

**EXPLANATORY MEMORANDUM TO
THE MEDICINES (PHARMACIES) (APPLICATIONS FOR REGISTRATION AND FEES)
AMENDMENT REGULATIONS 2008**

2008 No. [2946]

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

This memorandum contains information for the Joint Committee on Statutory Instruments.

2. **Description**

- 2.1 This instrument increases the fees payable to the Royal Pharmaceutical Society of Great Britain (RPSGB) for the registration of pharmacy premises from 1 January 2009.

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

- 3.1 The premises fees 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.

- 3.2 Most of the RPSGB's premises fee income is derived from an annual retention fee payable by existing pharmacies. These fund the main operating costs of the RPSGB Inspectorate relating to staff wages and associated costs, which rise ahead of the GDP Deflator of 3% forecast for 2009. An increase in the retention fee is being allowed, which reflects the growth in average earnings in the year to August 2007 of 3.7%, so the RPSGB can maintain its inspection activity. This increases the retention fee by £6 from £162 to £168.

- 3.3 The levels of the initial registration fee and the restoration fee were examined in detail 4 years ago and were set at a level, which reflected the cost of two days of an inspector's time. An increase in line with salary inflation of 3.7% will increase these fees by £19 from £510 to £529. The registration and restoration fees are not levied frequently. The initial registration fee is payable only when a new pharmacy is entered in the register. Collectively, the revised premises fees are seen as providing the RPSGB with a reasonable income to fulfil its quality assurance functions, while limiting the rise payable by pharmacies. The RPSGB may need to make some efficiency savings to meet the predicted shortfall in income.

4. **Legislative Background**

- 4.1 This instrument increases the fees payable for the registration of pharmacy premises where the premises are in Great Britain from 1st January 2009, by amending the Medicines (Pharmacies) (Applications for Registration and Fees) Regulations 1973. The fees charged are for initial registration, an annual fee for retention on the register and a penalty fee for late payment of the retention fee and restoration to the register. The registration system is administered by a registrar appointed by the RPSGB (in accordance with sections 69(3), 75 and 76 of the Medicines Act 1968). The RPSGB also has statutory responsibilities under the Medicines Act 1968 and the Poisons Act 1972 to inspect pharmacy premises.

5. **Territorial Extent and Application**

- 5.1 This instrument applies to Great Britain.

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

Policy

7.1 Under the Medicines Act 1968, registration of pharmacy premises is a matter, in Great Britain, for the RPSGB. However, it is for Ministers to make regulations setting fees payable to the RPSGB. The fees are reviewed annually and updated following consultation with the relevant organisations.

Consultation

7.2 Before making regulations under the Medicines Act 1968, Ministers are obliged by section 129(6) of the Act to consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations. With regards to the RPSGB's proposed changes to the level of pharmacy premises registration fees, the following were consulted: the National Pharmacy Association (NPA), the national body representing all community pharmacy owners, including owners of small businesses; the Pharmaceutical Services Negotiating Committee (PSNC), which represents all pharmacies providing NHS pharmaceutical services in England; the Company Chemists Association (CCA), the organisation representing UK multiple community pharmacies, such as Boots, Lloydspharmacy, and Asda among others; the Association of Independent Multiple Pharmacies (AiMP), which represents private companies owning between 5 and 200 pharmacies; the Co-operative Pharmacy Technical Panel, which looks after the interests of Co-op pharmacies, and the Guild of Healthcare Pharmacists (GHP), part of the health sector of the union Unite, represents over 4,000 pharmacists UK wide employed in hospitals, primary care organisations and other public bodies.

7.3 The Department of Health also consulted the Welsh Assembly Government and the Scottish Government, which in turn sought views from Community Pharmacy Scotland, a body that represents community pharmacies in Scotland.

7.4 RPSGB's proposal for the increase in fees was made to the Department of Health in late August. To meet their timetable to have the increased fees effective from 1 January 2009 the consultation took place over a 6 week period. All but one of those consulted replied.

7.5 The majority of the organisations consulted were opposed to the level of increase in registration fees proposed by the RPSGB. Those opposing were all of the opinion that an increase equivalent to the GDP deflator was appropriate. One organisation supported the RPSGB's proposed fees increase. That organisation opined that any deficit in income for registration and inspection would be made up from the fees paid by individual pharmacists and this would fall disproportionately on the managed sector as many community pharmacists have their fees paid by their employers. A fuller analysis is in the Impact Assessment attached to this memorandum.

7.6 The Department of Health, supported by the Welsh Assembly Government and the Scottish Government, has decided to agree an increase in the fees for the registration of pharmacy premises in line with salary inflation, which meets in part the majority view of those who responded.

Guidance

7.7 Guidance is not required.

8. Impact

8.1 An Impact Assessment is attached to this memorandum.

8.2 The impact on the public sector is minimal as there are only a small number of NHS hospital pharmacies, which choose to register with the RPSGB.

9. Contact

9.1 Mrs D Kenworthy at the Department of Health Tel: 020 7972 2820 or e-mail: Diana.Kenworthy@dh.gsi.gov.uk can answer any queries regarding the instrument.

Summary: Intervention & Options

Department /Agency: DH	Title: Impact Assessment of Fees for the Registration of Pharmacy Premises	
Stage Final	Version: 3	Date: 21 October 2008
Related Publications:		

Available to view or download at:

<http://www.dh.gsi.gov.uk>

Contact for enquiries: Diana Kenworthy

Telephone: 020 792 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. If fees are not updated, then the real value of the fees would fall.

What are the policy objectives and the intended effects?

The RPSGB has sought an increase in the pharmacy premises Registration Fees to ensure they meet the costs incurred by the Society from January 1st 2009 for maintaining this activity. These fees fund the majority of the cost RPSGB's Inspectorate, the maintenance of the premises register and related disciplinary activity. If these activities are not adequately funded, it could result in a reduction in the quality and quantity of inspections, with a risk that the quality of services provided by 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 Retention fee by predicted GDP deflator (3%).

Option 3: Increase Retention fee by Salary Inflation (Average Earnings Index 3.7%).

Option 4: Increase Retention fee to include higher costs plus CPI inflation (4.4%) (total increase of 13%)

Preferred option: Option 3 is the preferred option.

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

Ministerial Sign-off For final stage Impact Assessments:

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:

Phil HopeDate: **8th November 2008**

Summary: Analysis & Evidence

Policy Option: 1	Description: No change in existing policy
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COSTS	ANNUAL COSTS	Description and scale of key monetised costs by 'main affected groups' There are no additional costs to government of this policy option				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">One-off (Transition)</td> <td style="width: 30%; text-align: center;">Yrs</td> </tr> <tr> <td style="background-color: #ffff00;">£ 0</td> <td style="text-align: center;">0</td> </tr> </table>		One-off (Transition)	Yrs	£ 0	0
	One-off (Transition)		Yrs			
	£ 0		0			
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">Average Annual Cost (excluding one-off)</td> </tr> <tr> <td style="background-color: #ffff00;">£ 0</td> </tr> </table>	Average Annual Cost (excluding one-off)	£ 0				
Average Annual Cost (excluding one-off)						
£ 0						
Total Cost (PV)	£ 0					
Other key non-monetised costs by 'main affected groups'						

BENEFITS	ANNUAL BENEFITS	Description and scale of key monetised benefits by 'main affected groups' There are no private benefits of this policy option.				
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 70%;">One-off</td> <td style="width: 30%; text-align: center;">Yrs</td> </tr> <tr> <td style="background-color: #ffff00;">£ 0</td> <td></td> </tr> </table>		One-off	Yrs	£ 0	
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	£ 0					
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Average Annual Benefit (excluding one-off)						
£ 0						
Total Benefit (PV)	£ 0					
Other key non-monetised benefits by 'main affected groups' The reduction in the real value of fee income could limit the number of inspections taking place, as well as on their quality. This could have a detrimental effect on the service provided and hence the health of the population.						

Key Assumptions/Sensitivities/Risks

If charges were not increased, this would result in a fall of fees to pharmacies and fall in fee income to RPSGB, in real terms.

Price Base Year 0	Time Period Years 0	Net Benefit Range (NPV) £ 0	NET BENEFIT (NPV Best estimate) £ 0
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What is the geographic coverage of the policy/option?	GB			
On what date will the policy be implemented?	01/01/09			
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?	N/A			
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 NA	Small NA	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: (Net) Present

Summary: Analysis & Evidence

Policy Option:
2

Description: Increase in the Retention fee by GDP deflator

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups' There are no additional costs to government of this option.
	One-off (Transition)	Yrs	
	£ 0	0	
	Average Annual Cost (excluding one-off)		
	£ 0	0	Total Cost (PV) £ 0
Other key non-monetised costs by 'main affected groups'			

BENEFITS	ANNUAL BENEFITS		Description and scale of key monetised benefits by 'main affected groups' Private sector transfer: additional disbenefit to Pharmacies of £65,000 for 2009 / additional benefit to the RPSGB of £65,000 in 2009 from Pharmacies.
	One-off	Yrs	
	£ 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 2008	Time Period Years 1	Net Benefit Range (NPV) £ 0	NET BENEFIT (NPV Best estimate) £ 0
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What is the geographic coverage of the policy/option?	GB		
On what date will the policy be implemented?	01/01/09		
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?	Yes/No		
Annual cost (£-£) per organisation (excluding one-off)	Micro NA	Small NA	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

Kev: Annual costs and benefits: Constant Prices

Summary: Analysis & Evidence

Policy Option: 3

Description: Increase in the Retention fee b

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'
	One-off (Transition)	Yrs	
	£ 0		There are no additional costs to government with this policy option.
	Average Annual Cost (excluding one-off)		
£ 0		Total Cost (PV) £ 0	
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	
	£ 0		Private sector transfer: additional disbenefit to Pharmacies of £78,000 for 2009 / additional benefit to the RPSGB of £78,000 in 2009 from Pharmacies.
	Average Annual Benefit (excluding one-off)		
£ 0	1	Total Benefit (PV) £ 0	
Other key non-monetised benefits by 'main affected groups' This option maintains the real value of fees and takes into account inflation on the primary cost of the activity, that is salary costs. It should better enable the RPSGB to continue with its current inspection work, helping to provide better health care and hence better health to the UK population.			

Key Assumptions/Sensitivities/Risks

Price Base Year 2008	Time Period Years 1	Net Benefit Range (NPV) £ 0	NET BENEFIT (NPV Best estimate) £ 0
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What is the geographic coverage of the policy/option?	GB		
On what date will the policy be implemented?	01/01/09		
Which organisation(s) will enforce the policy?	RPSGB		
What is the total annual cost of enforcement for these organisations?	£ N/A		
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 NA	Small NA	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	

Kev: Annual costs and benefits: Constant Prices

Summary: Analysis & Evidence

Policy Option: 4

Description: Increase in Retention Fee to include costs, uprated by CPI inflation.

COSTS	ANNUAL COSTS		Description and scale of key monetised costs by 'main affected groups'
	One-off (Transition)	Yrs	
	£ 0		There are no additional costs to government with this policy option.
	Average Annual Cost (excluding one-off)		
£ 0		Total Cost (PV) £ 0	
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	
	£ 0	0	Private sector transfer: additional disbenefit to Pharmacies of £273,000 for 2009 / additional benefit to the RPSGB of £273,000 in 2009 from Pharmacies.
	Average Annual Benefit (excluding one-off)		
£ 0	1	Total Benefit (PV) £ 0	
Other key non-monetised benefits by 'main affected groups' With increased revenue, the RSPGB is better situated to carry out a higher number of inspections. If this produces a higher standard of care, it could potentially result in better health for the population.			

Key Assumptions/Sensitivities/Risks

Price Base Year 0	Time Period Years 1	Net Benefit Range (NPV) £ 0	NET BENEFIT (NPV Best estimate) £ 0
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What is the geographic coverage of the policy/option?	GB		
On what date will the policy be implemented?	01/01/09		
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?	£		
What is the value of changes in greenhouse gas emissions?	£		
Will the proposal have a significant impact on competition?	Yes/No		
Annual cost (£-£) per organisation (excluding one-off)	Micro NA	Small NA	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 £	Decrease of £	Net Impact	£

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

[Use this space (with a recommended maximum of 30 pages) to set out the evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Ensure that the information is organised in such a way as to explain clearly the summary information on the preceding pages of this form.]

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), but 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.

It is planned that the future regulation of Pharmacists and Pharmacy premises will transfer to the General Pharmaceutical Council (GPhC). The Royal Pharmaceutical Society, it is hoped, will emerge as the foundation of a future professional body that will work closely with the new regulator on behalf of the profession.

Introduction

Pharmacists pay fees to the RPSGB under three different headings: restoration fees, retention fees and registration 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 2009 is 13,000), while the other fees are smaller and paid relatively infrequently (the predicted number paying either the Registration or Restoration Fee in 2009 is 500).¹

The Registration Fee of £510 (for 2008) is payable on the registration of a new pharmacy. This is compulsory for pharmacies wishing to open in the UK. The Retention Fee of £162 per annum (for 2008) 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 was £510 for 2008.

A breakdown of costs and income for the RPSGB is provided below. It shows the actual costs incurred in 2007, forecasted costs for 2008 and a projection of costs for 2009. It illustrates that the majority of costs borne by the RPSGB are persistently employee costs.

	2007 Actual £'000's	2008 Forecast £'000's	2009 Projection £'000's
Premises Retention Fee Income	(1,953)	(2,079)	(2,379)
Premises Registration Fee	(280)	(248)	(260)
Miscellaneous Income	(50)	(62)	(62)

¹ The figures come from budgets produced by the RPSGB.

Employee Costs	1,948	2,248	2,564
Property & Office Costs	75	102	95
Professional costs	411	280	290
Finance, MIS & others costs	145	133	143
Society Overhead	516	537	560
Occupancy Charge	21	30	31
Recharge to inspection	0	0	
Total Costs:	3,115	3,330	3,683
Surplus / (deficit)	(833)	(941)	(982)

The proposed increase in the level of Restoration and Registration fees is 3.7%, which is the rate of salary inflation, increasing the fee from £510 to £529 for 2009 in both cases. Assuming that the number of pharmacies joining the RPSGB will be 500, this will amount to a total increase in fees going to the RPSGB from this source of £9,500.

Pharmacies	500
Current Charge	£510
increase in charge	3.7%
	£19
total increase in revenue	£9,500

The total income that the RPSGB would gain from charging the new level of Retention and Registration fee would be £264,500, assuming that 500 pharmacies are charged these fees.

Since the change in the income for the RPSGB is £9,500 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 Minister was asked by the RPSGB to consider a rise in Retention fees with the rate of inflation based on the Consumer Price Index (CPI, 4.4%), along with a further adjustment for exceptional costs incurred through higher pension contributions and fuel costs.

The Society states it has struggled with the challenges of funding their defined benefit pension scheme to which many of the inspectors belong. Mindful of its responsibilities to the future regulator and in particular to retain experienced staff the Society contends that it has sought to keep this scheme open rather than close the scheme, which would have been their financially preferred alternative. However, as a result of the Government's announced intention of establishing the General Pharmaceutical Council, the RPSGB Trustees have felt uncertain of the new regulator's continued involvement in the scheme. The RPSGB maintains that the resultant uncertainty over the future, compels them to impose a contribution schedule which substantially increases costs for 2008 and 2009, effectively doubling their contributions into the scheme. Without some relief for this additional burden the RPSGB maintains it may have to re-evaluate the future of the scheme. It believes that the additional costs of the Pension Scheme should be reflected in the fees for 2009. They have valued the additional pension costs at £164,338. Additional fuel costs of £11,335 have also been claimed. This request is reflected in Option 4.

Options to consider

Option 1: Do nothing

Option 2: Increase the Premises Retention Fee by GDP Deflator

Option 3: Increase the Premises Retention Fee by Salary Inflation (AEI)

Option 4: Increase the Premises Retention Fee by the Consumer Price Index, plus a contribution for increased pension and fuel costs.

Option 4 is based on the proposal put to the Minister by the RPSGB.

The preferred option is Option 3.

COSTS

Option 1: Do nothing

The premises Retention Fee remains at its 2008 level for 2009. With 13,000 Premises registered in 2008 (and with no particular risk for this figure to change significantly), the resulting Premises fee income will be £2,106,000. However, this option does not take into account inflation in the level of costs for the RPSGB. The gap between the costs of pharmacy premises registration and the level of funds received by the RPSGB through the Premises Fees will grow and there could be significant impacts on the number of inspections and on their quality.

Option 2: Increase the Premises Retention Fee by the GDP deflator.

The GDP deflator rate predicts the rate of change in the real value of GDP in the UK economy. Using this inflation index to increase the retention fee would keep the level of income to the RPSGB constant in relation to the growth of GDP in the UK economy. The Treasury has forecasted that GDP deflator will be 3% for 2009. (http://62.164.176.164/data_gdp_fig.htm)

Premises Fees Revenue 2008	£2,106,000
plus GDP Deflator (3%)	£2,169,180
Number of Pharmacies	13,000
2009 fee	£167
increase in fee	£5
percentage increase in fee	3%

The 2008 Premises Fees Revenue is calculated from the fee receipts from 2008. It is the number of pharmacies (13,000) paying the 2008 fee that was set at £162. This figure is then inflated by the predicted GDP deflator for 2008/9, set at 3% by HMT. The 2009 fee is then calculated by dividing the inflated revenue by the number of pharmacies that would be paying the fee. Under this option, the 2009 fee would be £167, an increase of £5. The percentage increase in the fee is 3%.

The total increase in the amount of money being paid to the RPSGB by the Pharmacies would be the increase in the fees (£5) multiplied by the number of Pharmacies who would be paying the new charge (13,000) equalling £65,000.

In the first year, the increase in the transfer of cash from Pharmacies to the RPSGB will be £65,000. Since this is a direct transfer of money from Pharmacies to the RPSGB, there is no monetary cost to the economy as a whole.

Option 3: Increase in the Premises Retention Fee by salary inflation

As shown by the breakdown of costs (see above) the majority of costs incurred by the RPSGB comes in the form of salaries paid to staff. Hence, the appropriate index to uprate fees is the Average Earnings Index compiled by the Office for National Statistics. The Average Earnings Index measures the rate of growth of salaries, giving a salary inflation rate. Since the majority of RPSGB costs incurred are through salaries, it gives a tailored figure to maintain the real level

of income to the RPSGB. Taking an average figure for January to August 2008, this calculates to 3.7%. (<http://www.statistics.gov.uk/STATBASE/Product.asp?vlnk=9537>)

Premises Fees Revenue 2008	£2,106,000
plus AEI inflation, 3.7%	£2,183,922
Number of Pharmacies	13,000
2009 fee	£168
increase in fee	£6
percentage increase in fee	3.7%

The Premises Fees revenue for 2008 is calculated from the 2008 fee multiplied by the number of pharmacies who paid the fee to the RPSGB. This is inflated by the Average Earnings Index, a measure of salary inflation, calculated by the Office for National Statistics. This is the revenue the RPSGB could receive from Pharmacies in 2009 in order to maintain the real income of the RPSGB. To calculate the fee each pharmacy should pay, the total revenue figure is then divided by the number of pharmacies who will be charged. This leads to a fee of £168 per pharmacy, an increase of £6 for each pharmacy to pay. The percentage increase in the fee for the pharmacy is 3.7%.

The total increase in the fees that the pharmacies will be paying in the first year is £6 (the increase for each pharmacy) multiplied by 13,000 (the number of pharmacies) which equals £78,000.

Option 4: Increase the Premises Retention Fee to account for both the increase in Pension and Fuel costs. This would then be uprated by the Consumer Prices Index (CPI) inflation figure of 4.4% (as at July 2008). The CPI is a measure of inflation for across the economy, based on the price increases of a selection of goods bought by the public and as such does not reflect the costs incurred by the RPSGB.

Fee Income for 2008	£2,106,000
Plus additional Fuel costs	£11,335
Plus Pension Costs	£164,338
Total fee requested	£2,281,673
plus CPI inflation (4.4%)	£2,382,067
Number of Pharmacies	13,000
2009 fee	£183
increase in fee	£21
percentage increase in fee	13%

The Fee income for 2008 is calculated from the number of pharmacies paying the 2008 fee (13,000*£162). This has increased pension and fuel costs added to it and is then inflated using the CPI figure for inflation (4.4%) as requested by the RPSGB. This is the revenue that the RPSGB requested for 2009 from Pharmacies in order to cover higher fuel and pension costs plus inflation of other costs. This figure, divided by the 13,000 Pharmacies, gives the fee for 2009 as £183. This is an increase of £21 or 13%.

The total increase in revenue for the RPSGB would be £21 (fee increase) multiplied by 13,000 (the number of pharmacies). This gives an increased revenue figure of £273,000. Although this is an increase in fees, it is neither a cost nor a benefit since fees pay for a service that the pharmacies will receive. As such, it is a transfer of wealth between Pharmacies and the RPSGB.

BENEFITS

Option 1: This is the baseline case. Although not costing pharmacies any extra money, and would result in the real terms fall in fees, this could result in a reduction in the frequency of inspections carried out by the RPSGB due to measurements 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.

Option 2: Uprating the fees by the GDP deflator would increase the income for the RPSGB and would maintain the real income for the RPSGB in line with the growth in the UK economy.

Option 3: Uprating the fees by the increase in salary costs would increase the income for the RPSGB and would maintain the real income for the RPSGB in line with the growth in salaries. As real income is maintained, standards of inspection would be maintained on account of costs.

Option 4: Taking account of increased pensions and fuel costs would increase the real level of income for the RPSGB. The Society would then be better able to meet the costs of the pension scheme and to cover higher fuel bills.

Under all of the options the RPSGB would need to consider funding any gap between income from Premises Registration Fees and costs through efficiency savings or through other sources of income.

Response to Consultation

Seven interested organisations representing pharmacy were consulted by the Department of Health and the Devolved Administrations in Great Britain - the Pharmaceutical Services Negotiating Committee (PSNC), the National Pharmacy Association (NPA), the Company Chemists Association (CCA), the Association of Independent Multiple Pharmacies (AIMp), the Co-Operative Pharmacy Technical Panel, Community Pharmacy Scotland (CPS) and the Guild of Healthcare Pharmacists (GHP). Of the organisations consulted, five opposed the fee increases, one supported the RPSGB's proposal and one organisation chose not to respond. A collective response from four organisations suggested a rise no more than the GDP deflator would be acceptable. They further opined that the 2009 increase should meet the appropriate costs of maintaining the register in 2009 and not prejudice the case made for the fees to be charged by the new pharmacy regulator from 2010. The fifth organisation that opposed the RPSGB proposal was of a similar view and contended that an increase beyond inflation could not be justified.

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. These Regulations set the level of the fees. 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 England and Wales. By March 2006 small businesses accounted for around 43% of all contractors. 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 is represented by the NPA. In responding to the RPSGB's proposed fee levels for 2009, they have 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. In agreeing a proposal 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 2009 premises fee income.

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 the pharmacy organisations.

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 increase proposed this will not be a significant factor.

Equality impact assessment

Equality impact screening and report is attached as Appendix A to this document.

Legal aid, sustainable development, carbon assessment, other environmental issues

The proposed increase in the fees for registration of pharmacy premises will have no effect in these areas.

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 by the RPSGB. Medicines may only be supplied to the public from registered pharmacies, except for medicines on the General Sale List. No additional monitoring is required.

Implementation and delivery plan

These proposals will be implemented through the Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 2008. The RPSGB will then invoice all registered premises to collect the retention fee, which is due in January 2009. Fees for initial registration are collected when new premises enter the register.

Post implementation review

The level of the fees for pharmacy premises registration is reviewed each year by the RPSGB as part of its business planning. The level of the Fee proposed for the following year is then subject to agreement by Ministers.

Summary and recommendation

On balance, increases in Premises Fees based on option 3 are recommended, taking the Retention, Registration and Restoration Fees to £529, £168 and £529 respectively. The Welsh Assembly Government and Scottish Executive Health Department support this approach. This provides a reasonable increase, taking account of increases in salary costs, which is the main cost of the activity. For the future, further consideration of the activities and costs in relation to premises registration and the inspectorate will be undertaken as part of the role of the Pharmacy Regulation and Leadership Oversight Group, in overseeing the establishment of the future General Pharmaceutical Council.

..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	<i>Results in Evidence Base?</i>	<i>Results annexed?</i>
Competition Assessment	Yes	No
Small Firms Impact Test	Yes	No
Legal Aid	Yes	No
Sustainable Development	Yes	No
Carbon Assessment	Yes	No
Other Environment	Yes	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

APPENDIX A – EQUALITY IMPACT ASSESSMENT

The Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 2008

The Royal Pharmaceutical Society of Great Britain (RPSGB) is 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 preferred option for the fees payable in 2009 is to increase the retention fee, the initial registration fee and the restoration fee to reflect the growth in average earnings in the year to August 2007 (3.7%) so the RPSGB can maintain its inspection activity. This increases the retention fee by £6 from £162 to £168. The levels of the initial registration fee and the restoration fee will increase by £19 from £510 to £529. The registration and restoration fees are not levied frequently.

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, the Department is not aware that any pharmacists have registered as disabled with 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. The 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 Royal Pharmaceutical Society of Great Britain's (RPSGB) 2006 register of pharmacists, a greater proportion of pharmacists are from black and ethnic minority backgrounds (27%) than for the general population as a whole (9%), (drawing on 2001 Population and Census data). 18% are Asian, 4% Chinese, 3% black and 2% other or mixed race with 73% 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 the proposed 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, at 1st November 2007, there were 48,449 pharmacists registered in Great Britain, of whom 27,252 (56%) are women. There are 36,805 pharmacists in England (20,340 women and 16,465 men) of whom 32,913 are practising. 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 the 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 2006 register of the RPSGB were aged 49 or less. A higher proportion of female pharmacists are 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 the increase in the pharmacy premises registration fees which impact on pharmacists in any particular age range. Nor will the 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 fees for the registration of a pharmacy premises will have an effect related to religion or belief.

None of the respondents to this years' consultation on the increase in the fee for the registration of pharmacy premises raised any specific equality issue. Nor have such issues been raised in previous years. Please see consultation information in the Impact Assessment (Page 10)


For the future, further monitoring of activities and consideration of the activities and costs in relation to premises registration and the inspectorate will be undertaken as part of the role of the Pharmacy Regulation and Leadership Oversight Group, in overseeing the establishment of the future General Pharmaceutical Council, the new regulator for pharmacy.

An increase in the pharmacy premises registration fees 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:

A handwritten signature in black ink, appearing to read "Bruce Keogh", written over a horizontal line.

Date: 1 November 2008