EXPLANATORY MEMORANDUM TO

THE MEDICINES (PHARMACIES) (APPLICATIONS FOR REGISTRATION AND FEES) AMENDMENT No. 2 REGULATIONS 2009

2009 No. 3071

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument increases the fees payable to the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society of Northern Ireland (PSNI) relating to the registration of pharmacy premises from 1st January 2010.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative Context

4.1 The Registrars of the Societies are required by section 75 of the Medicines Act 1968 to keep registers of pharmacy businesses carrying on the retail sale (or supply in circumstances corresponding to retail sale) of medicinal products. By virtue of section 75(2) of that Act, applications for registration have to be made in the prescribed manner, and by virtue of section 75(1) entries will only be made in the register on payment of the prescribed fee.

4.2 The prescribed fees are set out in The Medicines (Pharmacies)(Applications for Registration and Fees) Regulations 1973 (S.I. 1973/1822). The prescribed fees are for initial registration, an annual fee for retention and a penalty fee for late payment of the retention fee and restoration to the register. The fees payable in Great Britain have been £529, £168 and £529, respectively and in Northern Ireland are £102, £142 and £295 respectively. These fees were last uprated as from 1 January 2009 in Great Britain and 1 January 2008 in Northern Ireland.

4.3 As regards the premises fees paid to the RPSGB, they fund the majority of the cost of the RPSGB's Inspectorate, the maintenance of the premises register and related disciplinary activity. The fees charged are monitored and reviewed annually to reflect as far as possible the activities which they fund. Most of the premises fee income derives from the annual retention fee which is the annual fee paid by pharmacies which are already entered on the register. In the spring of 2010 it is planned that the RPSGB's responsibility for the regulation of pharmacists, pharmacy technicians and pharmacy premises will transfer to the new regulator the General Pharmaceutical Council (GPhC).

4.4 As regards the premises fees paid to the PSNI, they are designed to cover costs associated with the maintenance of the premises register and related disciplinary activity as well as inspection activity. The fees are paid to the Department of Health, Social Services and Public Safety (The Department) and the Department allocates a proportion of the monies received, to the PSNI in accordance with legislation.

5. Territorial Extent and Application

5.1 This instrument applies to the United Kingdom.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

7.1 Under the Medicines Act 1968, although registration of pharmacy premises is a matter for the RPSGB in Great Britain and the PSNI in Northern Ireland it is for Ministers to make the regulations setting the fees payable for registration of pharmacy premises.

Great Britain

7.2 In preparation for establishing the new regulator, the GPhC, to take over the regulatory role currently undertaken by the RPSGB, the Department of Health commissioned a review of the income which the GPhC will require in its first calendar year, all of which will be derived from registration fees. Looking at the level of fees required to generate the income needed by the GPhC and taking into account that:

- during 2010, the regulatory role will be undertaken by the RPSGB until the GPhC is established in law and running two organisations is inherently more costly; and
- the regulator will need to cover costs which are currently covered by direct payments from Government such as the inspections undertaken around controlled drugs,

an increase across all fees of around 2.2% was recommended. For the retention fee for the registration of pharmacy premises this worked out as an increase £4 taking the fee to £172.

7.3 The RPSGB, as the current regulator, proposed a rise in the retention fee of £7 to £175. In seeking this 4.17% increase to the retention fee for 2010, the RPSGB contends that the draft Pharmacy Order 2009 will give the GPhC new powers to set standards to ensure entry and retention on the Register of only those pharmacies that are fit for purpose. It also provides the GPhC with additional sanctions in relation to pharmacy premises to assist with compliance. RPSGB argues that these changes will lead to increased costs for the regulator.

Northern Ireland

7.4 The Department of Health, Social Services and Public Safety calculated the proposed fees to be charged from 1 January 2010 taking into account:

- The existing fee structure as the baseline level
- The fact there was no increase in 2009
- additional regulatory requirements
- the current fee structure in Great Britain
- the desirability of consistency of approach between Northern Ireland and Great Britain given that a significant number of pharmacies in Northern Ireland are part of UK-wide chains and are subject to comparative controls.

8. Consultation outcome

Great Britain

8.1 The consultation took place between 7th August and 30th October 2009. In total, 9 responses were received by the closing date covering 12 individuals and organisations. All responses were reviewed as part of the consultation process. The respondents represented a mix of pharmacy bodies/organisations and healthcare professionals in the field of pharmacy.
The consultation response is available on the Department of Health website at:
http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_108885

8.2 8 respondents were of the opinion that fees should not be increased in 2010. 3 advocated an increase but were not specific as to the level of fees to be charged and one respondent said that while the proposed increase did not appear excessive they did not have the knowledge and experience to judge whether the increase was fair or reasonable.

8.3 The Department of Health took the view that, although the majority of respondents were in favour of no increase in the premises registration fee in 2010, it was necessary to ensure that the new regulator for pharmacy was adequately funded in its initial operation. This would give the new management team the opportunity to develop the regulator's financial model. Ministers therefore agreed to an increase of 2.2% to the fees for the registration of pharmacy premises. The new fees will be payable to the RPSGB from 1st January 2010, with an agreed proportion being transferred to fund the GPhC when it is established which, subject to Parliamentary process, agreement and time, is expected to be in spring 2010.

Northern Ireland

8.4 The consultation took place between 1st September and 6th November 2009. In total, 10 responses were received by the closing date, covering individuals and pharmacy organisations. All responses were reviewed and given due attention as part of the consultation process. The respondents represented a mix of pharmacists and pharmacy organisations.

8.5 6 respondents were of the opinion that the proposed increases were too high and should not come into effect in 2010. 3 respondents thought that in setting the proposed fees, Northern Ireland should not be using a comparison with Great Britain, and one respondent appreciated that increases were not made for 2009 and the fees were not unreasonable.

8.6 Given the opposition to the proposed increases and recognition of the current financial climate in which the fees would apply, the Department decided to revise its fee proposals and apply a 5-6% increase across the board. A more detailed examination of premises fees will be under taken in advance of any revisions in 2010.

9. Guidance

9.1 Guidance is not required.

10. Impact

Great Britain

10.1 The impact on business is minimal in terms of its monetary implications. There is no impact on charities or voluntary bodies. This and the more general impact issues are discussed in the attached Impact Assessment.

10.2 The impact on the public sector is minimal in terms of its monetary implications. The impact issues for the public sector are also explained in the Impact Assessment.

Northern Ireland

10.3 The Department carried out an equality impact assessment during the last review of the criteria. The changes proposed under this review have been screened for the purposes of the Section 75 equality duty and as a result of that screening exercise, the Department has concluded that an equality impact assessment of these proposals is not required.

11. Regulating small business

11.1 The legislation applies to small business. The fee for registration of a premise is a flat annual fee and impacts on all pharmacies. The absolute level of the fee is small in relation to the running costs of a pharmacy business. The interests of small independent pharmacies are represented by the National Pharmacy Association. In responding to the consultation on the fees to be charged in Great Britain they have voiced the same reservations on the need for an increase in 2010 as the organisations representing the chains of pharmacies.

12. Monitoring & review

Great Britain

12.1 Subject to Parliamentary timetable and process, the Pharmacy Order 2009, when it comes into force, will deliver a new regulatory body for pharmacists, pharmacy technicians and pharmacy premises, the General Pharmaceutical Council, in spring 2010. Responsibility for the fee structure and the level of fees payable for both personal registrants and registered pharmacy premises will rest with the GPhC. The GPhC is expected to develop its own methodology of assessment and inspections in line with the Hampton Principles of Better Regulation.

Northern Ireland

12.2 Advice on this matter will be sought from the Departmental Solicitors as to the correct procedures to take to implement the premises fees for Northern Ireland.

13. Contact

Diana Kenworthy at the Department of Health Tel: 020 7972 2820 or email: diana.kenworthy@dh.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency:	Title:	
DH	Impact Assessment of Fees for the Registration of Pharmacy Premises	
Stage Final	**Version:** 1	**Date:** November 2009
Related Publications:		

Available to view or download at:

http://www.

Contact for enquiries: Diana Kenworthy **Telephone:** 020 7972 2820

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

Under the Medicines Act 1968, pharmacy premises in Great Britain must be registered with the Royal Pharmaceutical Society of Great Britain (RPSGB). Fees payable by pharmacy owners to the RPSGB for the registration of pharmacy premises are set by Ministers through regulations under the Medicines Act 1968. There are three categories of fees: registration, retention and restoration. These fees are reviewed annually to reflect the cost of registration of pharmacy premises.

What are the policy objectives and the intended effects?

The RPSGB has sought an increase in the pharmacy premises registration fees, from 1 January 2010, to ensure they meet the costs incurred by the Society for maintaining their activity. These fees fund the majority of the cost of RPSGB's Inspectorate, the maintenance of the premises register and related disciplinary activity. The objective of this policy is therefore to ensure that these activities are adequately funded, and to avoid any reduction in the quality and quantity of inspections – which could lead to the risk that the quality of services provided by registered pharmacies may fall.

What policy options have been considered? Please justify any preferred option.

Option 1: No change in existing policy (no increase in fees).

Option 2: Increase pharmacy registration fees

As described above, increasing registration fees will ensure that registered pharmacies continue to be appropriately inspected and managed, and will ensure maintenance of pharmacy service quality.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

Subject to the successful passage of the draft Pharmacy Order 2009, this will be the last year in which such fees will be agreed under this procedure

Ministerial Sign-off For Final Impact Assessment:

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:

Mike O'Brien.....Date: ***12/11/2009***

Summary: Analysis & Evidence

Policy Option: 2	Description: Increase pharmacy fees

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups'
One-off (Transition)	**Yrs**	Pharmacies will pay increased fees.
£ 0	0	
Average Annual Cost (excluding one-off)		
£ 33k	1	**Total Cost** (PV) **£ 33k**

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

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups'
One-off	**Yrs**	None monetised
£ 0	0	
Average Annual Benefit (excluding one-off)		
£ 0	1	**Total Benefit** (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups' Maintaining of the real value of fees should enable the RPSGB to continue with its current inspection work, supporting the provision of better health care and hence better health to the UK population.

Key Assumptions/Sensitivities/Risks

Price Base Year 2009	Time Period Years 1	**Net Benefit Range** (NPV) £	**NET BENEFIT** (NPV Best estimate) **£ -57k**

What is the geographic coverage of the policy/option?				GB
On what date will the policy be implemented?				01/01/2010
Which organisation(s) will enforce the policy?				RPSGB
What is the total annual cost of enforcement for these organisations?				£ NA
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ NA
What is the value of changes in greenhouse gas emissions?				£ NA
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro	Small	Medium	Large
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ None Decrease of £ None **Net Impact** £ None

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

1. Background

Under the Medicines Act 1968, registration of pharmacy premises is a matter, in Great Britain, for the Royal Pharmaceutical Society of Great Britain (RPSGB). It is for Ministers to make regulations setting fees payable to the RPSGB after consultation required by S129(6) of the Act. The premises fees fund the majority of the cost of the Society's inspectorate, the maintenance of the premises register and related disciplinary activities.

The future regulation of pharmacists, pharmacy technicians and pharmacy premises will transfer to the General Pharmaceutical Council (GPhC) in the spring of 2010, subject to the Parliamentary timetables and processes. Until then the RPSGB will continue to be responsible for the regulation of the pharmacy profession and, it is expected, it will emerge as the foundation of a future professional body, working closely with the new regulator on behalf of the profession.

2. Introduction

Pharmacy owners pay fees to the RPSGB under three different headings: registration fees, retention fees and restoration fees. These are fees to cover RPSGB's activities in relation to the initial registration of pharmacy premises (registration fee), inspection of the premises (retention fee) and imposing any penalty fees for late payment (restoration fee). This impact assessment focuses on the retention fee, which is by far the largest component of the fees (the predicted number of pharmacies paying the retention fee in 2010 is circa 12,500), while the other fees are paid relatively infrequently (the predicted number paying either the registration or restoration Fee in 2010 is circa 500).[1]

The registration fee of £529 (for 2009) is payable on the registration of a new pharmacy. This is compulsory for pharmacies wishing to open in Great Britain. The retention fee of £168 per annum (for 2009) is paid for continued registration of pharmacy premises and is paid by pharmacies that wish to continue to operate in Great Britain. The restoration fee is chargeable to pharmacies that do not renew their registration with the RPSGB within a given deadline. This is £529 for 2009.

A breakdown of costs and income for the RPSGB is provided below. It shows the actual costs incurred in 2008, forecasted costs for 2009 and a projection of costs for 2010. It illustrates that the majority of costs borne by the RPSGB are persistently employee costs.

	2008 Actual £'000's	2009 Forecast £'000's	**2010 Projection £'000's**
Premises Retention Fee Income	(2,071)	(2,141)	(2,184)
Premises Registration Fee	(271)	(260)	(266)
Miscellaneous Income	(59)	(47)	(42)
Employee Costs	2,263	2,306	2,353
Property & Office Costs	83	60	61

[1] Figures provided by the RPSGB.

Professional costs	428	384	391
Finance, MIS & others costs	169	103	105
Society Overhead	737	688	702
Occupancy Charge	29	49	50
Recharge to inspection	0	0	
Total Costs:	**3,709**	**3,590**	**3,662**
Surplus / (deficit)	**(1,308)**	**(1,142)**	**(1,165)**

The proposed increase in the level of restoration and registration fees is 2.2%, increasing the fee from £529 to £541 for 2010 in both cases. Assuming that the number of pharmacies joining the register will be 500, this will amount to a total increase in fees from this source of £6,000.

Pharmacies	500
Current Charge	£529
increase in charge	2.2%
	£12
total increase in revenue	£6,000

The total income that would be gained from charging the new level of registration and restoration fees would be £270,000, assuming that 500 pharmacies are charged these fees.

Since the change in the income from a 2.2% increase to the registration and restoration fees is £6,000 it is small in comparison with the changes in the value of the retention fee. Hence, the Impact Assessment concentrates on the retention fee increase.

The establishment of the GPhC

In preparation for establishing the new regulator for pharmacy and pharmacy premises, the GPhC, to take over the regulatory role currently undertaken by the RPSGB, the Department of Health commissioned a review of the income which the GPhC would require in its first calendar year. This income will be derived from registration fees. Looking at the level of fees required to generate the income needed by the GPhC and taking into account that

- during 2010 the regulatory function will be undertaken by the RPSGB until the GPhC is established in law and running two organisations is inherently more costly
- the regulator will need to cover costs which are currently covered by direct payments from Government such as the inspections undertaken around controlled drugs

an increase across all fees of around 2.2% was recommended. For the retention fee for the registration of pharmacy premises this worked out as an increase £4 taking the fee to £172.

Until the GPhC is established the RPSGB remains the regulator for the pharmacy profession and pharmacy premises. 2010 will be the year of transition. It will be for the RPSGB to collect the income from fees for 2010 and then pass to the GPhC a proportion of the regulatory fee income, based on the point in the year at which the GPhC assumes responsibility for regulation.

Ministers set up the Pharmacy Professional Regulation and Leadership Oversight Group (PRLOG) to oversee the change of regulatory functions to the GPhC, including consideration of the financial aspects. Consideration of the activities and costs in relation to premises registration and the inspectorate was included in PRLOG's work programme and advice was prepared for and endorsed by PRLOG relating to both the level of fees for regulatory activities and a basis for the apportionment of fee income between the GPhC and the RPSGB in 2010

The RPSGB's proposal

The RPSGB has proposed a rise in the retention fee of £7 to £175. In seeking this 4.17% increase to the retention fee for 2010 the RPSGB contends that the draft Pharmacy Order 2009 gives the GPhC the new power to set standards in Rules to ensure entry and retention on the Register of only those pharmacies that are fit for purpose. It also provides the GPhC with additional sanctions in relation to pharmacy premises to assist with compliance. RPSGB argues that these changes will lead to increased costs for the regulator.

The RPSGB is concerned that both the GPhC and the new professional leadership body are financially sustainable. They also argue for fair distribution of the costs of regulation between the individuals who are regulated and the owners of premises that are registered with and regulated. In 2008 the RPSGB implemented a substantial increase (39.6% to £395) in its retention fee for pharmacists, in preparation for the future and the move away from its publishing activities contributing to the support of regulation and professional leadership activities. The RPSGB has agreed an increase in its fees for individual registrants for 2010 taking the pharmacists retention fee from £413 to £422 and for pharmacy technicians from £135 to £138. The RPSGB contends that under recovery of costs for pharmacy premises results in a larger fee for individual registrants, both pharmacists and pharmacy technicians.

Last year the RPSGB argued for the premises retention fee to be raised sufficiently to cover actual increases in pension and fuel costs. From 1 January 2009 that would have set the fee at £175 plus a further increase to cover anticipated inflation. However the economic situation has now changed and inflation has declined. As a result of efficiency gains and improved use of space in the building the overall full economic recovery of costs allocated to the premises fee has fallen by £11 between 2008 and 2009. It has consistently been argued by RPSGB that the premises fee should be set on a full economic cost recovery basis. On the RPSGB's figures in 2008 the premises fees income was insufficient to cover the cost of maintaining the inspectorate let alone the recovery of the associated regulatory activities.

Although it is a time of economic uncertainty, there are a number of potential threats to public health which, the RPSGB argues, make it imperative that the regulation of pharmacists, pharmacy technicians and pharmacy premises must still be pursued for the protection of patients and the public. In this year of transition to the GPhC, the RPSGB was not seeking to try and balance the premises fees with those paid by individual pharmacists, but to increase the premises retention fee to £175 (4.1%), to reflect the increase in cost referred to above, and for the registration and restoration fee for premises to be increased by 2.2%.

The GPhC, when formed, will develop its own its own methodology of assessment and inspections in line with the Hampton Principles of Better Regulation.

3. Outcome of the consultation

The consultation took place between 7th August and 30th October 2009. In total, 9 responses were received by the closing date covering 12 individuals and organisations. All responses were reviewed as part of the consultation process. The respondents represented a mix of pharmacy bodies/organisations and healthcare professionals in the field of pharmacy.

Eight respondents were of the opinion that fees should not be increased in 2010. Three advocated an increase but were not specific as to the level of fees to be charged and one respondent said that while the proposed increase did not appear excessive they did not have the knowledge and experience to judge whether the increase was fair or reasonable.

The Department of Health took the view that, although the majority of respondents were in favour of no increase in the premises registration fee in 2010, it was necessary to ensure that the new regulator for pharmacy was adequately funded in its initial operation. This would give the new management team the opportunity to develop the regulator's financial model, Ministers therefore agreed to an increase of 2.2% to the fees for the registration of pharmacy premises. The new fees will be payable to the RPSGB from 1 January 2010, with an agreed proportion being transferred to fund the GPhC when it is established which, subject to Parliamentary process, agreement and time, is expected to be in spring 2010.

4. Options considered

Option 1: Do nothing
Options 2: Increase pharmacy registration fees; the preferred option.

5. Analysis of Costs

Option 1: Do nothing

With no increase in the level of pharmacy fees, the funding of the RPSGB / GPhC will fall in real terms.

The 2009 charges, and resulting fees for the RPSGB / GPhC are as follows:

Item	2009 fee, £	2009 fees paid, £000s
Retention fee	168	2,141
Initial registration fee	529	260
Penalty (restoration fee)	529	-
Total fees		2,401

As this is the base-case for analysis, this outcome is considered to correspond with no change in costs.

Options 2: **the preferred option.** Increase pharmacy registration fees

Increasing pharmacy registration fees will result in greater costs for pharmacies.

It is proposed to increase retention fees by £4, to £172, and registration fees by £12 to £541 (ie 2.2% as for the individual registrant fees.)

The following table shows these changes, along with the forecast change in total fees paid as a result. These have simply been calculated by up-lifting the 2009 totals by the proportionate rise in the fee levels.

Item	2009 fee, £	2010 fees paid, £000s	Proposed 2010 fees, £	Forecast 2010 fees paid, £000s
Retention fee	168	2,141	172	2,192
Initial registration fee	529	260	541	266
Total fees		2,401		2,458
Cash increase in fees paid				57
Real terms increase in fees paid, after adjustment for 1% inflation in 2010				33

It can be seen that, after adjustment for expected inflation of 1% in 2010, the forecast fees paid are estimated to rise in real terms by £33,000.

6. Analysis of Benefits

Option 1: This is the baseline case. Although not costing pharmacies any extra money, this would result in the real terms fall in fees and could lead to a reduction in the frequency of inspections carried out by the RPSGB due to actions to cut costs. There could also be a reduction in the quality of inspections carried out. This in turn could affect the quality of service provided by the pharmacies to the public, to the potential detriment of the health of the population.

Options 2: the preferred option. Increasing pharmacy fees would maintain real income for the RPSGB, and enable them to continue assuring the quality of pharmacy services.

These benefits have not yet monetised.

7. Specific Impact Tests

Competition impact assessment

The proposal to increase Premises Registration Fees will impact chiefly on retail pharmacies. These make up the majority of pharmacies, which are registered with the RPSGB, although a small number of hospital pharmacies and pharmacies belonging to pharmacy manufacturers are also registered. The competition filter was applied and did not indicate a detailed competition assessment was required.

The policy that a fee will be paid for the initial registration of a pharmacy premise and an annual fee for retention on the register, thereafter, has been long established. The Regulations which will come into effect on 1 January 2010 will set the level of the fees to be charged in 2010. The recommended increase in the annual retention fee will have a marginally greater impact on smaller pharmacies, which may be part of a chain or a single unit, as it will represent a slightly larger proportion of their costs than for larger pharmacies.

An increase in the initial registration fee when compared to the costs of establishing a new pharmacy, is unlikely to be a barrier to entry. As such, it is not expected that it will impact on the ability of new pharmacies to enter the market nor are the combined fee increases expected to change the structure of the market. As such, we do not expect the proposal to have a significant effect on competition.

No competition assessment was deemed to be necessary as the proposal for an increase in the existing fees does not directly or indirectly limit the number or range of suppliers of pharmaceutical services. Nor does the increased fee limit the ability of pharmacies to compete or reduce suppliers' incentives to compete vigorously.

Small firms impact assessment

Small businesses, defined as independent community pharmacies and chains with five or fewer pharmacies (Source: The Information Centre), are important to the supply of pharmaceutical

services in Great Britain. By March 2006 small businesses accounted for around 43% of all contractors in England and Wales. This represents a substantial decrease from two-thirds in 1991, resulting from a trend towards greater market concentration with take-overs and mergers, the entry of new low cost retailers and the expansion of supermarket pharmacies. This trend is likely to continue. By 2011 it is expected that around two thirds of pharmacies will be part of chains of six outlets or more.

The increase in the premises fee will affect all pharmacy premises. The fee for registration of a premise is a flat annual fee and impacts on all pharmacies. The absolute level of the fee is small in relation to the running costs of a pharmacy business. The interests of small independent pharmacies are represented by the National Pharmacy Association. In responding to the RPSGB's proposed fee levels for 2009, they voiced the same reservations on the amount of the increase as the organisations representing the chains of pharmacies.

Health Impact assessment

The increase to the premises registration fees has been screened for their impact on the wider determinants of health such as transport, housing, employment and lifestyle, as well as the demand it could cause on the health and social care services. The changes are not believed to have a significant impact on transport and the environment.

However if the RPSGB is not adequately resourced for the work that it undertakes, there could be a risk to human health in the longer term. If a proposal is agreed which falls short of the RPSGB's proposed level of increase, the Society will need to make efficiency savings or look to other income streams to address the shortfall in its proposed 2010 premises fee income., However the latter will not be an option for the GPhC.

The answer to the specific questions on health impact assessment is 'No' in all cases:

- Will your policy (increase in pharmacy premises registration fees) 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)

- Will your policy (increase in pharmacy premises registration fees) have a 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). Consider risk factors that influence the probability of an individual becoming more or less healthy.

- Will your policy (increase in pharmacy premises registration fees) cause 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 attendances, Social services, Health protection and preparedness response. Consider the likely contacts with health and social service provision.

Rural proofing

No issues affecting access to services in rural communities have been identified and this has not been an issue raised by pharmacy organisations in the past.

Economic impact

In addition to the economic impact elements identified in the Competition Assessment, larger companies may better absorb the increase in the premises registration fee, but in view of the low increases proposed this will not be a significant factor.

Equality impact assessment

Equality impact screening and report is attached as Appendix A to this document. No comments were received during the consultation relating to the areas covered in the equality impact assessment so this remains unchanged following the consultation.

8. Enforcement and monitoring

Those pharmacies which do not pay the increased fee would be removed from the register of pharmacy premises. This sanction would be exercised initially by the RPSGB, and, from spring 2010, by the GPhC. Medicines may only be supplied to the public from registered pharmacies, except for medicines on the General Sale List. No additional monitoring is required.

9. Implementation and delivery plan

These proposals will be implemented through an amendment to the Medicines (Pharmacies) (Applications for Registration and Fees) Regulations 1973. The RPSGB will then invoice all registered premises to collect the retention fee, which is due in January 2010. Fees for initial registration are collected when new premises enter the register and will be collected by the RPSGB or GPhC depending on the time of registration.

10. Post implementation review

The level of the fees for pharmacy premises registration has been reviewed each year by the RPSGB as part of its business planning. With the transfer of responsibility for regulation passing to the GPhC the fee structure and level of fees to be charged will become the responsibility of the GPhC in the future.

11. Review of Regulatory Impact Assessment

The Impact Assessment has been reviewed following public consultation and the analysis of the responses.

12. Summary and Recommendations

The preferred option Is Option 2, to increase the fees for the registration of pharmacy premises by 2.2%. This is based on the analysis, undertaken on behalf of and endorsed by the PRLOG.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	No	No
Sustainable Development	No	No
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	Yes	No

Annexes

APPENDIX A – EQUALITY IMPACT ASSESSMENT

The Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 2009

The Royal Pharmaceutical Society of Great Britain (RPSGB) is, currently, both the regulatory and professional body for pharmacists. Under the Medicines Act 1968, registration of pharmacy premises is also a matter, in Great Britain, for the RPSGB. However, it is for Ministers to make regulations setting fees payable to the RPSGB.

The pharmacy premises registration fees are monitored and reviewed annually to reflect, as far as possible, the cost of the activities which they fund. The pharmacy premises fee is levied on each registered pharmacy premise and is the same for each premise which is registered. It is paid only once in each year. There are no additional charges payable to the RPSGB for individual inspections, nor for the advice and assistance provided by the RPSGB pharmacy inspectors. Medicines may only be supplied to the public from registered pharmacies, except for those medicines which are on the General Sale List. The premises fees fund a proportion of the cost of the Society's inspectorate, the maintenance of the premises register and related disciplinary activities.

Disability impact assessment

The RPSGB started collecting disability data in March 2007 when all new pharmacists were asked to provide information, on the point of registration, in relation to disability. To date no pharmacist who has registered since March 2007 has declared a disability to the RPSGB.

It is a requirement that community pharmacy contractors, in fulfilling their responsibility to provide a range of essential services under the current contractual framework, comply with the requirements of the Disability Discrimination Act 1995. This includes ensuring the public can readily access pharmacy premises as well as a requirement that pharmacists assess and provide compliance support needed by those patients who fall within the protection of the Act and who have a need for assistance in taking their medicines.

Pharmacy contractors as service providers therefore have a duty to make reasonable adjustments to enable someone with a disability to utilise the service. Reasonable adjustment may include the provision of an auxiliary or compliance aid to enable a person, who is disabled, to take their medicines. In determining what is reasonable, consideration needs to be given to the individual circumstances of the patient and the pharmacy, and a judgement made by the service provider, the pharmacy. As such, it is not appropriate to determine and specify the nature of “reasonable adjustment” nationally, nor to set out different types of intervention and associated payments. Instead, the Department has made specific funding available within the overall contractual settlement (£2.2bn in 2008/09) as a contribution to contractors meeting the requirements of the Act. An increase in the pharmacy premises registration fees is not expected to have a negative or a positive impact on disability issues relating to pharmacy.

Race Equality impact assessment

From the registration data held by the Royal Pharmaceutical Society of Great Britain (RPSGB) in 2008, a greater proportion of pharmacists are from black and ethnic minority backgrounds (30%) than for the general population as a whole (9%), (drawing on 2001 Population and Census data). 20% are Asian, 4% Chinese, 4% black and 2% other or mixed race with 70%

white. As a greater proportion of pharmacists are from ethnic minority backgrounds than is the case in the general population overall, pharmacists are well placed to meet the needs of this section of the community.

The Department does not believe an increase in the premises registration fee will affect any of the three parts of the race equality duty i.e. to eliminate unlawful racial discrimination; to promote equal opportunities or to promote good relations between people from different racial groups.

Gender impact assessment
Women are well represented in the pharmacy workforce. According to the RPSGB's register, in 2008, there were 48,794 pharmacists registered in Great Britain, of whom 57% are women. The number of community pharmacists in England is estimated at 22,000. The proportion of female pharmacists working in the community sector is similar to the proportion of female pharmacists on the register as a whole. Information on the number of transgender pharmacists is not reported.

The Department does not consider an increase in the premises registration fee would have any impact on contractors owned or run by women. Nor does the Department consider this measure will impact on the availability of contractor services to those users who are women.

Age impact assessment
Over two-thirds of pharmacists in the 2008 register of the RPSGB were aged 49 or less. A higher proportion of female pharmacists is in the younger age groups.

Older people are more likely to be regular users of pharmaceutical services. A study conducted for the Office of Fair Trading in 2002 found that 22% of the sample of 1,434 households who had pharmacies make their prescriptions up were aged between 60 and 70, and 17% were over the age of 70, compared with 10% and 11% of the UK population generally.

No factors have been identified arising from an increase in the pharmacy premises registration fees which impact on pharmacists in any particular age range. Nor will an increase in the registration fee affect the pharmacy services available to users of the pharmacy service in any particular age range.

Sexual orientation
The RPSGB began collecting data in March 2007 when all new pharmacists were asked to provide information, on the point of registration, in relation to sexual orientation as well as disability. Information from this source is therefore relatively new and will be built up over time. An increase in the fee for the registration of pharmacy premises will not impact differently on pharmacists of a particular sexual orientation.

Religion or belief
Religion or belief of pharmacists is not recorded and there is no anecdotal evidence to suggest an increase in the fee for the registration of a pharmacy premises will have an effect related to religion or belief.

An increase in the pharmacy premises registration fee is unlikely to result in an adverse impact on pharmacists, pharmacy services or users of pharmacies, but positive impact is also unlikely. As no negative impacts across the equality strands have been identified a full impact assessment is not required.

Sign-off for Equality Impact Assessments:

I have read the Equality Impact Screening Assessment and am satisfied that given the evidence available it represents a true statement of the likely impact.

Signed by the senior responsible officer:



Date: 29 July 2009