EXPLANATORY MEMORANDUM TO THE

THE MEDICINES (PHARMACIES)(APPLICATIONS FOR REGISTRATION AND FEES) AMENDMENT REGULATIONS 2005

2005 No. 3259

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 The Regulations increase the fees payable to the Royal Pharmaceutical Society of Great Britain (RPSGB) and the Pharmaceutical Society for Northern Ireland (PSNI) for the registration of pharmacy premises from 1 January 2006.

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

Great Britain

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 fees are 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 Retail Price Index of 2.8%. A further factor for the rise in RPSGB costs is the withdrawal of funding by the Scottish Executive Health Department (SEHD) for the Scottish Drug Testing Scheme. An increase in the retention fee is being allowed, which reflects the growth in average earnings in the year to July 2005 of 4.4%, plus an additional £7 per pharmacy to compensate the RPSGB for the withdrawal of income from SEHD, so the RPSGB can maintain its inspection activity. This increases the retention fee by £13 from £137 to £150.

3.3 The levels of the initial registration fee and the restoration fee were examined in detail last year and were set at a level, which reflected the cost of two days of an inspector's time. The increase of 3%, to £474, in 2006 has not proved contentious. The registration and restoration fees are not levied frequently. The initial registration fee is payable only on the establishment of a new pharmacy. There is no separate fee payable for the amendment of the premises register where an existing pharmacy changes ownership during the year.

3.4 Most pharmacies derive significant income from the NHS. £1,766m has been allocated in 2005/06 for the new community pharmacy contractual framework in England, an average of £180k per pharmacy. In monetary terms, an increase in premises fees of £13 per pharmacy is not considered significant. Collectively, the new 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.

Northern Ireland

3.5 The increases in Northern Ireland are modest but reflect increases in salaries and national insurance costs for the Pharmaceutical Society of Northern Ireland. The appointment of an additional inspector by Department of Health, Social Security and Public Health (Northern Ireland) has increased costs but has enabled the target for inspections to be set at a 21 month cycle. For Northern Ireland the retention fee rises from £118 to £130 (10%), the initial registration fee from £90 to £93 (3%) and the restoration fee (penalty) from £262 to £270 (3%).

4. Legislative Background

4.1 These regulations increase the fees payable for the registration of pharmacy premises from 1st January 2006, 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 registrars appointed, in relation to Great Britain, by the Royal Pharmaceutical Society of Great Britain and, in relation to Northern Ireland, by the Pharmaceutical Society of Northern Ireland (in accordance with sections 69(3) and 75 of the Medicines Act 1968). Those bodies also have statutory responsibilities under the Medicines Act 1968 and the Poisons Act 1972 to inspect pharmacy premises.

5. Extent

5.1 This instrument applies to all of the United Kingdom.

6. European Convention on Human Rights

No statement is required.

7. Policy background

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

7.2 The Department of Health is obliged by section 129(6) of the Medicines Act 1968 to consult interested organisations. Such organisations include those representing owners of all types of pharmacy, large and small. The organisations consulted made strong objections to the proposed increase in the retention fee, which the majority of pharmacies pay. The RPSGB also published the proposed new retention fee in the Pharmaceutical Journal received by all pharmacists, including those owning independent pharmacies. In the light of the comments received, a lower retention fee was agreed by DH, which takes into account the increase in staff costs and the withdrawal of funding by SEHD.

8. Impact

8.1 A Regulatory Impact Assessment is attached to this memorandum.

9. Contact

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.

Full and Final Regulatory Impact Assessment

1. Title of proposal

The Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 2005.

2. Purpose and intended effect

(i) Objective

To ensure that fees payable to the Royal Pharmaceutical Society of Great Britain (RPSGB) by pharmacy owners, for the registration of pharmacy premises in Great Britain, from 1 January 2006 adequately meet the costs incurred by the RPSGB for maintaining this activity.

The 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 Royal Pharmaceutical Society of Great Britain. The Medicines Act 1968 says that it is for Ministers to make regulations setting fees payable to the RPSGB after consultation required by S129(6) of the Act.

Medicines may only be supplied to the public from registered pharmacies, except for medicines on the General Sale List. 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 fees charged are monitored and reviewed annually to reflect, as far as possible, the cost of the activities, which they fund.

(ii) Background

There are three types of fee, one of which applies to each individual pharmacy registered by the RPSGB on an annual basis. These are fee for:

- initial registration, which is payable when a new pharmacy is first established and placed on the register;
- retention, which is an annual fee to maintain a pharmacy on the register; or
- restoration to the register, as a penalty for late payment of the retention fee and to cover the associated administration.

For almost 70 years, the RPSGB has employed inspectors to ensure that professional standards of practice are maintained. The Society has responsibility for enforcing provisions of the Medicines Act 1968, concerning the sale and supply of medicines, on behalf of the Secretary of State for Health, and for enforcing provisions of the Poisons Act 1972, on behalf of the Home Secretary.

There are 18 pharmacy inspectors in Great Britain, each with responsibility for about 700 pharmacies. The inspectors visit the pharmacies regularly, to ensure that legal requirements and professional standards of practice are observed. All the pharmacy inspectors are themselves pharmacists, with substantial practical experience.

There are 12,300 registered pharmacies in Great Britain employing over 20,000 pharmacists. The Society's aim is for an inspector to visit each pharmacy routinely every 18-24 months. In 2005, to date, the inspectors have made 4,875 visits to pharmacies under the Medicines Act 1968 and the Poisons Act 1972. Most visits (75%) are routine and notified. Routine visits are made to ensure the maintenance of legal and ethical standards and to provide information and advice. The Inspectors liaise with other agencies, including Primary Care Trusts.

Other visits are made for investigation of complaints, alleged offences, contravention of the Code of Ethics and at the pharmacist's request. The inspectors investigate reports of illegal supplies of medicines, whether by pharmacists or others, and complaints of unprofessional practice. This includes breaches of labelling regulations and dispensing errors. They work closely with other enforcement bodies and health authorities/ primary care organisations.

(iii)Rationale for government intervention
The RPSGB is unable to change the fees without Ministerial approval to amend regulations.

3. Consultation

The Department of Health is obliged by S129(6) of the Medicines Act 1968 to consult interested organisations on the RPSGB's proposed changes to premises fees. Those consulted were the National Pharmaceutical Association (NPA), the Pharmaceutical Services Negotiating Committee (PSNC), the Company Chemists Association (CCA) and the Co-operative Pharmacy Technical Panel. The NPA is the national body representing the majority of community pharmacy owners, including those of small businesses. The PSNC represents all pharmacies providing NHS pharmaceutical services. The CCA represents UK multiple community pharmacies, such as Boots, Lloydspharmacy, Asda among others and the Co-operative Pharmacy Technical Panel looks after the interests of Co-op pharmacies. The Department of Health also consulted the Scottish Executive Health Department, which in turn sought views from the Standing Committee of the Pharmaceutical General Council (Scotland), the equivalent of the PSNC, and Welsh Assembly Government.

The RPSGB also published their proposed premises retention fee increase in the Pharmaceutical Journal, which is received by all pharmacists registered in Great Britain. All registered pharmacy premises are owned by a pharmacist or have a superintendent pharmacist. No comments were received by the RPSGB.

The results of the consultation were:

Organisation Consulted	Comment
Company Chemists' Association National Pharmaceutical Association (NPA) Pharmaceutical Services Negotiating Committee (PSNC) Association of Independent Multiple	The four organisations provided a combined response opposing the increase, particularly in the retention fee. Their view was that the reasons and issues cited by the RPSGB were insufficient justification for such a rise. They were particularly concerned that the RPSGB's paper did not assist in

Organisation Consulted	Comment
Pharmacies (AIMp)	understanding why increased costs associated with regulation should fall on premises fees. Nor did they understand the RPSGB's assertion that the basis of premises fee calculations, covering the cost of the inspectorate, is an anomaly. They were particularly concerned that the background should be fully explored and understood in the light of the Society's aim of increasing the retention fee over a period of 3 years to £200. In summary they opposed the proposed fee increases and felt them unwarranted and unjustified.
Co-Operative Pharmacy Technical Panel	The Co-operative Pharmacy Technical Panel chose not to respond.
Standing Committee of the Pharmaceutical General Council (Scotland) - equivalent of the PSNC	Did not object to the percentage uplift in the initial registration and restoration fees. However, they expressed reservations about the proposed retention fee of £160 for 2006 and remained to be convinced about the merits of the RPSGB's business case for a staged increase up to £200 over 3 years. They also felt that the increases would put an increased burden on pharmacists in Scotland as a mechanism, such as the future-proofing agreement within the new pharmacy contract in England, did not operate in Scotland.

The Welsh Assembly Government was also not convinced by the RPSGB's rationale for the 17% increase in the retention fee, although the reasoning behind the proposal to move costs from practitioners to premises was appreciated.

4. Options

Four options have been identified for reaching a decision on the pharmacy premises fees for 2006. As the retention fee is the main source of income the options focus on this fee alone. The registration and restoration fees are levied much less frequently. The principal of the initial registration fee and the restoration fee being set at the same level was accepted when the fees were set for 2005 and an increase of 3% for 2006 has not been challenged and appears acceptable.

The four options which have been identified for the retention fee are:

Option 1: Do nothing and leave the retention fee at £137

Option 2: Accept the RPSGB's proposed increased retention fee of £160; a rise of £23 (16.8%).

Option 3: Set the retention fee taking account of salary inflation plus unavoidable cost increases, giving a retention fee of £150; a rise of £13 (9.5%).

Option 4: Set the retention fee taking into account of the increase in Retail Price Index (RPI) plus unavoidable cost increases, giving a retention fee of £148; a rise of £11 (8%).

The impact of these options is summarised in the table below:

		Option 1	Option 2	Option 3	Option 4
Retention Fee	**2005**	£137	£137	£137	£137
	2006	£137	£160	£150	£148
	Amount (%) increase	£0 (0%)	£23 (16.8%)	£13 (9.5%)	£11 (8%)
Initial Registration Fee	**2005**	£460	£460	£460	£460
	2006	£474	£474	£474	£474
	Amount (%) increase	£14 (3%)	£14 (3%)	£14 (3%)	£14 (3%)
Restoration Fee (Penalty)	**2005**	£460	£460	£460	£460
	2006	£474	£474	£474	£474
	Amount (%) increase	£14 (3%)	£14 (3%)	£14 (3%)	£14 (3%)
Estimated additional cost to pharmacy sector		Negligible	£282,900	£159,900	£135,300

The current overall payment by the sector of retention fees is some £1.6m.

(i) Risks

In arriving at their proposed increase in fees for 2006 the RPSGB has had two main objectives:

a) The Society's financial strategy to fund professional and regulatory activity from its fees.

The RPSGB has three main streams of income. The registration fee for pharmacists wishing to remain on the UK register each year, the retention fee for every registered pharmacy premises and the substantial contribution it receives from the surplus generated by its publications division. The surplus from commercial publication activity has subsidised the costs of the Society's regulatory and professional activities for many years.

In recent years, the Society in line with other regulators has increased its cost base in response to increasing demands for greater professionalism, accountability and transparency from all of its stakeholder groups. However, the increased costs were not fully reflected in the retention and registration fees as the contribution from

publications had also been growing. As a result, the Society had become overly reliant on the contribution from publications with a corresponding deterioration in its level of reserves and its financial sustainability.

In 2005 the Council for the RPSGB adopted a financial strategy based on reducing the publications contribution as a subsidy for the Society's regulatory and professional activities. Over a period of time, the Society is seeking to ensure that the cost of its regulatory activities are funded through the fees it charges.

b) Correcting the imbalance in funding the costs of the Society's regulatory activity between its members and the premises fees.

Over the last five years, there has been a distinct difference in the rate at which members fees and premises fees have risen. Both are subject to scrutiny and approval by outside bodies - the Privy Council in the case of the members fees and the appropriate minister in the Department of Health in the case of the premises fee. Between 2000 and 2005 the members fee has risen by 85% from £138 to £256, while the premises retention fee has risen by 54% from £89 to £137.

As a matter of custom and practice, the only costs allocated against income from premises fees had been purely the cost of the Inspectorate. However, the inspectors themselves are only one element of the regulatory process relating to the discharge of the Society's responsibilities under the Medicines Act 1968 and the Poisons Act 1972. Following initial investigation, if there is any substance to a complaint made to the RPSGB it enters the Society's complaints procedure. This involves further examination of the details by the Investigations Department, a review by the Infringements Committee and, if further action is deemed necessary, a referral to the Statutory Committee for formal judgement.

The increasing complexity of regulation with the overriding need to be transparent in proceedings has added to the burden on the inspectors and reduced the amount of time available for normal inspection visits. The subsequent investigation and preparation for possible prosecution requires the same degree of meticulousness to ensure cases can withstand legal challenge, adding to the cost of the Society's regulatory responsibilities.

Even if there were agreement to agree the level of increase proposed by the RPSGB there would remain under recovery of these costs, which will need to be covered either by the fees paid by the RPSGB's members or from income generated by the RPSGB's commercial publishing activities.

If the RPSGB is not adequately resourced for the work it is required to undertake, essential activity on inspection and responding to complaints would need to be reduced, over time giving rise to greater risk to human health.

5. Costs and benefits

(i) Sectors and groups affected

The premises registration fees affect the pharmacy sector, of which the vast majority are community pharmacies, although there are a small number of registered pharmacies in hospitals and also registered pharmacies belonging to pharmacy manufacturers. The majority of the pharmacies, which are registered, would be

classed as small businesses. An estimated 30% of pharmacies (around 2,800) have ethnic minority owners. All pharmacy owners have to register with the RPSGB, not just those providing NHS pharmaceutical services, although they form the vast majority. There are 10,462 pharmacies (England and Wales) providing NHS pharmaceutical services, of which over half are in chains of more than five pharmacies (known as "multiples"). Premises fees are a legitimate tax-deductible business expense for all pharmacies.

(ii) Benefits

Option 1: The benefit would fall to registered pharmacies, who would pay the same retention fees as currently.

Option 2: The benefit is to the RPSGB, with the fees set at the level they propose. Even so, this will leave the Society with a shortfall of 18% on the overall costs they have allocated against the income from premises fees. That is why the Society indicates that in their view the retention fee should increase to £200 over the next 3 years. This will be a decision for the future.

Option3: The benefit would primarily fall to registered pharmacies, who will be paying higher fees than in previous years, but at a lower rate than proposed by the RPSGB.

Option 4 The benefit would primarily fall to registered pharmacies, who will be paying higher fees than in previous years, but at a lower rate than proposed by the RPSGB and £2 less per pharmacy than option 3.

(iii) Costs

Option 1: There would be no increase in premises fees for pharmacy owners. The RPSGB would face a shortfall of 14% on the 2006 fee income they have proposed to cover inspection activity and of 30% on the overall costs they have allocated against the income from premises fees. To cover such a large short-fall, it is expected that there would have to be a reduction in the Society's inspection activity and thus quality assurance of pharmacy premises.

Option 2: The cost of the full rise proposed by the RPSGB would be born by business. For the majority of pharmacy owners, it will represent an increase of £23 per premise.

Option 3: With an increase in the premises retention fee from £137 to £150, pharmacy owners will bear an increase of £13 per annum for each of the premises they own, ie an increase of cost on the sector of £159,900. The RPSGB would still have a shortfall on the income they proposed from premises fees for 2006 of 5.4%, but at a level more readily covered through income from other sources and efficiency savings. The higher fee would cover the loss of income from the Scottish drug testing scheme (£88,000, equivalent to £7 per pharmacy), plus a 4.4% increase for staff inflation and other costs, in line with wage inflation.

Option 4: With the premises retention fee increased from £137 to £148, pharmacy owners will bear an increase of £11 per annum for each of the premises they own, ie an increase of costs for the sector of £135,300. The RPSGB would have a shortfall on their proposed income from premises fees for 2006 of 6.7%. The increased fee would cover the loss of income from the Scottish drug testing scheme (£88,000, equivalent to £7 per pharmacy), plus a 2.8% increase for inflation. However as the

majority of the RPSGB's costs relate to staff costs the RPSGB would need to cover a larger shortfall than under option 3.

(iv) Race and equality
Race equality impact was considered and initial assessment indicated that a full race equality study was not required. 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.

(v) 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 or pharmacists.

(vi) Social
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. Option 2 meets the RPSGB's cost demands. Option 1 provides significant less income than the Society is seeking, which would need to be addressed by reducing the Inspectorate's quality assurance activity, thus over-time potentially increasing the risk to public health. Option 3 covers the loss of income from the Scottish drug testing scheme and wage inflation, in keeping with salaries being the major component of the cost base for the Society's Inspectorate. The Society would need to look to other income streams to address the 5.4% shortfall or trim non-essential activity. Option 4 has a similar impact to option 3, but with a higher shortfall of 6.7% to be addressed from other income or efficiency savings

(vii) Environment
There are no environmental costs or benefits associated with the fee structure of the RPSGB for the registration of pharmacy premises.

6. Small Firms Impact Test

Small businesses are important to the supply of pharmaceutical services in Great Britain. The largest three firms in the market, currently, hold less than 30% of the market. The increase in the premises fee will affect all pharmacy premises. It is notable that there are large individual pharmacies, as well as small pharmacies, operating within the large chains. 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 – for example, £1,766m has been allocated in 2005/06 for NHS community pharmacy services in England, an average of £180k per pharmacy. The interests of small independent pharmacies is represented by the NPA. In responding to the RPSGB's proposed fee levels for 2006, they have voiced the same reservations on the amount of the increase as the organisations representing the chains of pharmacies.

7. Competition assessment

The proposal 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 from £137 to £150 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. However, in cash terms the increase in the retention fee is not great.

The initial registration fee of £474, 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. Initial registration fees are only paid on the start-up of a new pharmacy. Where an already registered pharmacy changes hands, and over 1,000 pharmacies do each year, there is no additional fee payable to the RPSGB for the amendment to the registration. As such, we do not expect the proposal to have a significant effect on competition.

8. Enforcement, sanctions and monitoring

Those pharmacies that 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.

9. Implementation and delivery plan

These proposals will be implemented through the Medicines (Pharmacies) (Applications for Registration and Fees) Amendment Regulations 2005. The RPSGB then invoices all registered premises in January to collect the retention fee. Fees for initial registration are collected when new premises enter the register.

10. 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.

11. Summary and recommendation

Summary costs and benefits table

Option	Total benefit per annum: economic,	Total cost per annum:

	environmental, social	**- economic, environmental, social - policy and administrative**
1. Do nothing	Pharmacy owners benefit from no increase in premises fees.	No increased cost to pharmacy owners. RPSGB face 14% reduction in proposed premises fee income, which would need to be addressed by reducing the Inspectorate's quality assurance activity, thus over-time potentially increasing the risk to public health.
2. Accept RPSGB's proposed increased fees	The benefit is to the RPSGB, with the fees set at the level they propose.	The cost of the full rise proposed by the RPSGB would be born by business, estimated at an extra £283k per annum. For the majority of pharmacy owners, it will represent an increase of £23 per premise.
3. Raise fee in line with wage inflation and to cover loss of income	The benefit would primarily fall to registered pharmacies, who will be paying higher fees than in previous years, but at a lower rate than proposed by the RPSGB.	Pharmacy owners will bear an increase of £13 per annum for each of the premises they own, estimated at an extra £160k per annum for the sector as a whole. The RPSGB would still have a shortfall on the income they proposed from premises fees for 2006 of 5.4%, but at a level more readily covered through income from other sources and efficiency savings, thus maintaining the Inspectorate's quality assurance function. The higher fee would cover the loss of income from the Scottish drug testing scheme (£88,000, equivalent to £7 per pharmacy), plus a 4.4% increase for staff inflation and other costs, in line with wage inflation.
4. Raise fee in line with RPI and to cover the loss of income	The benefit would primarily fall to registered pharmacies, who will be paying higher fees than in previous years, but at a lower rate than proposed by the RPSGB and £2 per pharmacy less than option 3.	Pharmacy owners will bear an increase of £11 per annum for each of the premises they own, estimated at an extra £135k per annum for the sector as a whole. The RPSGB would have a shortfall on the income they proposed from premises fees for 2006 of 6.7%. The fee income would cover the loss of income from the Scottish drug testing scheme (£88,000, equivalent to £7 per pharmacy) plus a 2.8% increase for inflation. However as the majority of the costs relate to staff costs the RPSGB would need to cover a larger shortfall than under option 3.

On balance, increases in premises fee based on option 3 are recommended, taking the retention, registration and restoration fees to £137, £460 and £460 respectively. The Welsh Assembly Government and Scottish Executive Health Department support this approach. The percentage increase for the retention fee is also in line with the intended rise for pharmacies in Northern Ireland. This provides a reasonable increase and takes account of the loss of income from the Scottish drug testing scheme.

12. Declaration and publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Jane Kennedy

Date: 22nd November 2005

Minister of State, Department of Health

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