Title:	Impact Assessment (IA)
Recognition of pharmacist qualifications awarded in the European Economic Area and Switzerland: removing the "Three-year rule" from new pharmacies	**IA No:** 5059
Lead department or agency: Department of Health (England)	**Date:** 06/05/2011
Other departments or agencies: Scottish Government, Welsh Assembly Government	**Stage:** Final
	Source of intervention: Domestic
	Type of measure: Primary legislation

Summary: Intervention and Options

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

All pharmacists practising in Great Britain must be registered with the General Pharmaceutical Council (GPhC). EC Directive 85/433 (now Directive 2005/36) provided for mutual recognition of formal qualifications awarded in "relevant European States" to give the same effect as those which the Member State itself awards. However, Article 21.4 of Directive 2005/36/EC expressly enables Member States not to give effect to the principle of mutual recognition in certain circumstances. The UK operates this 'derogation' in respect of responsible pharmacist positions in pharmacies that have been registered for less than three years. This restriction potentially limits the flexibility of the pharmacist labour market, market competition and efficiency in the delivery of pharmaceutical services.

What are the policy objectives and the intended effects?

To consider the removal of the restriction and thus allow pharmacists registered with the GPhC via EC Directive 2005/36 to hold the position of responsible pharmacist in any registered pharmacy in Great Britain. This is in line with broader policy in pharmaceutical services provision to increase flexibility in the labour market, and to increase competition and efficiency in the delivery of pharmaceutical services.

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

1) Do nothing:

The restriction impacts a relatively small number of pharmacies - being confined to those that are registered for less than three years. It does not prevent any pharmacist from being a responsible pharmacist in any pharmacy that is registered for more than three years, nor from working in a pharmacy in any other capacity, or from owning a pharmacy.

2) Removal of the restriction:

The increased role of community pharmacies in primary care indicates that flexibility of resource will be important in delivering front line services. Changes in the broader domestic policy for pharmacy and a more flexible position on ownership of pharmacies in some other Member States suggests that the restriction should be removed. This is the preferred policy option.

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:** Month/Year	
What is the basis for this review? Not applicable. **If applicable, set sunset clause date:** Month/Year	
Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?	No

SELECT SIGNATORY Sign-off For final proposal stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister: _____ Date: 6.6.11

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Summary: Analysis and Evidence

Policy Option 1

Description:

Do nothing (by definition, all sections are left blank for the do nothing option)

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

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'

As this is the "do nothing" option, there are no key monetised costs.

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

As this is the "do nothing" option, there are no other key non-monetised costs.

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'

As this is the "do nothing" option, there are no key monetised benefits.

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

As this is the "do nothing" option, there are no other key non-monetised benefits.

Key assumptions/sensitivities/risks **Discount rate (%)**

As this is the "do nothing" option there has been no need to address any key assumptions, sensitivites, and risks in respect of the status quo.

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

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Options		
From what date will the policy be implemented?			01/01/2010		
Which organisation(s) will enforce the policy?			GPhC		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:**	**Non-traded:**	
Does the proposal have an impact on competition?			Yes/No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:**	**Benefits:**	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)		**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	Yes/No	Yes/No	Yes/No	Yes/No	Yes/No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	Yes/No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes/No	
Small firms Small Firms Impact Test guidance	Yes/No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	Yes/No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	Yes/No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	Yes/No	
Human rights Human Rights Impact Test guidance	Yes/No	
Justice system Justice Impact Test guidance	Yes/No	
Rural proofing Rural Proofing Impact Test guidance	Yes/No	
Sustainable development Sustainable Development Impact Test guidance	Yes/No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

Removal of the restriction

Price Base Year 2011	PV Base Year 2011	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 0.18	**High:** 1.4	**Best Estimate: 0.6**

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

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

This policy option is a regulatory simplification, and is not expected to impose any costs on businesses affected by the current three-year rule restrictions. The consultation responses identifed a number of risk factors that may generate costs. Careful analysis of these issues indicate that there are no tangible costs directly attributable to the removal of the three-year rule restriction.

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

- Risks to the quality of service was highlighted in some consultation responses. The main affected group would be NHS patients in this respect. In general, the evidence available suggests that the removal of the restriction would not generate any new, unique, risks (and thus costs) to the quality of service.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	None		0.02	**0.18**
High	None		0.17	**1.4**
Best Estimate			0.07	**0.6**

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

1) Regulatory burden directly associated with the three-year rule. The main affected groups are private companies, specifically pharmacy businesses and agencies used to recruit locum pharmacists.

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

1) Increased flexibility and competition in the market for pharmacutical services.

2) Greater continuity in the delivery of NHS pharmaceutical services.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

- The quantified benefits focus on the administrative time cost of undertaking checks that are a direct consequence of the three-year rule restriction. In effect the direct quantifiable costs of the three-year rule under the "do nothing" option reflect the potential quantifiable benefits of option 2.
- The quantification of benefits relate specifically to the group in question, i.e. the number of pharmacists that have registered in Great Britain under the mutual recognition arrangements.
- A central, best, and worst-case scenario have been analysed.
- In some areas it is very difficult to gather robust assumptions, and the strengths and weaknesses of the assumptions are laid out in E. iii.

Direct impact on business (Equivalent Annual) £m):			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0.07	**Net:** 0.07	Yes	OUT

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			Great Britain		
From what date will the policy be implemented?			To be determined		
Which organisation(s) will enforce the policy?			GPhC		
What is the annual change in enforcement cost (£m)?			Zero		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** Zero	**Non-traded:** Zero	
Does the proposal have an impact on competition?			Yes		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** 100	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro** N/A	**< 20** N/A	**Small** N/A	**Medium** N/A	**Large** N/A
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	Yes	17
Small firms Small Firms Impact Test guidance	No	18
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	18
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	18
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	18
Human rights Human Rights Impact Test guidance	No	19
Justice system Justice Impact Test guidance	No	19
Rural proofing Rural Proofing Impact Test guidance	No	19
Sustainable development Sustainable Development Impact Test guidance	No	19

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	Legislation or publication
1	General Pharmaceutical Services in England 2000-01 to 2009-10, NHS Information Centre, November 2010.
2	Briefing Paper: RPSGB Register Analysis 2010, Dr Liz Seston and Professor Karen Hassell, The University of Manchester, (currently unpublished).
3	Pharmacy Workforce Census 2008: Main Findings, Dr Liz Seston and Professor Karen Hassell, The University of Manchester, RPSGB, 2009.
4	Supply Of And Demand For The Pharmacy Workforce In Great Britain, Dr Karen Hassell Centre For Pharmacy Workforce Studies, The University of Manchester , 2003.
5	Recognition of pharmacist qualifications awarded in the European Economic Area and Switzerland: removing the “Three-year rule” from new pharmacies, Consultation Impact Assessment, Department of Health, England, January 2011.

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs	0	0	0	0	0	0	0	0	0	0
Annual recurring cost	0	0	0	0	0	0	0	0	0	0
Total annual costs	0	0	0	0	0	0	0	0	0	0
Transition benefits	0	0	0	0	0	0	0	0	0	0
Annual recurring benefits	0.06	0.06	0.07	0.07	0.07	0.07	0.08	0.08	0.08	0.09
Total annual benefits	0.06	0.06	0.07	0.07	0.07	0.07	0.08	0.08	0.08	0.09

* For non-monetised benefits please see summary pages and main evidence base section

Evidence Base (for summary sheets)

A. What is the problem under consideration? Summary of analytical narrative.

Problem under consideration:

- All pharmacists practising in Great Britain must be registered with the GPhC. EC Directive 85/433 (now Directive 2005/36) provided for mutual recognition of formal qualifications awarded in "relevant European States" to give the same effect as those which the Member State itself awards.
- However, Article 21.4 of Directive 2005/36/EC expressly enables Member States not to give effect to the principle of mutual recognition in certain circumstances. The UK operates this 'derogation' in respect of the position of the responsible pharmacist in pharmacies that have been registered for less than three years. This covers both new pharmacies, and pharmacies that have relocated to new premises over the last three years.
- Since the restriction was introduced, the community pharmacy landscape in Great Britain has changed and policy on community pharmacy has evolved. In England, for example, steps have been taken to further increase access and choice for the public, with new pharmacies opening, including extended opening hours. These arrangements are expected to be further developed with market-based entry on the assessment of local pharmaceutical needs. The ongoing and future development of pharmaceutical services will be aided by the removal of restrictions on resources, such as labour.

Background:

- There are over 12,000 community pharmacies in Great Britain, of which there are 10,691 in England (as at 31 March 2010 – *Source: NHS Information Centre*), 1,225 in Scotland (*Source: Community Pharmacy Scotland website)*, and over 700 in Wales (*Source: Community Pharmacy Wales website).* The community pharmacy sector has been increasing in size over the last few years. In England, the number of community pharmacies has risen by more than 8 per cent since 2005, compared to virtually no change in the number of pharmacies in England during the preceding five years. The majority of the increase can probably be explained by relaxation in the conditions of entry to NHS pharmaceutical lists. In the last three years (2008-2010), approximately 1,600 pharmacy premises have been registered in Great Britain (GPhC data), amounting to just over ten per cent of all registered pharmacies in Great Britain.
- In 2010 there were 50,664 pharmacists registered in Great Britain, of which 43,780 were currently practising (RPSGB Register Analysis). Of all registered pharmacists, 12.1 per cent qualified overseas. Included in this overseas definition are three groups: 1) "Reciprocal" registrants – pharmacists trained in Northern Ireland; 2) "European" registrants – covering pharmacists trained in the European Union (EU) Member States, plus Iceland, Norway, Liechtenstein and Switzerland ("relevant European States" herein referred to as those who qualify to register under the "mutual recognition" of qualifications); and 3) "Adjudication" registrants – all other non-European pharmacists who are required to meet the conditions of the Adjudication Committee, normally through completing a Masters level assessment and a period of pre-registration training.
- The specific ("three-year rule") restriction only applies to those registered to practice in Great Britain under the mutual recognition of qualifications. Over the last few years, there has been an increase in the number of pharmacists registering in Great Britain through the EU mutual recognition arrangements. For example in 2006, there were approximately 1,650 pharmacists (3.5 per cent) registered in Great Britain through these arrangements. In 2010, 5.4 per cent of pharmacists registered in Great Britain did so through this route, which equates to approximately 2,700 pharmacists (RPSGB Register Analysis). Hence, there has been an increase in the number of pharmacists registered in Great Britain through the mutual recognition arrangements by two-thirds over the period 2006 – 2010. This is small relative to the total number of registered pharmacists, but emphasises the increasing attractiveness of registering to practise in Great Britain under the mutual recognition arrangements.

B. What are the policy objectives and the intended effects?

- The policy objective is to consider the removal of the restriction provided by the derogation and to allow pharmacists registered with the GPhC via EC Directive 2005/36 to hold the position of responsible pharmacist in any registered pharmacy in Great Britain.

- The intended effect of the policy is to increase flexibility and competition, ensure greater continuity in service delivery, and to reduce regulatory burden in the market for pharmaceutical services in Great Britain.

C. What are the underlying causes of the problem?

- The restriction was originally put in place in 1985 for economic reasons. The derogation, as provided in the EC Directive, was sought because pharmacy owners in Great Britain felt they were not in a comparable position to those in other parts of Europe. In a number of EU countries, the owners of pharmacy businesses were required to be pharmacists. In the UK, this was not the case. Other member states supported the derogation.

D. What policy options have been considered? The Do Nothing Option (Option 1) and Derivation of Other Options

i. Set out the baseline (Do Nothing Option), against which other options are assessed:

- The baseline policy option is to leave the restriction in place, as it is, utilising the derogation. This is defined as the "Do Nothing" option (policy option (1). There are no additional costs or benefits from this option.

ii. Describe the full range of the plausible options to achieve policy objectives in light of the evidence regarding the underlying causes of the problem.

- The alternative policy option assessed is to remove the existing restriction, which would have the effect of enabling any pharmacist registered in Great Britain through the mutual recognition arrangements to act as the responsible pharmacist in any registered pharmacy in Great Britain.

iii. List and summarise briefly the options assessed in the rest of the IA.

- Option (1) – "do nothing" – i.e. leave the existing restriction in place.
- Option (2) – remove the restriction.

Consultation:

- A formal consultation on policy option (2), removing the three-year rule, was undertaken, and ran from 12 January 2011 until 7 April 2011. A final consultation response report has been prepared, which provides a complete analysis of the consultation findings. In summary, four-fifths of respondents were in favour of removing the restriction. Just over half of the respondents felt there would be benefits associated with removing the three-year rule. One-fifth of respondents identified potential risks with

the removal of the restriction. The benefits and risks identified have been incorporated into the final impact assessment analysis.

E. Impacts, Costs and Benefits of Option 2

i. Set out the mechanism by which Option 2 is intended to work, its expected scale of impact, and the evidence supporting these expectations:

Potential Benefits of Option (2):

- Currently, pharmacists registered through the EU mutual recognition arrangements can only undertake the position of responsible pharmacist in pharmacies that have been registered for more than three years. Removing the existing restriction would allow such pharmacists to work in any pharmacy in Great Britain as the responsible pharmacist. Continuing the existing restriction would maintain the status quo, i.e. do nothing (policy option (1)), utilising the derogation. The number of pharmacies and pharmacists affected by the restriction remain a relatively small proportion of the total number of pharmacies and pharmacists in Great Britain. Furthermore, pharmacy owners will already have built into their businesses process, the steps required to check relevant matters against the three-year rule restrictions.
- The potential benefits of policy option (2) are as follows:

  1) The removal of the restriction will equalise the position for pharmacists registering through the EU mutual recognition arrangements with other registered pharmacists who work in Great Britain.

  2) There will be increased flexibility and competition in the market for pharmaceutical services.

  3) Increased labour market flexibility will result in greater continuity in the delivery of pharmaceutical services.

  4) The removal of the restriction will reduce regulatory burden in the pharmaceutical services sector, notably for employers.

  The potential benefits do not stand alone, and to varying degrees, overlap with each other.

1- Equalisation of arrangements:

- The simplest benefit from policy option (2) is to equalise the arrangements of pharmacists who have registered under the mutual recognition arrangements, with all other pharmacists registered with the GPhC.

2- Increased flexibility and competition in the market for pharmaceutical services:

- Removing the restriction is expected to increase the flexibility of the pharmacists' labour market in Great Britain. This was identified in a number of consultation responses as a benefit of policy option (2). First, there would be an increase in labour supply flexibility through employers being able to utilise a larger pool of qualified candidates for responsible pharmacist jobs in pharmacies registered within the last three years. Based on the latest available data (presented above), there would be approximately 5 per cent more registered pharmacists available to undertake responsible pharmacist roles in new pharmacies. In respect of scope, this group would be able to operate as a responsible pharmacist in the 15 per cent of all pharmacies newly registered in the last three years.
- The removal of the restriction would be particularly beneficial for businesses that employ locums to undertake responsible pharmacist responsibilities. By their nature, locums are a flexible labour resource who would work in a number of different premises for short periods. Under the current restriction, those registered under mutual recognition arrangements are limited to acting as a responsible pharmacist in premises registered for at least three years.
- In line with a greater supply of qualified labour, there might be an increase in competition between pharmacy businesses in the recruitment of responsible pharmacists. In theory, there will be a larger supply of available candidates for responsible pharmacist jobs, which would be expected to have a

positive effect on the market through competition, assuming that such pharmacists were selected through traditional forms of recruitment. This is an “intangible”, which would be driven by market trends and the mobility of the labour force. Thus, it is very difficult to quantify any monetary benefit value of this impact in a robust manner. However, it is clearly a benefit in any market to have access to a larger pool of qualified candidates.

- In a competitive market, a business is likely to seek methods of cutting costs, increasing productivity or diversifying its risk to remain competitive. One option available to a business would be to relocate from one set of premises to another, as businesses may be able to benefit from lower (or relatively more competitive) rents, a better location to attract customers, or simply a better outlet to operate a pharmacy business. As noted above, the three-year rule covers both new and relocated pharmacies. Thus, under the current arrangements there is a disincentive for pharmacy businesses to relocate if they have a responsible pharmacist covered by the mutual recognition agreements, as the existing responsible pharmacist would be unable to fulfil the responsible pharmacist duties in a relocated pharmacy for three years. Evidence from the consultation responses indicate that a number of pharmacy businesses have chosen to relocate, and in doing so have encountered problems with the three-year rule. This issue overlaps with another issue, the continuity of service delivery, which is covered below. There is no evidence available to indicate the strength of the disincentive to relocate. This would only be identifiable from how many businesses would have liked to relocate, but then chose not to do so due to the knock-on effect of the three-year rule. However, regardless of a lack of quantitative evidence, it is clear that the disincentive may limit the degree of competition and flexibility in the market for pharmaceutical services.

3- Greater continuity in the delivery of pharmaceutical services:

- A related, but distinct point is that improving the continuity of delivery of pharmaceutical services has been highlighted as a potential benefit of policy option (2) in a number of consultation responses. For example, evidence from the consultation responses highlighted a number of cases, in both primary and secondary care, where there was the potential for continuity of care to be compromised due to the existence of the three-year rule.
- In primary care, the three-year rule is said to have been particularly problematic for businesses that have relocated their premises under the minor relocation regulation. Relocation means that a responsible pharmacist who has registered under the mutual recognition arrangements is no longer able to undertake the responsible pharmacist role in a pharmacy that has relocated within the last three years. Consultation feedback has acknowledged the existence of this outcome. This has been identified as an issue where an individual has been settled into a business, has developed client relationships in the community, and is qualified to provide a range of services, including enhanced services. Despite the business being the same, premises and address aside, a pharmacist registered under mutual recognition would be unable to continue in the responsible pharmacist role. The consequence is that a move to another location, no matter how minor, results in the need for a new responsible pharmacist under the existing three-year rule, and the risk of losing specific expertise, and a potential lack of career development opportunities for pharmacists registered under the mutual recognition arrangements. An important issue worth noting here is that a relocated pharmacy is likely to inherit the same operating procedures and practices as before, thus there is an inherent inflexibility in the market when a particular pharmacist is unable to undertake the responsible pharmacist duties due to a change in address alone. In some cases, an imposed change of the responsible pharmacist may have a negative impact on the business, as a new responsible pharmacist may not be able to provide the same range of services as the former responsible pharmacist. In addition, the intangible benefits of well-developed patient-pharmacist relationships may be compromised.
- Hospital pharmacies, when providing services to a third party, are required to register with the GPhC and operate within requirements of the Medicines (Pharmacies) (Responsible Pharmacist) Regulations 2008. An example from the consultation responses from the secondary care sector highlights the unusual impact of the three-year rule. A chief pharmacist in a hospital, who registered under the mutual recognition arrangements, was unable to act as the responsible pharmacist in the main dispensary of their hospital as it had been registered in the last three years.
- Moreover, a number of hospitals, in the last 3 years, have registered their pharmacies in order to maintain services to smaller NHS and charitable organisations. However, this has meant that their pharmacists registered under mutual recognition, who have been employed at the hospital for a number of years, have not been able to be on the rota for responsible pharmacist duties in those

pharmacies. This has led to pressure on other staff and, in some cases, difficulty in maintaining some out-of-hours services.

4- Reduction in regulatory burden:

- Regulatory burden resulting from the three-year rule was highlighted in a number of consultation responses. Specifically, this burden comes through the need to undertake various ongoing administrative tasks that impose a financial and time cost onto businesses. Tangible monetary costs are more readily identifiable in this respect, and are associated with the existing arrangements, i.e. the "do nothing" option. That is the current costs directly attributed to the current restrictions are quantifiable as the potential benefits of policy option (2) – removal of the restriction.
- To understand the direct regulatory burden cost associated with the three-year rule, one needs to walk through the different processes that the three-year rule impacts upon, to determine whether these processes would be required in the absence of the three-year rule.
- The consultation evidence flagged up a number of administrative processes that are linked, directly or indirectly, to the three-year rule restriction. The processes directly associated with the three-year rule represent the potential benefit achievable, in respect of reducing regulatory burden, from implementing policy option (2).
- Employers will undertake a check during the recruitment process to identify where the prospective employee has completed their pharmacy training. Thus, this will indicate whether the applicant in question has registered with the GPhC under the mutual recognition arrangements, and therefore whether the three-year rule needs to be adhered to in respect of responsible pharmacist positions. In the absence of the three-year rule employers would still be likely to undertake a check on where a prospective employee has qualified as a pharmacist, as this would apply to all prospective applicants, not just those who register under mutual recognition. Thus, there appears to be no direct benefit from removing the three-year rule restriction for this specific step in the process.
- To comply with the existing regulations, employers need to ensure that pharmacists registered under the mutual recognition arrangements do not work as responsible pharmacists in premises registered in the last three years. Thus, businesses need to develop, and maintain, a list of premises that have been registered for less than three years. This process is directly attributable to the three-year rule and will become obsolete in the event of removing the three-year rule restriction. In terms of the likely benefits (cost savings) from removing this process, it will be restricted to the cost of maintaining the list of premises. The rationale being that any pharmacy business that has needed to develop a list of premises will have already invested the time and effort into doing so. Hence, the development of a list can be considered a sunk cost.
- In addition to the ongoing cost of maintaining a list of premises that have been registered for three years and under, there will be an administrative cost associated with the management of allocating staff to responsible pharmacist positions in the premises on the list. This will be most apparent for the allocation of locum pharmacist into responsible pharmacist positions in listed premises. Whilst in the absence of the three-year rule, i.e. policy option (2), there will still be a need to undertake some careful management of responsible pharmacist jobs, this process can be directly attributable to the current arrangements, and its removal represents a potential benefit to businesses. In this situation, it would cover both pharmacy businesses and any other businesses that provide a service in this area, for example a locum pharmacist agency.
- Finally, employers who relocate a business that has a responsible pharmacist registered under the mutual recognition agreements may have to transfer the responsible pharmacist responsibilities to another pharmacist who has not registered under mutual recognition. Here, an employer may have to incur the cost of allocating their pharmacists to different premises, which may result in paying the cost of relocation, for example, the cost of moving a staff member to a new location; housing costs, and travel costs. It is difficult to derive a plausible set of assumptions, and sensitivity analysis around assumptions, to judge the likely monetary cost to all of those affected in this factor.
- In respect of the regulator, the GPhC, they would undertake a number of checks when a pharmacist wishes to register, including where the pharmacist qualified. Whilst this will include identifying those who qualify for registration under the mutual recognition arrangements, policy option (2) would not be expected to change the regulator's processes. The regulator also undertakes inspections as a matter of course. There is no direct check of the three-year rule for responsible pharmacists during an

inspection, although it may be checked as a matter of course. Once more, policy option (2) would not be expected to create any specific change to the regulator's inspection processes.

Summary of potential benefits:

- Looking at all the potential benefits, it is difficult to quantify many of the benefits that would result from the implementation of policy option (2). However, it is anticipated that these benefits are likely to be small. This is in part due to the size of the group affected by removing the derogation being relatively small – the 5 per cent of registrants who have come through the EU mutual recognition of qualifications – and the number of pharmacies, which have registered in the last three years (around 15 per cent of all registered pharmacies).
- Nevertheless, what can be deduced is that the removal of the restriction will create more flexibility in the sector, particularly at the margins, generating benefits for the pharmaceutical services market, notably through reduced regulatory burden that imposes an ongoing administrative cost on businesses in this sector. This administrative cost from the current arrangements focuses on the likely number of three-year rule checks required for regular and locum pharmacists across the pharmaceutical services sector. The number of checks are estimated using assumptions around some key factors including: i) the number of pharmacists registered under the mutual recognition arrangements, ii) the relative mobility of the pharmacist labour force, and the relative mobility of pharmacy businesses, and new pharmacy businesses entering the market. This is outlined in more detail in sections ii and iii, below.

Potential Costs of Option (2):

- In considering Option (2), it is necessary to weigh up the likely benefits of removing the three-year rule restriction against the likely costs associated with removing the three-year rule.
- At this point, it is worthwhile to revisit the scope of the three-year rule, and subsequently the purpose of policy option (2), to remove the restriction. Currently, pharmacists registered through the EU mutual recognition arrangements can only undertake the position of responsible pharmacist in pharmacies that have been registered for more than three years. Removing the existing restriction would allow such pharmacists to work in any pharmacy in Great Britain as the responsible pharmacist.
- In essence, policy option (2) is a regulatory simplification that would not require any businesses covered by the existing arrangements to undertake any new regulatory activities. Therefore, there are no costs directly attributable to removing the restriction.
- Some consultation responses highlighted a number of potential risks that could generate some negative impact on the pharmaceutical services sector from removing the three-year rule restriction. These were:

  1) Risks to the quality of service provided (e.g. risks to patient safety due to a language barrier, or a lack of understanding of NHS procedures.)
  2) A small number of consultation responses highlighted the risk of oversupply in the pharmacist labour market in Great Britain.

1- Risks to the quality of service:

- A crucial factor to consider when assessing a health policy change is whether there could be any increased risk from the proposed policy option (2). This can be thought of as an increased risk of malpractice in the delivery of pharmaceutical services. In respect of removing the three-year rule restriction, this may arise from problems in the quality of service occurring in a new pharmacy that has a responsible pharmacist who has registered under the mutual recognition arrangements. Risks to the quality of service delivered are unlikely to be any different from under the current arrangements, as all pharmacists are governed by the same professional regulatory body as pharmacists trained in Great Britain, i.e. through the GPhC. The GPhC's standards of conduct, ethics and performance, among other things, require the pharmacist to recognise the limits of their professional competence and practise only in those areas that they are competent to do so. Their continued registration is subject to adherence to the GPhC's requirement for continuing professional development (CPD) and standards

of conduct, ethics and performance. CPD must be relevant to the safe and effective practice of pharmacy and to the pharmacist's current scope of practice.

- Furthermore, the three-year rule does not imply any limits on professional competence or length of professional experience of pharmacists registering through the mutual recognition arrangements. The original reason for the implementation of the three-year rule was economic and a number of consultation responses remarked that the existing derogation, that is being tied to the period of time a particular pharmacy has been registered at a specific address is illogical. Finally, the restriction does not apply to the position of responsible pharmacist in a business registered for more than three years, which reflects the bulk of the community pharmacy sector.
- The effective operation of a pharmacy providing pharmaceutical services requires the pharmacist to be familiar with these services. The undergraduate education and the pre-registration training in Great Britain help the pharmacist to become familiar with the delivery of pharmaceutical services, including for example the wider range of services pharmacies now offer. Services provided in the rest of Europe can differ widely to those provided in Great Britain. However, the requirements of the responsible pharmacist mean that all such pharmacists, wherever they received their undergraduate education, must comply with the regulatory requirements.

2- Risk of oversupply of pharmacist labour in Great Britain:

- Some consultation responses highlighted the risks associated with a potential oversupply of labour in the GB pharmacist labour market. It is difficult to see how the removal of a restriction that applies to a relatively small number of pharmacists would itself create an oversupply of labour. There is evidence from the sector that there has been an increase in the supply of pharmacists, due to an increase in the number of people studying for an MPharm degree in Great Britain, and then subsequently completing pre-registration, and registering with the GPhC. Notably, pharmacists can already register to practice in GB under the mutual recognition arrangements. There is no evidence that the three-year rule acts as a disincentive to registering to practice in GB through this avenue. The removal of the "3 year rule" is not expected to increase the number of registered pharmacists under the mutual recognition arrangements substantially, if at all.

Summary of potential costs:

- In summary, there are no direct, and tangible, costs identifiable with the potential removal of the three-year rule restriction. Option (2) is a regulatory simplification, and the simplification simply removes the limitation on who can act as a responsible pharmacist in a pharmacy business registered with the regulator for less than three years. Pharmacy businesses, and other businesses affected by the three-year rule, are not expected to incur any new costs due to removal of the restriction. The other risk factors identified through the consultation are not anticipated to change directly as a result of removing the restriction.

ii. Set out the costs and benefits of the option arising from the impacts listed in section Ei.

Having identified all pertinent factors, the quantitative cost-benefit analysis in this impact assessment focuses on the administrative costs associated with the regulatory burden directly attributable to the current three-year rule arrangements. Despite there being other identifiable benefits of policy option (2), the only tangible elements that can be quantified are the administrative (opportunity) cost of a person's time to undertake a number of checks directly attributable to the three-year rule.

The logic is that under the current arrangements, i.e. the existence of the three-year rule, businesses (be it a community pharmacy business, or a locum agency) will need to undertake a series of checks specific to the three-year rule. These checks are identified as 1) crosschecking pharmacists who have registered under the mutual recognition arrangements with 2) a list of premises that have been registered in the last three years. This list also 3) needs to be updated periodically. The creation of a list of premises that have been registered in the last three years is assumed to be a sunk cost, and thus there is no quantifiable tangible benefit in respect of policy option (2) from this specific factor.

The various assumptions made to quantify costs and benefits can be found in section iii below. It is clear that it is very difficult to pin down a precise set of assumptions to model the extent of checking required, as the market is quite dynamic. The periodic maintenance of premises lists is not considered explicitly and is considered to be subsumed within the benefits quantified for the three-year rule checks.

It is worth distinguishing between two groups – locum pharmacists and "regular" pharmacists employed permanently with pharmacy businesses. Locum pharmacists by nature move around different premises on a regular basis, and are likely to incur a greater administrative time cost in respect of checking against the three-year rule. A markedly smaller administrative time cost will be incurred in the recruitment and placement of permanent staff in a pharmacy business.

In respect of the impact assessment, in comparing policy option (1) do nothing, with policy option (2) remove the restriction, the current checks required under the do nothing option represent the potential cost-savings achievable (benefits) from policy option (2). Tangible costs associated with policy option (2) are expected to be zero. The removal of the three-year rule restriction is a regulatory simplification, which in effect will not require businesses to undertake any new activities that would impose a cost on their operations.

In terms of quantifying these cost-savings (or benefits) of policy option (2), the following analysis has been completed:

1) Estimates of the "potential" number of checks for locum pharmacists, per year, have been made. A cost per hour of checking has been derived and these numbers are multiplied to compute the "potential" cost of undertaking the three-year rule checks. This has been projected over a ten-year period, and discounted by 3.5 per cent. The total costs associated with the checks reflect the "potential" benefits from policy option (2).
2) The same process has been undertaken for "regular" pharmacists.

The total "costs" of checks from the existing restrictions have been added together to quantify the total "potential" benefit of policy option (2). Net benefits reflect the central set of assumptions made, and the sum of discounted benefits (i.e. in present value terms) over a ten-year period. Table 1, below, outlines the aggregate position.

Table 1 – Net Benefits table for policy option (2)

OPTIONS (against Option 1)	COSTS (£)		BENEFITS (£)		NET BENEFITS	Equality/Other Impact	QIPP Compliance
	Central	Worst	Central	Worst	Central		
Option 2 - remove the restriction	0	0	£620,000	£180,000	£620,000	N/A	N/A

What is clear is that there is potentially a small, but significant, administrative time cost in checking the registration status, and length of premises registration, for locum pharmacists. For "regular" pharmacists the costs (or benefits in respect of policy option (2)) are more modest, yet positive.

The discussion of the assumptions in iii below indicates the strengths and weaknesses of the modelling. The simplest finding is that there are no anticipated costs from policy option (2) and there are positive benefits realisable from simplifying the regulatory process, which would ensure that checks directly attributable to the three-year rule no longer need to be undertaken. Over a period of 10 years, the net benefits are potentially substantial, and are estimated to be in the region of £600,000 in present value terms. This does not consider the other intangible benefits identified. Costs are considered as zero. On balance, this indicates significant net benefits from policy option (2).

iii. Set out the assumptions upon which projections for Option 2 have been based, and the risks to which they are subject.

The assumptions made in the analysis of policy option (2) are set out in two separate tables, below. The analysis focuses on the likely administrative time cost of dealing with tasks directly associated with the three-year rule. These are essentially costs incurred under policy option (1), i.e. the "do nothing" option.

The costs directly associated with policy option (1) reflect the potential quantifiable benefits of policy option (2), removing the restriction.

The scenarios are isolated to identifying the potential administrative time cost of matching a potential employee, who has registered under the three-year rule, with a list of premises that identifies the premises that have been registered in the last three years. As stated above, the administrative time cost of updating the list of premises is assumed to be subsumed within the analysis.

The scenarios are separated into the likely number of three-year rule checks, and thus administrative time cost, for locums; and the same checks for "regular" staff who are fully employed by a pharmacy business. This administrative time cost is based upon various assumptions, listed below, and is presented in two scenarios – Central and Worst (note – a best case scenario has been considered, but is not reported in the impact assessment).

The main scenario (Central) is intended to reflect the most likely outcome from policy option (2). The worst-case scenario reflects the minimum benefit that might be expected, ceteris paribus, from the removal of the restriction, i.e. eliminating the need to spend time undertaking a series of administrative checks on a regular basis.

Table 2 – Assumptions for the locum analysis

	2011	2011
ASSUMPTIONS - LOCUMS	Central	Worst
Number of mutual recognition locums	731	724
Number of days worked per year	225	225
Number of premises worked at per year	37	25
Average number of days per premise	6	9
Number of 3-year rule checks per year	27,359	18,099
Average time taken to check	10 mins	5 mins
Cost per hour for checking	£12.95	£12.95

1) The number of locums is derived from taking a reported proportion, from the 2008 Workforce Census (Seston and Hassell, 2009), which should be robust. The proportion of locums (approximately 26 per cent) came from their sample of nearly 70% of the pharmacy register. This proportion was applied to the 2010 register figures for mutually recognised pharmacists, uprated into 2011 terms, and projected for 10 years using different growth rates (by scenario – see Ten Year projections below).

2) The number of days worked per year by locums is derived from a finding in the study "Supply Of And Demand For The Pharmacy Workforce In Great Britain" (Hassell, 2003). Here, locum pharmacists were found to supply 22.76 hours per week on average, which when applied to a standard 37-hour working week, equates to 62 per cent of a standard working week. Annually this equates to 225 days work per year. The number of days worked does not vary by scenario as other factors, in 3) below, are used to derive a forecast number of checks against the three-year rule per annum.

3) A proxy is required for the likely number of different pharmacies that an individual locum will work in per year, which in turn indicates the potential number of checks, per locum, that someone would need to undertake in respect of the three-year rule. The central and worst estimates are derived from assuming that a proportion of the locum's time is in premises in which they are familiar. This in turn partially controls for some situations where the three-year rule is not an issue (i.e. a locum post for a non-responsible pharmacist job, or in a pharmacy to which an individual pharmacist regularly acts as a locum). Regardless, the person responsible for the checking might still undertake the three-year rule as a matter of course. It is assumed that 50 per cent of a locum's days (i.e. 225 days / 2 = 112.5 days) are in regular premises where the three-year rule may not apply. This is an assumption with no strong evidence to support it. Of the remaining 50 per cent of the locum's days, an assumed number of consecutive days in a single premise are made to derive a potential number of premises that a locum might work in during a single year. This assumed number of days is three, which results in a potential of 37 premises ([225*50%]/3 = 37 premises). For the worst-case scenario, the number of potential

premises is lowered to 25 premises in one year. It is difficult to judge whether these numbers are an over or under-estimate, as there are conflicting factors at play including the frequency and distribution of movement by locum pharmacists around premises.

4) The (overall) average number of days per premise is simply the total number of days (225) divided by the number of "new" premises per year (i.e. 37 or 50). This implicitly assumes that locum pharmacists spend 50 per cent of their working days in premises where there is no need for a three-year rule check.

5) The number of premises is assumed as an average per locum, and this number is multiplied by the number of locums to aggregate the number of "potential" three-year rule checks per year. This excludes regular premises where checks are less likely to be needed.

6) The average time taken to complete the check is based upon some evidence provided during the consultation – 10 minutes – but it is likely to be specific to the individual business and the competence of the person making the check. Hence, this may be open to wide variation.

7) The average cost of a check per hour is based upon an assumed average salary for an HR manager of £25,000. HR manager salaries for community pharmacy businesses were researched, with figures varying between £20,000 and £30,000, hence the final number was chosen as a reasonable central scenario. This does not reflect the reduction in cost from a more junior member of staff undertaking checks, nor the potentially higher cost of a superintendent pharmacist or a pharmacy owner undertaking the same or additional checks (e.g. an independent pharmacist). Furthermore, it assumes on costs are included in the £25,000 for simplicity. Once more, this estimate may be open to variation.

Table 3 – Assumptions for the regular staff analysis

	2011	2011
ASSUMPTIONS - REGULAR STAFF	Central	Worst
Number of mutual recognition responsible pharmacists	2,059	2,039
Number of advertised jobs	5,625	3,750
Proportion of advertised jobs resp pharm	35%	20%
Number of 3-year rule checks per year	711	408
Average time taken to check	10 mins	5 mins
Cost per hour for checking	£12.95	£12.95

1) The number of responsible pharmacists covered by mutual recognition is calculated from the total number of mutual recognition pharmacists on the register in 2010 (2,736), uprated to 2011, multiplied by the proportion of regular pharmacists, i.e. 100% - 26.2% = 73.8 per cent, giving (2,736*73.8 per cent = 2,019). The worst-case scenario uses a lower growth rate for the number of registered pharmacists.

2) Some feel for the likely number of advertised "regular" pharmacist jobs is required to feed into an estimate of the likely number of responsible pharmacist jobs advertised. Evidence was sourced from one consultation response on the number of vacancies filled per annum, and this was aggregated up to estimate the likely number of "regular" vacancies in the entire community sector (= 7,500 vacancies). This may be an overestimate, as firms may have different workforce mobility and/or different degrees of business expansion. Thus, in the central scenario the number of estimated vacancies is assumed as 75 per cent of the upper limit estimated (7,500*0.75 = 5,625 vacancies). In the worst-case scenario, the estimate used is 50 per cent (7,500*0.50 = 3,750 vacancies). These are assumptions with no strong evidence to support the numbers used.

3) A complicated issue to resolve is how many of the "regular" pharmacist jobs advertised are responsible pharmacist jobs, to feed into quantifying a likely number of three-year rule checks for regular pharmacists. These jobs would require some checking of the registration status of a pharmacist as well as how long ago the relevant pharmacy premises were registered. First, the relative size of the responsible pharmacist market is identified. This is achieved by dividing the minimum number of responsible pharmacists (i.e. one for each pharmacy = 10,691 pharmacists) by the total number of "regular" staff (equal to 30,959 pharmacists - this is based on 74 per cent of the "active" workforce of

41,950 for 2010), to give (10,691/30,959) = 35 per cent. This percentage is assumed the proportion of all advertised jobs that are responsible pharmacist positions (central scenario.) A lower proportion (20 per cent) is assumed for the worst-case scenario.

4) The estimated number of three-year rule checks for regular pharmacist staff is calculated as the potential number of responsible pharmacists (who qualify under mutual recognition) multiplied by the proportion of advertised jobs that could be responsible pharmacist jobs (35 per cent). This assumes that all mutually recognised pharmacists could be a responsible pharmacist, i.e. 2,059 for 2011 in the central scenario, multiplied by 35 per cent = 711 jobs (checks). The strength of these assumptions are unknown, as mutually recognised pharmacists may be more or less likely to take on a responsible pharmacist role, with less being more likely due to the restrictions currently in place. It underestimates the true number of responsible pharmacists in the sector as some business employ, or requires more than one, responsible pharmacist. Moreover, the assumptions may also be weak as locums can also be used as responsible pharmacists. However, it does give an indication of the potential quantum of checks.

5) The average time taken to complete the three-year rule check is the same as for locums.

6) The average cost of a check per hour is the same as for locums.

Ten-year projections –

b) The standard government discount rate of 3.5 per cent has been applied to projected costs.

c) The number of registered pharmacists is uprated over time (2 per cent central, 1 per cent worst). This is not an official forecast.

d) The proportion of “active” pharmacists on the register remains the same over the projection period (83 per cent), as does the proportion of locums (26 per cent).

e) The average days worked per year by a locum remains the same (225 days).

f) The “potential” number of premises worked in varies by scenario (in Table 2), but not over time.

g) The average time taken to complete a check varies by scenario (in Table 2 and Table 3), but not over time.

h) The proportion of all advertised responsible pharmacist vacancies of all advertised vacancies remains the same over the projection period.

i) The cost per hour checking is uprated by real wage growth, applied to the baseline number, and varies by scenario (2 per cent central scenario, 0 per cent worst-case scenario).

v. Set out expected impacts upon Equality and Human Rights:

Specific Impact Tests:

Equality Assessment:

- An Equality Impact Assessment is attached with this Final Impact Assessment.

Competition Assessment:

Would the proposal directly limit the number or range of suppliers?

- Option (2) is not expected to directly limit the number or range of suppliers in the market for pharmaceutical services, and may in fact cause an increase.

Would the proposal indirectly limit the number or range of suppliers?

- There is no evidence to suggest any indirect impact on the number or range of suppliers in the affected market.

Would the proposal indirectly limit the ability of suppliers to compete?

- The proposed approach is more likely to increase the ability of suppliers to compete.

Would the proposal reduce the incentives of suppliers to compete vigorously?

- The proposed removal of the restriction is more likely to increase the incentive to compete, as the pool of available pharmacists will be increased.

Small Firms Impact Test:

- The cost-benefit analysis indicates that there are no direct costs associated with policy option (2). Thus, in respect of any potential impact on small firms, there is no reason to expect any cost impact. This measure is a regulatory simplification, which should generate a number of benefits, including a reduction in regulatory burden cost, which would be expected to be a positive outcome for smaller businesses in the pharmaceutical services market.

Health Impact Assessment:

The health impacts of the proposed policy have been considered in the main Evidence section of this document.

Will your policy have a significant impact on human health by virtue of its effects on the following wider determinants of health (income, crime, environment, transport, housing, education, employment, agriculture, social cohesion)?

- The proposed policy option of removing the restriction is not expected to have any impact on human health as depicted by the determinants of health listed above.

Will there be any significant impact on any of the following lifestyle related variables (physical activity, diet, smoking, drugs or alcohol use, sexual behaviour, accidents and stress at home or work)?

- The proposed policy option of removing the restriction is not expected to have any impact on the listed lifestyle variables.

Is there likely to be a significant demand on any of the following health and social care services (primary care, community services, hospital care, need for medicines, accident or emergency services, social services, health protection and preparedness response)?

- There is no reason to expect any significant demand on the listed health and social care services.

Environmental impacts:

Will the policy option have any significant environmental impacts?

- There is no reason to expect the proposed policy option to have significant environmental impacts.

Greenhouse Gas Impact Assessment

- The anticipated impact on Greenhouse Gas emissions has been addressed in the Summary: Analysis and Evidence pages at the top of this document. There are no impacts anticipated.

Justice system impacts:

Does the proposal affect the justice system?

- There are no anticipated impacts on the justice system.

Rural Proofing:

- There are no anticipated impacts on rural communities.

Human Rights:

Will the proposals have 'human rights' implications?

- There are no anticipated impacts on Human Rights.

Sustainable Development:

- There are no anticipated impacts on Sustainable Development.

H. SUMMARY AND WEIGHING OF OPTIONS

i. Present the best estimate of the overall net benefit of each option, from sections Eii, Fii, Gii,

ii. Summarise other factors, including equality and natural justice factors that weigh for or against each option, using the criteria that were cited for this IA in section Diii.

iii. Draw conclusions:

In conclusion, there are a number on unquantifiable benefits of removing the restriction (policy option (2)) in respect of greater flexibility and competition in the market for pharmaceutical services, and the potential for greater continuity in the delivery of pharmaceutical services. This impact assessment has focused on quantifying, using a number of assumptions, the directly attributable costs of the existing provision (i.e. the “do nothing” option), as these costs translate into the quantifiable benefits of policy option (2).

These benefits relate to the administrative time cost associated with a number of checks directly attributable to the three-year rule. The analysis has shown that there is a small, but significant, benefit from policy option (2). Crucially, no costs are anticipated from policy option (2), and therefore it is concluded that the net benefits of this policy option are positive.

To align the findings of this impact assessment with the analysis and reporting of the formal consultation of this issue, it is also noted that the majority of consultation responses were in favour of policy option (2).

Table 4 – Final Net Benefits table

OPTIONS (against Option 1)	COSTS (£)		BENEFITS (£)		NET BENEFITS	Equality/Other Impact	QIPP Compliance
	Central	Worst	Central	Worst	Central		
Option 2 - remove the restriction	0	0	£620,000	£180,000	£620,000	N/A	N/A

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)]; The basis of the review will be to analyse the impact of removing the pharmacy "three-year rule" restriction, and to determine whether any further course of action is required.
Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?] The review objective is to analyse to what extent the removal of the pharmacy "three-year rule" restriction has met its policy objectives, and to determine whether there are any unintended consequences of the proposed regulatory simplification.
Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach] The review approach will involve revisiting evidence presented in the impact assessment, other evidence available in the sector (e.g. from the regulator), and a scan of stakeholder views. Key stakeholders here would include the GPhC, the Company Chemists' Association (CCA), and the Pharmaceutical Services Negotiating Committee (PSNC), as well as other representative bodies and interested parties.
Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured] The baseline will use the policy context, qualitative & quantitative evidence, and analysis presented in this impact assessment.
Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives] The success criteria will include to what extent this policy met the policy objectives to increase competition and efficiency in the delivery of pharmaceutical services, and flexibility in the pharmacist labour market. This could include identifying whether the regulatory burden has reduced as a consequence of removing the "three-year rule", and looking at indicators such as the number of pharmacists available to undertake the role of responsible pharmacist in Great Britain.
Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review] A process to undertake a review will be developed. This will include the preparation of background context, questions, data sources, and a list of stakeholders who could be contacted during the scan of stakeholder views for a review to be held in three years time.
Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here] It is considered proportionate to focus on considering stakeholder views against a set of questions that relate to the original policy objectives set out in this impact assessment, rather than anything more detailed and resource intensive. Furthermore, stakeholder relationships in this sector are such that any significant unintended consequences of this regulatory simplification would become apparent quickly then policy action would be considered, as appropriate.

Annex 2: Equality Impact Assessment (EqIA)

Screening template

Equality Impact Assessment

Title of policy: Removal of derogation from Article 21 of the EC Directive 2005/36 on the recognition of professional qualification of Pharmacists in Great Britain
Short description of policy: EC Directive 85/433 (now Directive 2005/36), Article 21 provided for mutual recognition of formal qualifications awarded in EU Member States plus Iceland, Norway, Liechtenstein and Switzerland ("relevant European States") to give the same effect as those which a Member State itself awards. The EC Directive includes a derogation in Article 21(4) that allows Member States not to give effect to the mutual recognition arrangements in respect of new pharmacies, defined as pharmacies open for less than three years. Under this, the UK has put a restriction in domestic legislation to provide that pharmacists who there are registered under the mutual recognition arrangements are not permitted to become a 'responsible pharmacist' in a pharmacy that has been registered for less than three years. Pharmacies in GB do not have to be owned by a pharmacist - they may be owned by corporate bodies, partnerships or individual pharmacists whereas this is not the case in other Member States where, for example, pharmacy ownership is usually restricted to pharmacists. When the Directive was settled it was believed that the mutual recognition of qualifications could lead to an influx of pharmacists to the UK who would have the freedom to establish pharmacy businesses, but pharmacy owners in GB would not in a comparable position. Since the restriction was introduced the community pharmacy landscape in GB has changed and policy on community pharmacy has evolved. In England, for example, steps have been taken to further increase access and choice, including opening of new pharmacies and extended hours of service. Similarly, in a number of other European countries, restrictions on pharmacy ownership have been relaxed. Therefore, we are now proposing to remove the restriction.

Negative impact
How could the policy have a **significant** negative impact on equality in relation to each area?
Age, Disability, Ethnicity, Gender, Transgender, Religion or belief, Sexual orientation, socio-economic - no negative impact has been identified in respect of these groups.

Positive impact
Could the policy have a **significant** positive impact on equality by reducing inequalities that already exist? Explain how will it meet our duty to:
1. Promote **equal opportunities** – the change in legislation is likely to be positive but not significant.
2. Get rid of **discrimination** – the change in legislation is likely to be positive but not significant.
3. Get rid of **harassment** – the change in legislation is likely to be positive but not significant.

4.	Promote **good community relations** Under the current legislation there is no evidence to suggest this policy impacts, in any way, on good community relations
5.	Promote **positive attitudes** towards disabled people – no positive impact has been identified
6.	Encourage **participation** by disabled people – no positive impact has been identified
7.	Consider **more favourable treatment** of disabled people – no positive impact has been identified
8.	Promote and protect **human rights** – no positive impact has been identified

Evidence
What is the evidence for your answers to the above questions? **There is little evidence available since appointment to the position of 'responsible pharmacist' is the responsibility of the pharmacy owner who are regulated by the General Pharmaceutical Council.** **The removal of the restriction is anticipated to be positive but insignificant. Removing the restriction will only impact on pharmacies registered during the last three years, which relates to just over ten per cent of all registered pharmacies, and the five per cent of registrants who have registered through the EU mutual recognition arrangements. Even with a small increase in the available pool, the appointment to the position of 'responsible pharmacist' is usually based on skill match and decisions on this are the preserve of the appointing authority.**
What does available research say? There is no research on the likely impact of removing the restriction on the position of 'responsible pharmacist' in pharmacies registered for less than three years
What further research or data do you need to fill any gaps in your understanding of the potential or known effects of the policy?
Have you thought about commissioning new data or research? The number of pharmacists is recorded by the General Pharmaceutical Council, it would constitute a duplication and therefore an unnecessary burden to create further ways to capture the data required for this document. It would not be normally collected or used by the regulatory body or other stakeholders and would therefore be disproportionate in terms of the opportunity to use this to advance equality.
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Screening assessment
Now that you have looked at the evidence, do you think that the policy needs a **Full EqIA**? **Yes/No NO**

For the record
Name of person who carried out the EqIA: **Tracy Ellis**
Date EqIA completed: **16 December 2010**
Name of Director/Director General who signed the EqIA: **Professor Sir Bruce Keogh**
Date EqIA was signed: **16 December 2010**