EXPLANATORY MEMORANDUM TO

The Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013

S.R. 2013 No.

1. Introduction

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety (DHSSPS) to accompany the Amendment Order (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Order is made under section 56 of, and Schedule 4 to, the Health and Personal social Services Act (Northern Ireland) 2001, and is subject to the draft affirmative procedure before the Assembly.

2. Purpose

- 2.1. The main purpose of the Order is to introduce a statutory requirement for all pharmacists registered with the Pharmaceutical Society of Northern Ireland (PSNI) to have in place suitable indemnity arrangements.
- 2.2. The Order also provides the PSNI with the power to deal with any breaches of the indemnity requirement by removal from the register or through existing fitness to practice procedures.

3. Background

3.1. The Department is required to transpose the EU Directive on Patients Rights in Cross Border Healthcare (Directive 2011/24/EU), which requires member states to have systems of professional liability insurance or similar indemnity arrangements transposed into domestic law by 25 October 2013.

4. Consultation

- 4.1. A Consultation exercise on the amending Order began on the 7 March 2013 and ended on the 30 May 2013.
- 4.2. 5 responses were received. All respondents agreed in principle with the requirement that pharmacists should have an indemnity arrangement in place in order to practice. However, in relation to community pharmacists particularly, two respondents believed that the current position should be maintained, i.e that indemnity cover should continue to remain a professional obligation rather than a statutory requirement.

5. Equality Impact

5.1. The Department concluded that the new arrangements were not likely to 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 EQIA was not recommended.

6. Regulatory Impact

6.1. A regulatory impact assessment has not been produced for this rule as it has no impact on the costs of business, charities 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. Not appropriate

10. Parity or Replicatory Measure

10.1. The amendments proposed mirror provisions introduced in England, Wales and Scotland.

11. Additional Information

11.1. Not applicable.

TRANSPOSITION NOTE

Transposition Note for Directive 2011/24/EU of the European Parliament and of the Council of 9th March 2011 on the application of patient rights in cross-border healthcare.

Directive 2011/24/EU of the European Parliament and of the Council on the application of patient's rights in cross-border healthcare ("the Directive") clarifies citizens' rights to access health care in another member state of the EEA and sets out the grounds on which they may claim reimbursement of the eligible costs of treatment from their home health care system.

The NI Assembly is required to implement these changes in law by 25th October 2013.

This transposition note sets out the way in which Article 4(2)(d) of Directive 2011/24/EU is to be implemented through rules made by, and other measures taken by, the Department of Health, Social Services and Public Safety.

The Directive will be transposed by separate measures in relation to England, Wales and Scotland.

In these Notes:

• MS means "Member State";

Article of Directive	Subject Matter	Implementation
Article 4(2)(d)	Article 4(2)(d) requires MS to ensure system of professional liability insurance or equivalent provision	In relation to liability insurance for Pharmacists, this is to be transposed by the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013. This Amendment Order
		makes amendments to the Pharmacy (Northern Ireland) Order 1976 and requires that pharmaceutical chemists must have in operation an indemnity arrangement which provides appropriate cover in respect of liabilities which may be incurred in practising as a pharmaceutical chemist.