

**EXPLANATORY MEMORANDUM TO
THE MEDICINES (PHARMACIES) (APPLICATIONS FOR REGISTRATION AND
FEES) AMENDMENT REGULATIONS 2007**

2007 No. 3282

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) and the Pharmaceutical Society for Northern Ireland for the registration of pharmacy premises from 1 January 2008.

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 GDP Deflator of 3.25% forecast for 2008. 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 £156 to £162.

- 3.3 The levels of the initial registration fee and the restoration fee were examined in detail 3 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 will increase these fees by £18 from £492 to £510. 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. 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.

Northern Ireland

3.4 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 the Department of Health, Social Security and Public Health, Northern Ireland (DHSSPSNI) 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 £135 to £142 (5%), the initial registration fee from £97 to £102 (5%) and the restoration fee (penalty) from £281 to £295 (5%).

3.5 Arrangements are different in Northern Ireland regarding Departmental roles in relation to inspection and registration of pharmacy premises. The DHSSPSNI has both an inspectorate and enforcement role across all of the pharmaceutical legislation; namely, the Medicines Act 1968, Misuse of Drugs Act 1971, Pharmacy (NI) Order 1976 and Poisons (NI) Order 1976. Although the Department retains its responsibility for inspection, the independence of which is valued, the registration function has been devolved by the Department to the Pharmaceutical Society of Northern Ireland. The DHSSPSNI effectively has two whole time equivalent officers responsible for inspections and the apportionment of fees reflects this resource. Given the geography of Northern Ireland the proportion of travel and subsistence is very small.

3.6 Under the Pharmacy (NI) Order 1976 the premises fees paid to the Registrar of the Pharmaceutical Society of Northern Ireland are remitted by him to the DHSSPSNI. Following deduction of the Department's inspection costs a portion of the fees, of not less than half, as may be determined by the Department, are paid to the Pharmaceutical Society of Northern Ireland to cover its administrative expenses.

4. Legislative Background

4.1 This instrument increases the fees payable for the registration of pharmacy premises from 1st January 2008, 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 RPSGB 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). The RPSGB also has statutory responsibilities under the Medicines Act 1968 and the Poisons Act 1972 to inspect pharmacy premises. In Northern Ireland the statutory rights for inspection are retained by the DHSSPSNI.

5. Territorial Extent and Application

5.1 This instrument applies to all of 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, registration of pharmacy premises is a matter, in Great Britain, for the RPSGB, and in Northern Ireland for the Pharmaceutical Society of Northern Ireland. However, it is for Ministers to make regulations setting fees payable to those Societies. The fees are reviewed annually and updated 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 55.8% increase in the retention fee proposed by the RPSGB, which the majority of pharmacies pay. The RPSGB published the proposed new fees in the Pharmaceutical Journal (11 August), which is received by all pharmacists, including those owning independent pharmacies. No comments were received by this route. In the light of the comments received from the pharmacy organisations, a lower level of fees increase has been agreed by the Department of Health, which takes into account the increases in staff costs.

8. Impact

8.1 An Impact Assessment has not been prepared for this instrument, as it amends an existing regulatory regime to increase the fees by a pre-determined formula in relation to Great Britain, namely, in line with the Average Earnings Index. (Last year a Regulatory Impact Assessment was prepared, as the increase in fees exceeded inflation. The new guidance does not require an Impact Assessment to be prepared where a formula is used to determine the fee increase and that increase exceeds inflation).

8.2 This instrument amends an existing regulatory regime to increase the fees by 5% in relation to Northern Ireland.

9. Contact

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