

EXPLANATORY MEMORANDUM TO

The Council of the Pharmaceutical Society of Northern Ireland (Indemnity Arrangements) Regulations (Northern Ireland) 2014

SR 2014 No. 126

1. Introduction

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety (DHPSSPS) to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Statutory Rule is made under Articles 11A(4) to (7) of , and Paragraphs 15(1)(b), (2) and (3), to the Pharmacy (Northern Ireland) Order 1976 and is subject to the negative resolution procedure.

2. Purpose

- 2.1. The main purpose of the Regulations is to implement the statutory requirement arising from the The Pharmacy (1976 Order) (Amendment) Order 2013 that practising pharmacists must have in place insurance or indemnity cover (referred to as an indemnity arrangement in the Regulations).
- 2.2. The Regulations set out matters relating to the requirement for practising pharmacists to have in operation an indemnity arrangement which provides appropriate cover; the information to be provided to the registrar regarding such arrangements and gives the Pharmaceutical Society of Northern Ireland (the Society) powers to deal with those who do not have in place adequate indemnity arrangements by removal from the register or through existing fitness to practice procedures.

3. Background

- 3.1. The Department has brought into effect the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 (the Amendment Order). The legislation came into operation on 7 November 2013; introduction was mandatory in order to meet the requirements of Article 4(2)(d) of EU Directive on Patients' Rights in Cross Border Healthcare (Directive 2011/24/EU).
- 3.2. The Amendment Order made provision for the Society to make regulations relating to the requirement for practising pharmacists to have an appropriate indemnity arrangement in place.
- 3.3. Implementation of the Regulations will have little or no impact on the vast majority of pharmacists in Northern Ireland as, before it was a statutory requirement, the requirement to have indemnity cover was already a professional requirement and as such in the vast majority of cases is provided for by an employer's vicarious liability or via a trade union or other body.

4. Consultation

- 4.1. A targeted consultation exercise on the Regulations began on 23 December 2013 and ended on 14 March 2014. Seven responses were received and the respondents were broadly content with the proposals in the Regulations.
- 4.2. One respondent strongly disagreed with the proposal that the Society could require evidence from registrants and from third parties believing this may place an unnecessary burden on registrants, employers and the Society and that these powers would be of no practical benefit to registrants or the public.
- 4.3. However, the Department is clear that the intention of the Regulations, and indeed the Society's wish in implementing these, is that this will not be an onerous exercise for any party involved. The Society will not routinely seek evidence of indemnity cover but may ask for this in circumstances where a complaint has been made or where there are concerns that appropriate indemnity cover may not be in place. The primary purpose of the regulations is to enhance public protection by ensuring that that appropriate cover is in place and, were it required, an avenue to seek redress is secured.

5. Equality Impact

- 5.1. The Department concluded that the proposed changes 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 therefore a full Equality Impact Assessment has not been considered necessary.

6. Regulatory Impact

- 6.1. A regulatory impact assessment has not been produced for these regulations as it is not anticipated there will be any adverse impact on business, charities, social economy or the voluntary sector. .

7. Financial Implications

- 7.1. None

8. Section 24 of the Northern Ireland Act 1998

- 8.1. Legal advice confirms that the provisions of this rule comply with section 24 of the Northern Ireland Act 1998.

9. EU Implications

- 9.1. These Regulations will implement the requirements of Article 4(2)(d) of EU Directive on Patients' Rights in Cross Border Healthcare (Directive 2011/24/EU).]

10. Parity or Replicatory Measure

- 10.1. Regulation of pharmacists is undertaken by the Society locally in Northern Ireland, while all other professionals are regulated on a UK wide basis. DHSSPSNI officials continue to work with colleagues in the other three UK Health Departments to introduce legislation requiring the other regulated healthcare professionals to have appropriate indemnity arrangements in place.

- 10.2. The timetable for introducing this legislation has not yet been finalised but current thinking is that it should come into operation sometime before the end of 2014. For the vast majority of regulated healthcare professionals the new legislation will mean no change as it is already a professional requirement to have indemnity cover.

11. Additional Information

- 11.1. Not applicable.