EXPLANATORY MEMORANDUM TO

The Medicines (Pharmacies) (Applications for Registration and Fees) (Amendment) Regulations (Northern Ireland) 2026

S.R. 2026 No.

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule is made under powers conferred by the Medicines Act 1968 ("the Medicines Act") and is subject to the negative resolution procedure.

1.3 In accordance with paragraph 6 of Schedule 4 to the Medicines Act, the Minister for Health makes these Regulations alone rather than acting jointly with the UK Secretary of State for Health and Social Care as set out in Section 1(1) of the Medicines Act due to special circumstances: there is no other available power to amend the 2010 Regulations; the proposed amendment is limited to an uplift in premises fee amounts in Northern Ireland only; and given the significant financial pressures facing the Pharmaceutical Society of Northern Ireland ("the Society"), this is considered an expedient approach in terms of timing of any fee increase.

2. Purpose of the Regulations

2.1 The purpose of this Statutory Rule is to increase the fees payable to the Society relating to the registration and retention of pharmacy premises from 1st January 2027.

3. Background and Legislative Context

3.1 The Society is required by section 75 of the Medicines Act to keep a register 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.

3.2 The prescribed fees are set out in the Medicines (Pharmacies) (Applications for Registration and Fees) Regulations (Northern Ireland) 2010 (S.R. 2010 No. 404). The prescribed fees are for initial registration, an annual retention fee to remain on the register and a late penalty fee along with the retention fee, for restoration to the register.

3.3 Premises fees paid to the Society, are designed to cover costs associated with developing and promoting standards and guidance relating to the operation of registered premises, conducting Fitness to Practice investigations and to fund staff and IT related costs.

3.4 This Statutory Rule amends the Medicines (Pharmacies)(Applications for Registration and Fees) Regulations (Northern Ireland) 2010 to increase the fee to be paid for the registration of premises under section 75 of the Act from £113 to

£300, and the retention fee payable under section 76(1) of the Act from £155 to £300. These fees were last uplifted in January 2011.

4. Consultation

4.1 The Department conducted an eight-week targeted consultation between 8th June and 3rd August 2026 on six options to increase premises fees. In total, 112 responses were received from pharmacy owners, pharmacists, pharmacy managers, Health and Social Care (HSC) organisations, professional and academic bodies and other interested stakeholders. Most responses received were from pharmacy owners. All responses were reviewed and given due attention as part of the consultation process.

4.2 The consultation did not however identify a clear consensus in favour of any single increase option. Concerns focused primarily on the affordability and impact of increases on pharmacy owners, the financial pressures facing community pharmacy, the need for greater transparency regarding the Society's finances and consideration of alternative or additional funding arrangements for the Society.

4.3 Taking account of all the evidence, the Department concluded that a phased increase in premises fees represents the most balanced and proportionate approach resulting in the premises fees for registration and retention increasing to £300 from January 2027.

5. Equality impact

5.1 The Department of Health has concluded that the proposed amendments will not have a significant impact on equality of opportunity for any group referred to in section 75 of the Northern Ireland Act 1998 and a full Equality Impact Assessment has not been considered necessary.

5.2 The Department has completed a Regulatory Impact Assessment on the increase of pharmacy premises fees given that it applies to business, which will be published on the Department's web site.

5.3 Concerns on the affordability and impact of any increases on pharmacy owners given the financial pressures currently facing community pharmacy were raised in the consultation responses, however there was also acknowledgement that the Society requires a sustainable source of funding to continue delivering its statutory functions.

5.4 The phased increase in premises fees is considered the most balanced and proportionate approach resulting in the premises fees for registration and retention increasing to £300 from January 2027.

6. Financial implications

6.1 Responsibility for setting the amount of pharmacy Premises Fees lies with the Department of Health under the Medicines Act 1968.

6.2 The Society has operated in a financial deficit since 2021-2022 with the shortfall being met using strategic reserves. These reserves are finite and have eroded sharply over recent years.

6.3 Fees are the Society's primary source of income with some minor income from investments and pharmacy. Premises Fees have not increased since 2011 and it is vital that the Society is resourced to continue delivering its statutory regulatory functions, with patient safety and public protection at the centre of pharmacy practice. The current level of premises fees no longer makes an adequate contribution to the cost of delivering modern pharmacy regulation in Northern Ireland and an increase in the premises fees is necessary to generate additional income for the Society.

7. Section 24 of the Northern Ireland Act 1998

7.1 The Department of Health has considered section 24 of the Northern Ireland Act 1998 and is satisfied that these Regulations are not incompatible with any of the Convention rights; are not incompatible with Community law; do not discriminate against a person or class of person on the grounds of religious belief or political opinion; and do not modify an enactment in breach of section 7 of the Northern Ireland Act 1998.

8. EU implications

8.1 There are no anticipated EU implications as a result of these amendments.

9. Parity or Replicatory Measure

9.1 This Statutory Rule has no parity or replicatory measures.

10. Additional information

10.1 Not applicable