already have in place mechanisms for ensuring that they and their staff keep up to date. In England, for example, for the overwhelming majority of retail pharmacy businesses that wish to dispense NHS prescriptions, this has already been formalised as part of the NHS terms of service into a requirement on pharmacy owners to have in place clinical governance arrangements that include a premises standards programme and a staffing and staff management programme, including training for all staff.

37. Because the GPhC would no longer be required to make information-gathering rules and instead would have a discretion to do so, the changes anticipated in relation to those rule-based powers should essentially be cost neutral. Indeed, there is the potential for a cost saving if the GPhC exercised their discretion not to make the rules. If they did make rules, then although the new requirements are more fit for purpose than the existing requirements, the impact on businesses should be negligible in terms of the expected relative cost compliance.

What would happen without this change

38. Without any change to the legislation, the GPhC would be required to implement standards for registered pharmacies based on rules, which would be necessarily prescriptive in a way that the new outcomes based approach is not. The rule-making power is expressed in mandatory terms, although the current testing of the new prototype has meant that no rules reflecting the old, prescriptive approach have as yet been made. The current enforcement arrangements, relying on a number of different approaches, are potentially more costly since businesses need to adapt to a number of enforcement models. However, as the current rules based approach has not yet been implemented, this implies further potential costs down the line which have not been quantified. A unified system avoids overlapping enforcement requirements and should help mitigate the costs for business that compliance with different systems necessarily involves. However, it is not possible at this stage to give a value to those costs.

How this might work in practice

39. To illustrate how this might operate, a "worked" example is set out below.

ILLUSTRATION OF HOW THE PROPOSED NEW SYSTEM MIGHT WORK COMPARED TO THE CURRENT SYSTEM

1. The following example, is, in practice, an extremely remote possibility but helps illustrate the proposals simply.
2. If it does not prove possible for the GPhC to move to an "outcomes" based set of standards on the "code of practice" model, the GPhC would need to follow a more prescriptive approach – most likely, one which would be based on a series of standards for registered pharmacy premises.
3. Such standards would likely set out a series of detailed indicators (which may run to over 100), of which a proportion would be described as "essential" and a proportion as "desirable". This is the approach currently taken by PSNI, who are also hoping to move to an outcomes based approach.
4. In contrast, the GPhC's model standards are organised around 5 "principles". 26 "standards" attach to those principles, so an average of just over 5 standards to each principle.
5. Using an example in the current PSNI non-statutory standards of the availability of references resources, a current "essential" indicator is that "*Current editions of essential reference books are available in the dispensing area, accessible in a paper or electronic format*".
6. With the GPhC approach, pharmacy owners are guided by '*principle 2*' which is that "*Staff are empowered and competent to safeguard the health, safety and well-being of patients and the public*". Standard 2.3 then provides: "*Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public*"".
7. It is reasonable to assume that, for staff to be empowered in this way, they will need to have access to current editions of essential reference books, so this is not *per se* a critique of the specific 'essential' indicator approach. What this points to is a different approach. Either one specifies the "outcome" of empowering staff to exercise their professional judgement or one specifies a list of specific obligations, such as having essential reference books, with that or a similar

outcome unexpressed but in mind.

8. The framework established by the Pharmacy Order 2010 is currently drafted with the "specific obligations" approach in mind. Without second-guessing whether or not the GPhC would choose to express any specific obligation in its standards, if the obligation to set standards in rules is not removed, and if the GPhC chose to express this particular standard, then if the GPhC's inspectors found no text books at a particular pharmacy (and no access to online subscriptions), they would have the power to serve an improvement notice on the pharmacy owner.

9. If the pharmacy owner failed to comply with the improvement notice, the GPhC could bring criminal proceedings in a magistrate's or sheriff's court, and the pharmacy owner could face an unlimited fine for, in effect, failing to provide a textbook. Additionally or alternatively, the Registrar of the GPhC could suspend or remove the relevant pharmacy entry from the premises register, without any further "due process".

10. If the pharmacy owner chose to appeal the improvement notice, they could do so – to a magistrate's or sheriff's court, but the court would not be looking at the reasonableness of the notice, rather whether the breach alleged was supported by the facts, i.e. whether or not the pharmacy in fact had the relevant text book.

11. Similarly, if the Registrar chose to suspend the premises from the premises part of the GPhC's register until the text book was provided, the pharmacy owner could appeal to the Registration Appeals Committee of the GPhC, but that Committee's consideration would start from whether or not the standard had been breached, not whether or not the standard should have been imposed.

12. Under the proposed new system, if a current edition of an essential reference book was missing, a GPhC Inspector could serve an improvement notice, but it would have to be on the basis that staff at the pharmacy were not empowered to exercise their professional judgement in the interests of patients and the public, rather than simply on the basis that the textbook was missing.

13. In this case, if the improvement notice was appealed, the GPhC would need to satisfy the magistrate's or sheriff's court, going back to first principles, that the absence of the textbook in question did indeed mean that the pharmacy owner had failed to empower their staff to exercise their professional judgement in the interests of patients and the public. It is very unlikely that the absence of a textbook, on its own, would satisfy the court that a standard had been breached.

14. If, in other circumstances, the court was satisfied that the standard was breached, and the improvement notice stood, then if the breach continued, the GPhC would not then have the option of bringing a criminal prosecution for the breach. Instead, the matter would have to be referred to the Fitness to Practise Committee of the GPhC. If immediate suspension pending a full hearing were considered necessary, breach on its own of the standard would not be sufficient to justify that. The Fitness to Practise Committee would also need to be satisfied that the suspension was necessary for protection of the public or otherwise in the public interest, and its judgement in that regard could be tested in the High Court or, in Scotland, the Court of Session.

15. If the matter went to a full hearing before the Committee, again, breach of the standard on its own would not be a sufficient basis for imposing sanctions against the pharmacy premises in question. The Fitness to Practise Committee would need to be satisfied that the pharmacy owner was unfit to carry on a pharmacy business safely and effectively at the premises in question.

16. If the present arrangements do have to be implemented fully because no amendments to them could be secured, it is of course anticipated that the GPhC would act reasonably and proportionately, and that premises would not be closed and prosecutions brought simply because of the absence of a textbook. However, in a system predicated on specific "do's" and "don'ts", sanctions come back to the question of the breach of such specific obligations, rather than the sort of principles that underpin an "outcomes" based approach.

17. Similarly, it is, of course, acknowledged that PSNI acts reasonably and proportionately under its current indicators-based approach, and would not seek the removal of an entry in its premises register simply because a textbook was absent. As matters stand, if sanctions against a pharmacy owner are contemplated, two things would need to be shown: firstly, that a board member, officer or employee of the company was guilty of misconduct, and secondly that the misconduct was such that, if the person in question were a pharmacist, it would render them unfit to be a pharmacist.

18. So, whilst the current system in Northern Ireland based on indicators would set out detailed measures of the conduct required, the Statutory Committee would have to consider from first principles whether or not the breach would justify a finding of unfitness against a particular individual. Furthermore, to impose sanctions, the Committee would have to show that the failure was instigated or connived at by the board of the company, or that this was part of a pattern of misconduct. This means that securing a suspension or removal from the premises register would already be difficult.

19. The PSNI do not have a statutory scheme of improvement notices, unlike the GPhC. Instead, they operate the same sanctions regime in the Medicines Act 1968 as the GPhC. This means that, under the new arrangements, the arrangements in Northern Ireland would be:

    - the PSNI would be specifically empowered to produce the sort of 'outcomes' based standards that the GPhC has

already sought to adopt;

- breach of those standards would be sufficient of itself to bring proceedings against the pharmacy owner, rather than needing separately to show misconduct;
- however, before any sanction could be imposed, the Statutory Committee would have to be satisfied additionally that the pharmacy owner was unfit to carry on a pharmacy business safely and effectively at the pharmacy premises in question.

20. Overall, the procedure would be simpler, but the focus would move away from specific "do's" and "don'ts" to one focused instead on outcomes. At the heart of a case under the Medicines Act procedures, the issue would not be: "*What does the Statutory Committee think about a persistent failure to provide textbooks?*" but "*Does the Committee think the staff are unable to exercise their professional judgement in the interests of patients and the public, and what does that mean in terms of whether or not the business can be run safely and effectively?*".

21. From the point of view of the pharmacy owner, this could bring significant benefits in terms of the underlying approach being less bound up in "red tape" and more focused on matters that go to the heart of whether or not their business is being run safely and effectively.

Option 3 – issue guidance

40. Instead of changing the current legislation, there is an option for the Health Departments and the regulators to issue further guidance to business etc. on how the existing legislation is to be interpreted with a view to minimising the impact of the current regulatory requirements and, in Northern Ireland, substituting this guidance for the existing registered pharmacy standards guidance that is already in place there. This would be a non-legislative solution which may be implemented more quickly than Option 2.

41. However, such guidance could not substitute for the current legislative requirements which would have to be implemented. As such, guidance alone would cause unnecessary additional costs and confusion for regulators and business in trying to reconcile differing legislative and professional requirements and standards. In the case of the information gathering obligations, because these relate to fitness to practice matters and so to sensitive personal information, data-requesting obligations need to be included in rules in order to fit with the requirements of the Data Protection Act 1998. Those requirements are also behind the reason for giving clear statutory authority for the publication of inspection reports.

42. It would be possible for the PSNI to amend its guidance but if the GPhC were forced into following a "rules-based" approach to inspections, because a change in the law was considered too costly, it is not clear what incentive the PSNI would have to move to an approach that was being rejected for the GPhC.

43. For these reasons, this option is not considered to deliver the policy objectives.

Economic analysis of the options for registered pharmacy standards and related matters

The problem

44. The system for regulating registered pharmacies is currently in transition.

45. The GPhC is responsible for developing standards for registered pharmacy premises. Current legislation would require that these standards are developed as a set of rigid rules that stipulate in detail the requirements for registered pharmacies. These prescriptive rules would aim to guarantee that pharmacy owners comply with the minimum standards for the consumer to receive an acceptable quality of service.

46. The problem is that, due to their detailed and prescriptive nature, this system of rules would increase costs to business and divert resources into activities that may be unnecessary to assure the standards of pharmacy premises.

The objective

47. The objective of the policy is to develop options which appropriately assure standards of pharmacies, while avoiding the imposition of additional and unnecessary costs for businesses and the regulators.

Development of options

48. The GPhC has developed a set of standards[1] to guide what registered pharmacies are expected to achieve for their premises in a flexible way. This provides an alternative to the rules-based approach. These standards are focused on the services provided by pharmacies and are outcomes-based, instead of on the processes that achieve them. The consultation process with the relevant stakeholders confirmed that businesses have committed resources to familiarising themselves with these standards. Moreover, the process also provided evidence that the implementation is well underway. More information on these Principles is available at http://www.pharmacyregulation.org/standards/standards-registered-pharmacies. Responses to the consultation have allowed us to partially monetise some of the costs, in line with the suggestions from the Regulatory Policy Committee. As a result, we have complemented the previous qualitative approach of costs and benefits to incorporate some of the additional information and data acquired in the consultation process..
49. Implementation of these newly developed standards is not possible in the current legislative framework. As well as the difficulty of expressing outcomes-based standards in rules, they cannot, unlike rules, be enforced under the current arrangements set out in the Pharmacy Order 2010.
50. Therefore, either the Pharmacy Order 2010 needs to be amended or the GPhC needs to re-develop a set of enforceable and prescriptive registered pharmacy standards in rules.
51. Options have therefore been considered on how best the regulation of premises using the GPhC's standards can be implemented, whilst avoiding the need for the development of a rules-based system which would impose unnecessary costs on business.

Option 1 - Do nothing

52. Without any changes to the Pharmacy Order 2010, the current registered pharmacy standards developed by the GPhC would not be suitable. As a result, the GPhC would have to design a new set of standards, for incorporation in rules that are more rigid and prescriptive in order to align them with the current legal requirements. Businesses would be obliged to comply with these rules. GPhC confirmed this during the consultation.
53. This approach is also reflected in the "Pharmaceutical Society of Northern Ireland's (PSNI) Standards for Registered Pharmacy Premises"[2]. They provide a very specific description of actions that pharmacy businesses must carry out in order to be considered "compliant" with the different criteria. These in turn are supported by a number of detailed indicators (referring to issues such as security, training, staff facilities, dispensing equipment and area, sales area, etc.).
54. This option is used as the baseline policy against which to assess the potential costs and benefits of other approaches. Therefore the net impact of this option is, by definition, set at zero for the purposes of calculating net impacts of alternatives. However the impacts of alternative options are mainly the avoidance of costs to business that would be implied by the "do nothing" option. For this reason, the expected costs to business under the "do nothing" option are set out below. We have asked businesses to provide any estimates of such costs during consultation. Even though, the consultation revealed general support for the analytical approach in the IA, the nature of the policy made it difficult for businesses to provide hard estimates on cost or benefits.

Description of likely future costs to business under the "do nothing" option

[1] http://www.pharmacyregulation.org/sites/default/files/Standards%20for%20registered%20pharmacies%20September%202012.pdf

[2] http://www.psni.org.uk/documents/521/Community+Pharmacy+Premises+Standards.pdf

55. Under the "do nothing" option, the GPhC's outcome-based standards could not be used as the basis of a system of assuring premises standards. GPhC confirmed during the consultation that over 4,000 inspections had already been carried out under the already developed new 'outcomes-based' model. Therefore, under the 'do nothing' option the GPhC would be forced to develop a new, process-based system that could be used, given the current legal framework. Also, this option imposes costs on the GPhC and it would also impose costs on businesses. These include transition costs of adapting to the process-based system, and the ongoing costs of complying with the new system.

56. Transition costs of the do-nothing option include some costs of **familiarisation** with the new system of process-based rules. This follows from the fact that respondents to the consultation supported the view that "businesses have already begun the process of familiarising themselves with the GPhC's outcomes-based system, and in preparing for its implementation" (see Question 21 in Appendix B), with 96% of those answering this question agreeing with this view.. Hence, if the outcomes-based system was to not be implemented, pharmacy professionals would have to become familiar with a process-based system, which GPhC has confirmed during the consultation, would have to be designed from scratch. In addition, following the inspections already made of preparing for an outcome-based system of standards (See Question 21 in Appendix B.). Implementation of process-based rules would therefore impose costs related to the **redesigning of their business plans** in order to meet every detailed stipulation of the new system.

57. A system of process-based rules would also entail **ongoing compliance costs** related to satisfying the prescriptive set of detailed rules by demonstrating adherence to all their provisions, and undergoing inspection across all aspects of their operations affected.

58. Implementing new process-based rules will also impose costs on the GPhC, in designing and enforcing the new system. During the consultation period we sought feedback on the logic behind this argument. In particular, we asked whether respondents agreed with our assumptions regarding ongoing and transitions costs. Of the 83 respondent who answered this specific question (out of 159), 96% agreed with our logic regarding transition and on-going costs.

***Option 2* - Amend the current legislation concerning registered pharmacy standards, and information gathering and publication**

59. This policy option entails changing the Pharmacy Order 2010 that applies in England, Scotland and Wales in order to permit the implementation of an outcomes-based system, guided by the standards which have already been developed by the GPhC.

60. Under this approach, the suitability of registered pharmacies would be based on the services provided to the consumer (outcomes-based) and judged against the inspection model already developed by the GPhC. In the case of Northern Ireland, it means reducing the 13 criteria and over 80 indicators for compliance, to a smaller set of principles (the GPhC has 5 principles) and standards, underpinned by statute.

61. Importantly, businesses have already begun the process of familiarising themselves with the GPhC's outcomes-based system in preparing for its implementation, as confirmed by the consultation responses. Over 4,000 (as of the end-May 2015) inspections have taken place under the new standards-based prototype regime since roll-out began in November 2013. It is expected that the remainder would be inspected over the course of the next 3 – 5 years.

62. Using this approach, it is recognized that observed and measurable outcomes can be achieved in a variety of ways – and that businesses are best able to determine the most appropriate way in which those outcomes can be achieved, according to their particular circumstances and the needs of their service users. The requirement for registered pharmacy standards to be in rules would be removed, so that these outcome-based standards, which have already been developed, could form the basis of registered pharmacy premises regulation. Hence, this policy avoids large transaction costs as described in the objectives.

Description and quantification of likely impacts

63. The impacts of option 2 are considered in terms of the costs to business, compared with those expected under option 1 ("do nothing").

Transition costs

64. As described above, Option 1 would impose transition costs on business, as they familiarise themselves with the new process-based system, and redesign their business models in order to comply with it. In contrast, as confirmed by the consultation process, businesses are already substantially familiar with the outcomes-based system based on the GPhC's standards as the prototype has been in operation for 18 months.

65. Through the consultation, we were able to obtain estimates for the cost to GPhC of redesigning a rules based system. GPhC suggests that the cost of this would be in region of £200,000. On the other hand, it is clear that there are no additional transition costs to GPhC from proceeding with the outcomes-based premises standards.

66. Another important transition cost under Option 1 is the cost to businesses of familiarising themselves with the new legislation. Up until the May 2015, there have been 4,105 inspections under the standards-based prototype that have already taken place by GPhC. Additional feedback from pharmacies also confirms that pharmacies have already spent time familiarising themselves with the current outcomes-based inspections. Hence, the familiarisation cost of this option would be smaller relative to the familiarisation cost in the 'do nothing option' (Note that this contrast with the 'dispensing errors IA', where we do identify familiarisation costs to businesses relative to the 'do nothing' option for that policy). To support this, we asked in the consultation (see Question 21 in Appendix B) if our suggestion that there are 'no significant transition or ongoing costs relative to the current framework' is correct. Out of 159 respondents, 83 answered this question. Of these, 96% indicated that this suggestion (and our other assumptions) was correct.

67. The nature of the outcomes-based system is that it does not prescribe a particular means of achieving satisfactory standards. Instead, it specifies the standards which must be achieved, and leaves the means of achieving them to the pharmacy business. Therefore it is expected that an outcomes-based system, as proposed in option 2, would impose fewer costs of redesigning processes on business – as they would be able to choose the means of achieving the outcomes based standards that were most appropriate and cost-effective for their particular operations and premises.

68. In particular, using the evidence gathered from the consultation, transition costs under Option 1 would be at least £200,000 compared to Option 2. This relates to the cost to GPhC of redesigning a rules-based inspection model. It is therefore considered that the transition costs associated with Option 2 will be clearly lower than those required under the "do nothing" option. Therefore, in respect of transition costs, implementing Option 2 would be expected to result in clear cost savings to business.

Ongoing costs

69. An outcomes-based system of assurance will also result in ongoing compliance costs for business. These are considered in comparison with the ongoing costs expected under the "do nothing" option.

70. Under the "do nothing" option, businesses will be forced to adhere to a specific set of rules that define the processes they must follow when providing services. In contrast, under option 2, businesses will be judged in terms of the standards of the services they deliver, and the outcomes achieved – and will be free to choose whatever processes they consider to be the most appropriate and cost-effective ways of achieving these outcomes. Because businesses have a greater understanding of the operations of their individual services, they are naturally incentivised to find the most cost-effective means of achieving such outcome based standards. Indeed, during the consultation process we were able to obtain statistics from GPhC regarding the satisfaction levels of pharmacy owners and pharmacists that have already undergone an inspection under the outcomes-based model. For instance, 94% of pharmacies strongly agreed/ agreed that the inspector's findings were accurate. Moreover, 92% strongly agreed/agreed that feedback from the inspector helped them to think about how they can improve the quality of services they provide to patients and the public.

71. Moreover, it can be expected that a rules-based system, envisaged under Option 1, would lead to more frequent minor transgressions that impose costs on business – even though the failure to adhere to prescribed processes may have no impact on the outcomes or standards achieved.

72. Following the feedback from the consultation ,it is expected that Option 2 will also result in lower ongoing costs to businesses, compared with Option 1.

Summary of the impacts of Option 2

73. The analysis above explains why both transitional and ongoing costs to businesses are expected to be lower under Option 2. The outcomes-based system is already familiar to businesses, which gives them freedom to choose the most cost-effective way of achieving the required standards. This compares with the "do nothing" option, that would require the development of rules with which businesses are not yet familiar, In addition, it would specify the means by which they must conduct their operations, even though they may not be the most cost-effective approach of achieving the required standards.
74. Partial quantitative analysis of the costs to business for the options has now been carried out supported by the responses from the consultation. This suggests that costs under the 'do nothing' option would be at least £200,000 higher. GPhC's outcomes-based standards have been developed in close consultation with business and the profession. The consultation confirmed that businesses have already incurred any significant costs arising as a result of the approach by GPhC when developing the outcomes-based measures.
75. Whilst the nature of the policy makes it difficult to provide specific monetisation of all the costs and benefits, the likelihood of clear transition and ongoing costs allows for a robust qualitative and partially quantitative approach to arrive to a conclusion. Confirmed by the consultation responses, the analysis suggests that option 2 is likely to produce, at least, no extra cost to businesses compared to the 'do nothing' option. Hence, we have conservatively estimated that the preferred option, at the minimum, produces a Zero Net Cost to business, but we know that it generates direct cost savings of at least £200,000 in respect of the GPhC.

Option 3 - Issue guidance on registered pharmacy standards and information obligations without amending legislation

Description of the option

76. This option does not involve any change in legislation and simply requires further communication efforts to clarify the existing policy.

Description of likely impact

77. The benefit of this option is the speed and small cost incurred to make the change. However, it does not achieve the policy objective and is not considered in detail. In addition, the effects of Option 1 – in terms of the costs imposed unnecessarily on business – would not be avoided. The GPhC would be required to introduce a rules based registered pharmacy standards and inspection system. As guidance cannot of itself change the law, this option would cost pharmacy businesses and the GPhC more, because option 1 would have to be implemented alongside option 3. For Northern Ireland, this would effectively be no change, because the PSNC's registered pharmacy standards are already set out as guidance. The benefits of option 2 would not be realised.

Additional impacts

COMPETITION

77. No impact is expected.

SMALL AND MICRO BUSINESS ASSESSMENT (SaMBA)

78. The proposals considered in this impact assessment cover both small and large businesses. The Department considers at this stage that the proposals would not have any specific adverse impacts on small or micro businesses (SaMB).

79. The above was confirmed by the consultation period, which allowed us to consider the question as to whether small and micro businesses could be disproportionately affected by the proposed changes. Both conversations with different stake holders and responses to the consultation were supportive of the fact that Small and Microbusinesses will not see a disproportionate impact from the policy change. Regarding the latter, of the 89 people (out of the 159 of consultation respondents) who answered the question as to whether they agree that 'there will be [no] specific adverse impact from this proposal on small or micro businesses', 98% responded affirmatively (i.e. the significant majority felt there was no adverse impact on small or micro businesses).

80. It was highlighted by some respondents that in general it may take longer for some smaller businesses to familiarise themselves with policy changes.

81. In general terms, pharmacy law does not differentiate between pharmacies in terms of their overall business size, nor the requirements for premises registration. To do so otherwise would:

- jeopardise public safety (because SaMB pharmacy businesses might seek to operate without such safeguards in place);
- stimulate larger pharmacy businesses to divide their existing businesses up and so further promote proliferation of smaller pharmacy businesses;
- have potential knock-on effects across the pharmacy sector as a whole if this led to the general high levels of public confidence in pharmacy being reduced or undermined.

82. The GPhC has confirmed to the Department that it has developed its standards in consultation with all types of pharmacy business, and that a representative proportion of the inspections it has already carried out under the new outcomes-based inspection regime has been of SaMBs. Regular and systematic feedback has been received from pharmacies about the inspection model. The GPhC reports that this feedback is overwhelmingly positive with the vast majority of pharmacy owners and pharmacists who commented on their inspection felt that there was either no, or minimal disruption to the pharmacy. Similarly, SaMBs have not so far identified costs arising which are specific to their sector rather than to pharmacy businesses as a whole. Indeed, failure to include pharmacy SaMBs in the preferred approach would disadvantage them in comparison with larger pharmacy businesses and may be detrimental to competition because SaMB would have to comply with rules which specify the means by which they must conduct their operations, even though they may not be the most cost-effective approach for SaMBs of achieving the required standards. SaMBs would, as a result, incur higher compliance costs. This was confirmed by conversations during and responses to the consultation.

WIDER ENVIRONMENTAL

83. The proposals are not expected to have any impacts on the wider environment.

HEALTH AND WELL-BEING

84. The proposals are expected to be complementary to wider initiatives to improve patient safety through a change in culture to ensure safe operational practice in registered pharmacies.

HUMAN RIGHTS

85. The proposals are not expected to have any impacts on human rights.

JUSTICE SYSTEM

86. 84. The proposals in this impact assessment shift the balance from dealing with matters in legislative rules to doing so in professional regulation, by the pharmacy regulators, including, as necessary, through registration sanctions. One new criminal offence in relation to the General Pharmaceutical Council's (GPhC) information obligations is created, although this is a back-stop should a pharmacy business fail to comply with an improvement notice from the GPhC. Clearance for the creation of this new offence is being sought through the Ministry of Justice Criminal Offences Gateway.

87. RURAL PROOFING

88. 85. The proposals are not expected to have any differential impacts on rural areas.

89. SUSTAINABLE DEVELOPMENT

90. The proposals are not expected to have any impacts on sustainable development.

Table 1

91. Table 1 below describes the various legislative changes to take place under Option 2, assesses their regulatory and cost impacts and provides additional commentary.

TABLE 1 – Proposals to change registered pharmacy standards requirements **Medicines Act 1968 – relating to pharmacy owners**					
Section	**Requirement**	**Replacement**	**Regulatory impact**	**Cost impact on pharmacy businesses**	**Comments**
Section 74	Modification of a rule making power to allow suspended entries in the premises registers of GPhC and PSNI to be treated as still in the register. This is in part a consequential amendment relating to the new section 82A and the modifications to article 56 of the Pharmacy Order 2010, but it is a new rule making power for PSNI.	N/A	GPhC will be able to treat premises entered in its premises register as still registered, if they are suspended either during disciplinary proceedings against a pharmacy owner or after an adverse finding but pending an appeal. The PSNI will be able to treat premises entered in its premises register as still registered after an adverse finding against a pharmacy owner but pending an appeal.	The most likely use of this power would be to allow the GPhC and PSNI to treat suspended entries in its premises register as still registered for fee paying purposes. Pharmacy owners with suspended entries could be expected to continue to pay their registration fees. Fees for premises registration is already a part of pharmacy business operation, so this would not be a new cost burden.	Regulatory bodies fund their disciplinary proceedings out of registration income, so if the GPhC and/or the PSNI did use these powers to enable them to continue to receive fees from suspended pharmacy owners, this would be considered a reasonable use of those powers.
Sections 74B and 74H	Technical amendments	N/A	N/A	N/A	The Medicines Act 1968 contained references to rules made under article 7(1) of the Pharmacy Order 2010, which need to be changed to references to standards set. These are purely consequential amendments.

Section 75	Removal of redundant Northern Ireland only provisions relating to powers to make regulations that have been repealed	N/A	N/A	N/A	Reviewing the legislation identified redundant provisions which are being repealed in this Order.
Section 80	Amend the disqualification procedures for pharmacy owners, and the procedures for removing premises from the premises register (i) so they apply to retail pharmacy businesses owned by a pharmacist or a partnership, as well as bodies corporate; and (ii) to clarify that the test to apply sanctions, where registered pharmacy standards are not met (which will now also include NI registered pharmacy standards), is whether or not the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively.	This replaces in part the powers under article 14 of the Pharmacy Order 2010 which allowed the Registrar of the GPhC to suspend or remove entries from its register where a pharmacy owner failed to comply with an improvement notice that related to breaches of registered pharmacy standards in the GPhC's rules. Those powers could be used against pharmacy owners that were individual pharmacists or partnerships, as well as bodies corporate	For GB, this is intended to facilitate more proportionate sanctions by the pharmacy regulator where there are breaches of registered pharmacy standards, and focus enforcement action on the GPhC's disciplinary procedures. Limiting sanctions to cases of unfitness to carry on retail businesses safely and effectively will remove the possibility (for GPhC registrants) of removal of premises from the premises register for purely technical breaches of the registered pharmacy standards.	Cost neutral in the sense that disciplinary arrangements are already in place, and potential sanctions for breaches of GPhC registered pharmacy standards are already a feature of the legislation (breaches of the current PSNI registered pharmacy standards would have to be treated as a misconduct matter). However, streamlining GB processes creates potential savings as relying on a number of different approaches is potentially more costly in terms of businesses needing to adapt to a number of enforcement models. Removing the possibility of sanctions in GB for purely technical breaches of registered pharmacy standards also creates potential savings, although heavy handed enforcement was never anticipated. See the above	The oddity that the disciplinary regime for pharmacy owners in the Act only applied to bodies corporate rather than individual pharmacists or partnership arose because of the limitations on who can own a pharmacy. Generally, partnership owners have to be partnerships of pharmacists, so the expectation has been that action against partnership owners or pharmacist owners would be by way of disciplining them as individual pharmacists. This left a gap in the case of owners that are Scottish partnerships, where currently action would need to be taken against the one pharmacist needed to be a partner. However, correction of this anomaly is believed in practice to be cost neutral.

				example - paragraph 39.	
Section 82	Technical amendments	N/A	N/A	N/A	Purely consequential amendments so that section 80 will apply to pharmacy owners that are pharmacists or partnerships as well as bodies corporate.
New Section 82A	Amend the disqualification procedures for pharmacy owners, and the procedures for removing premises from the premises register, to provide for interim suspensions from the register, prior to a disqualification decision or removal decision taking effect.	This replaces in part the powers under article 14 of the Pharmacy Order 2010 which allowed the Registrar of the GPhC to suspend or remove entries from its register where a pharmacy owner failed to comply with an improvement notice that related to breaches of registered pharmacy standards in the GPhC's rules. However, the new powers would apply to all disqualification and removal decisions under section 80.	The powers will only be exercisable for the protection of members of the public or where otherwise in the public interest. The pharmacy owner by this stage will already have a disciplinary committee finding that they are unfit to carry on the business safely and effectively against them. The sanctions are therefore likely to be only very rarely applied.	No significant costs on business. The sanctions, although necessary for public protection, are likely only to be very rarely applied. Business failure at this level can be costly to other businesses, and it is impossible to predict whether overall the business community would suffer financial benefit or detriment from such sanctions. Familiarisation costs would be negligible because the new orders are modelled on existing fitness to practise procedures for individual registrants.	At this level of business failure, if the business was still viable, it is almost inevitable that it would be transferred/sold to a new owner.
Section 84B	Technical amendment that has the effect of applying article 5 of the Pharmacy (Northern Ireland) Order 1976 to PSNI Rules under section 74.	N/A	N/A.	Cost neutral	The changes to the powers under section 74 mean that, for the first time, these are exercisable by PSNI. It previously had no powers to suspend entries in the premises register and so no need of powers under

					section 74. The procedure means the PSNI rules would require approval by the Department of Health, Social Security and Public Health of Northern Ireland.

Pharmacy (Northern Ireland) Order 1976 – Pharmacy owners					
Article	**Requirement**	**Replacement**	**Regulatory impact**	**Cost impact on pharmacy businesses**	**Comments**
Article 5A	Places the power of PSNI to set registered pharmacy standards, currently set in guidance, on a statutory footing, so that in future they can be set in statutory codes of practice, and clarifies what the standards can cover.	N/A	Wording of the provision supports an 'outcome based' approach, rather than the 'prescriptive' registered pharmacy standards in the current guidance. The standards will however now feed directly into the disciplinary arrangements in section 80 of the Medicines Act 1968. The list of what the standards can cover is the same as the list in article 7(3) of the Pharmacy Order 2010, so see comments below.	Potential for familiarisation costs if, as anticipated, PSNI change their standards, but these costs are unlikely to be significant because pharmacy owners, in order to operate their businesses within an area of law and practice where constant change is inevitable, already have in place mechanisms for ensuring that they and their staff keep up to date. As explained in relation to section 80 of the Medicines Act, the new link to its procedures is likely to be cost neutral.	Although the current standards have no statutory basis, it is inevitable that pharmacy businesses take them very seriously, not least because they are the standards of the body that registers them and of the inspectorate that inspects them. In practice, the change to a statutory footing is likely to be less significant than the anticipated change in content.
Article 20 and paragraph 8 of Schedule 3	Enable interim suspension orders to be made pending hearings in respect of the owners of pharmacy premises in NI.	This is a modification of the current powers to make interim suspension orders in relation to individual registrants.	The new arrangements mirror the new arrangements being introduced for Great Britain and so ensure that a uniform scheme applies across the UK (see below in relation to article 56 of the Pharmacy Order 2010)	Familiarisation costs would be negligible because of the use of existing fitness to practise procedures. The powers are only exercisable for the protection of the public or where it is otherwise in the public interest to do so, so should not impact on any	These changes and the changes to articles 14 and 56 of the Pharmacy Order 2010, together with the changes to sections 80 and 82A of the Medicines Act, need to be understood together. The net effect is a set of disciplinary provisions for

				business that is functioning normally. They are backed up by procedural safeguards including rights of appeal.	breaches of registered pharmacy standards by pharmacy owners, similar to the disciplinary arrangements for individual registrants, which allow for a proportionate, risk-based response and which contain a number of procedural safeguards in terms of notifications, hearings and rights of appeal.
Paragraph 15 of Schedule 3	Consequential change to the regulation-making powers in respect of the disqualification procedures for pharmacy owners in section 80 of the Medicines Act 1968 so that they will apply to retail pharmacy businesses owned by a pharmacist or a partnership as well as bodies corporate.	N/A	The change ensures that all types of owner will be treated in the same way under the procedures in section 80 of the Medicines Act 1968.	Cost neutral, but the comments made in relation to the changes to section 80 of the Medicines Act 1968 above again apply.	See the comments in relation to the changes to section 80 of the Medicines Act 1968 above.

Pharmacy Order 2010 – Pharmacy owners					
Article	**Requirement**	**Replacement**	**Regulatory impact**	**Cost impact on pharmacy businesses**	**Comments**
Articles 3 and 29	Transfers the requirement to notify the GPhC of the death of a pharmacist from the Registrar General to the relevant local registrar of deaths.	Correction of existing provisions.	The legislation currently requires the wrong officer to notify the GPhC of the deaths of pharmacists.	N/A	This simply corrects an error in the Pharmacy Order 2010. Notification of deaths by the correct officer should limit the occasions on which bereaved families might be asked for information from the GPhC.
Article 7(1) to (3) and 8	Removes the requirement for the GPhC's registered pharmacy standards to be in rules, so that in future they can be set in statutory codes of practice, and clarifies what the standards can cover.	Replaces a rule-making power to similar effect, but with a different list of matters that the standards are expected to cover.	This is deregulatory. Rule-making powers are replaced with code of practice type provisions. The new list of the matters that the standards are expected to cover supports a more flexible and 'outcomes based' approach, rather than traditional 'prescriptive' registered pharmacy standards. The list uses wording such as 'governance arrangements', 'working environments', and 'the patient and public experience', with less emphasis on specific matters like 'record keeping', 'standard operating procedures' and	Potential for familiarisation costs but these costs are unlikely to be significant because the new standards are already being rolled out as part of a new inspection model, and pharmacy owners, in order to operate their businesses within an area of law and practice where constant change is inevitable, already have in place mechanisms for ensuring that they and their staff keep up to date. In England, for the retail pharmacy businesses that wish to dispense NHS prescriptions, this has already been formalised into a requirement on pharmacy owners to have	The list in article 7(3) now also makes express reference to setting standards in respect of 'associated premises', i.e. premises at which activities are carried on which are integral to the provision of pharmacy services at or from registered pharmacy premises. This reflects the fact that the traditional model of pharmacy premises being entirely self-contained operations is becoming outdated. Integral parts of the businesses operation – for example electronic data storage – may be elsewhere. This therefore permits the GPhC to set

			'incident reporting mechanisms', which characterise the current list.	in place clinical governance arrangements that include a premises standards programme and staff training.	standards that work equally well for both the traditional 'self-contained' pharmacy operation and more flexible models.
Article 7(4) to (7)	Changes to the requirements that GPhC can include in rules relating to the information that is to be supplied to them by pharmacy owners. These rules deal, principally, with details of the key people responsible for the business (e.g. directors and superintendent pharmacists of bodies corporate, and partners in partnerships), information about investigations of and offences committed by those key people (and in some cases by the business itself), business addresses, and details of other activities undertaken at registered pharmacy premises.	Modification of existing provisions.	In part, deregulatory. The obligation to make rules becomes a power to make them. The obligation to include in the rules a requirement that the pharmacy owner submits a compliance statement is removed. Other modifications give greater flexibility to the GPhC in terms of the how it may require the information to be provided, and in the case of notification of offences, the information gathering net is cast slightly wider to encompass cautions as well as convictions. The changes also allow the GPhC to require additional information about offences by businesses that are partnerships, where the partnership is charged corporately, and about superintendent pharmacists.	Although the GPhC is currently under a duty to make rules under these provisions, no rules have yet been made, so it is impossible to cost the impact of changing that duty to a mere power. The cost saving from removal of the requirement to require provision of a compliance statement is only notional as the requirement has not been imposed. The costs of assembling and providing this information should not be significant, as the information should be within the corporate knowledge of the business, not least because, for the overwhelming majority of businesses that provide NHS services, this is the type of information that generally has to be provided to commissioners of those services.	If changes are not made to article 7(4) to (8) the GPhC will have no alternative other than to make rules under the existing provisions. Apart from a small cost saving produced by not having to make a compliance statement, there should be no significant difference between the potential compliance cost of complying with rules under the revised powers and the potential compliance cost of complying with rules under the unrevised powers.

Article 9	Clarifies that the GPhC can publish registered pharmacy inspection reports, which may include an account of the outcome of the inspection.	N/A	Clarification of existing expectation so that results of inspections are transparent and publicly available and can be published and shared more widely e.g. with other regulators, NHS commissioners etc. No impact on the volume or frequency of inspections is expected.	Cost neutral	In England, publication of inspection reports by the Care Quality Commission (CQC) is a key driver both to improve public confidence and public choice, and to reward good performance and highlight poor performance, without imposing costs. Retail pharmacies generally do not have to register with the CQC. The new arrangements will enable GPhC to meet consumer expectations in ways that are more familiar to them.
Article 13	Amendment of the powers to service improvement notices so that they can be served in respect of breaches of rules under article 7(4) to (7).	Modification of existing provisions	There is currently no enforcement mechanism for breaches of article 7(4) to (7) rules. Action would currently have to be taken, once the rules are made, as 'misconduct' disciplinary proceedings. See the worked example above – paragraph 39.	Providing a workable enforcement mechanism for the rules does not, of itself, impose any new cost burdens. Under the present arrangements, pharmacy owners would still have to comply with the rules and potentially face sanctions if they did not. Familiarisation costs would be negligible because of the use of existing improvement notice procedures that are already being rolled out.	An improvement notice would be appealable through the lower courts. If a valid notice was breached, the GPhC could itself refer the matter through the courts, where the maximum penalty would be a fine on level three of the standard scale. Alternatively, the Registrar could suspend or remove entries from the premises part of the register, subject to a right of appeal to the GPhC's Registration Appeals Committee.

Article 14	Amendments to the sanctions provisions relating to breaches of improvement notices so that prosecutions cannot be brought in cases of breaches of registered pharmacy standards and the matter must be dealt with as a disciplinary matter, by the Fitness to Practice Committee, rather than potentially as a registration matter by the Registrar.	N/A	Ensures that all breaches of registered pharmacy standards are dealt with via the route of disciplinary sanctions by the Fitness to Practice Committee, rather than by any other route, which means sanctions are limited to the revised circumstances described in relation to section 80 of the Medicines Act above.	Cost neutral in the sense that disciplinary arrangements are already in place, and potential sanctions for breaches of GPhC's registered pharmacy standards are already a feature of the legislation. However, streamlining GB processes creates potential savings as relying on a number of different approaches is potentially more costly in terms of businesses needing to adapt to a number of enforcement models.	Limiting sanctions to cases of unfitness to carry on retail businesses safely and effectively will remove the possibility (for GPhC registrants) of removal of premises from the premises register for purely technical breaches of registered pharmacy standards. Without these changes, the Registrar would in theory be able to do that, even though that would be unexpected.
Article 56	Enable interim suspension orders to be made pending hearings in respect of the pharmacy owners.	This is a modification of the current powers to make interim suspension orders in relation to individual registrants. The change is in part to replace the powers of the Registrar to make suspension orders for non-compliance with improvement notices in respect of registered pharmacy standards, which are omitted by virtue of the changes to article 14.	The loss of the ability of the Registrar to suspend entries in the premises register where registered pharmacy standards are breached creates a gap in the enforcement arrangements where there is a risk to the public. These changes fill that gap, and by using procedures more suited to dealing with fitness issues than the current arrangements (i.e. the Fitness to Practice Committee rather than the Registrar and Registration Appeals Committee of the	Cost neutral in the sense that pharmacy owners already face the potential jeopardy of suspension of entries in the premises register for non-compliance with the GPhC's registered pharmacy standards. However, as above, streamlining GB processes creates potential savings as relying on a number of different approaches is potentially more costly in terms of businesses needing to adapt to a number of enforcement models. Familiarisation	The GPhC will not need to serve an improvement notice before it can use the article 56 procedures, but these powers are only exercisable for the protection of the public or where it is otherwise in the public interest to do so, and are backed up by procedural safeguards including rights of appeal. The changes to articles 14 and 56, the changes to section 80 of the Medicines Act, and the new section 82A of the Medicines Act need to be

			GPhC).	costs would be negligible because of the use of existing fitness to practise procedures.	understood together. The net effect is a set of disciplinary provisions for breaches of registered pharmacy standards by pharmacy owners, similar to the disciplinary arrangements for individual registrants, which allow for a proportionate, risk-based response and which contain a number of procedural safeguards in terms of notifications, hearings and rights of appeal.
Article 61	Consequential change to the rule making powers in respect of the disqualification procedures for pharmacy owners in section 80 of the Medicines Act 1968 so that they will apply to retail pharmacy businesses owned by a pharmacist or a partnership, as well as bodies corporate.	N/A	The change ensures that all types of owner will be treated in the same way under the procedures in section 80 of the Medicines Act 1968.	Cost neutral, but the comments made in relation to the changes to section 80 of the Medicines Act 1968 above again apply.	See the comments in relation to section 80 of the Medicines Act 1968 above.

Annex A

Assumptions:

a. Businesses have already begun the process of familiarising themselves with the GPhC's outcomes-based system, and in preparing for its implementation. Hence, transition cost of Option 2 of this Impact Assessment (IA) should be small.

b. A premises standards system based on prescriptive rules would entail transition costs related to familiarisation costs and redesigning of business models to comply with those rules. Hence, transition cost of this option would be higher than under Option 2.

c. A premises standards system based on prescriptive rules would entail ongoing costs related to complying with the prescriptive set of detailed rules by demonstrating adherence to all their provisions and undergoing inspection across all aspects of their operations affected.

d. Under the outcomes-based premises standards system (Option 2) pharmacies can make use of their greater understanding of the operations of their individual services. Hence, they are naturally incentivised to find the most cost-effective means of achieving such outcome based standards. This makes the ongoing costs under Option 2, lower than under a system based on prescriptive rules.

Annex B

Premises standards IA

Question 20:

We have prepared an IA covering costs and benefits of the premises standards proposals. Do you agree our assessment? If not, please provide additional information (with estimates) regarding other costs or benefits that you think have not been considered in the IA.

Question 21:

Our initial analysis of the proposed changes to pharmacy premises standards suggests that our preferred option, Option 2, has no significant transition or ongoing costs relative to the current framework. This is based on assumptions in Annex A of the IA. Are our assumptions valid? If not, please identify what other costs and assumptions have not been identified and provide examples and estimates that will help us quantify and monetise the costs.

Question 22:

We do not consider there will be any specific adverse impacts from this proposal on small or micro businesses. Do you agree? If not, please identify what these impacts are and their likely costs and explain why they are specific to small and micro businesses. Also, please provide evidence on how small and micro businesses would be affected by an alternative prescriptive rules-based approach compared to an outcome-based system. Please say (i) what assumptions we should use (ii) identify the impacts and (iii) estimate their likely costs and explain why they are relevant to small and micro businesses.