

Draft Order laid before the Assembly under paragraph 9(1) of Schedule 4 to the Health and Personal Social Services Act (Northern Ireland) 2001 for approval by resolution of the Assembly

DRAFT STATUTORY RULES OF NORTHERN IRELAND

2013 No.

PHARMACY

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

Made - - - -

Coming into operation

25th October 2013

The Department of Health, Social Services and Public Safety⁽¹⁾, in exercise of the powers conferred by section 56 of, and Schedule 4 to, the Health and Personal Social Services Act (Northern Ireland) 2001⁽²⁾, makes the following Order.

In accordance with paragraph 9(2) of Schedule 4 to that Act the Department of Health, Social Services and Public Safety has published a draft of this Order and invited representations to be made to it about the draft by—

- (a) persons appearing to the Department appropriate to represent the profession;
- (b) persons appearing to the Department appropriate to represent those provided with services by the profession; and
- (c) any other persons appearing to the Department appropriate to consult about the draft.

Citation, commencement and interpretation

1.—(1) This Order may be cited as the Pharmacy (1976 Order) (Amendment) Order (Northern Ireland) 2013 and shall come into operation on 25th October 2013.

(2) In this Order—

“the Department” means the Department of Health, Social Services and Public Safety; and

“the principal Order” means the Pharmacy (Northern Ireland) Order 1976⁽³⁾.

(1) S.I. 1999/283 (N.I. 1) Article 3(6)

(2) 2001 c.3 (N.I.)

(3) S.I. 1976/1213 (N.I. 22) as amended by 1981 c.45 & c.55; 1983 c.54; S.I. 1984/703 (N.I. 3); S.R. 1987 No. 457; S.I. 1994/429 (N.I. 2); S.R. 1996 No. 393; 2004 c.33; S.R. 2004 No. 78; S.R. 2008 No. 192 and S.R. 2012 No. 308

Amendments to the principal Order

2. After Article 11 of the principal Order (*Evidence of qualification to be registered*) insert the following Article—

“Indemnity arrangements

11A.—(1) A registered person who practises as a pharmaceutical chemist must have in operation an indemnity arrangement which provides appropriate cover in relation to that registered person in respect of liabilities which may be incurred in practising as a pharmaceutical chemist.

(2) For the purposes of this Article, an “indemnity arrangement” may comprise—

- (a) a policy of insurance;
- (b) an arrangement made for the purposes of indemnifying a person; or
- (c) a combination of the two.

(3) For the purposes of this Article, “appropriate cover”, in relation to practice as a pharmaceutical chemist, means cover against liabilities that may be incurred in practising as such which is appropriate, having regard to the nature and extent of the risks of practising as such.

(4) The Council may make such provision in regulations in connection with the information to be provided to the registrar—

- (a) by or in respect of any person seeking to be registered (including on an application for restoration) for the purposes of determining whether if that person is so registered, there will be in operation in relation to that person by the time that person begins to practise an indemnity arrangement which provides appropriate cover; and
- (b) by or in respect of a registered person who practises as a pharmaceutical chemist for the purposes of determining whether, at any time, there is in operation an indemnity arrangement which provides appropriate cover in relation to that registered person.

(5) Regulations under paragraph (4)(b) may require information to be provided—

- (a) at the request of the registrar; or
- (b) on such dates or at such intervals as the registrar may determine, either generally or in relation to a registered person or registered persons of a particular description.

(6) The Council may also make regulations requiring a registered person who practises as a pharmaceutical chemist to inform the registrar if there ceases to be in operation in relation to that registered person an indemnity arrangement which provides appropriate cover.

(7) The Council may also make regulations requiring a registered person who practises as a pharmaceutical chemist to inform the registrar if there is in operation in relation to that registered person appropriate cover provided under an indemnity arrangement by an employer.

(8) Where there is a failure to comply with the regulations under paragraph (4) by or in respect of a registered person who practises as a pharmaceutical chemist or a person who is seeking to be registered, the registrar may refuse to enter or retain the person’s name in, or to restore their name to, the register.

(9) If a registered person who practises as a pharmaceutical chemist is in breach of paragraph (1), or fails to comply with regulations under paragraph (4)(b), (6) or (7), or there

is a failure to comply with regulations under paragraph (4)(b) in respect of that registered person—

- (a) the registrar may remove that person’s name from the register; or
- (b) the breach or failure may be treated as misconduct for the purposes of paragraph 4(1)(a) of Schedule 3 and the registrar must consider, in accordance with paragraph 5(1) of that Schedule, whether or not to refer the matter to the Scrutiny Committee or (where regulations under paragraph 5(1) of that Schedule so provide) to the Statutory Committee.

(10) Where the registrar—

- (a) refuses to enter or retain a person’s name in, or restore their name to, the register pursuant to paragraph (8); or
- (b) removes a person’s name from the register, pursuant to paragraph (9)(a),

the registrar must send to the person a statement in writing giving the person notice of the decision and the reasons for it and the right of appeal to the Statutory Committee under paragraph (11).

(11) A person in respect of whom a decision has been made by the registrar to—

- (a) refuse to enter or retain a person’s name in, or restore their name to, the register pursuant to paragraph (8); or
- (b) remove a person’s name from the register, pursuant to paragraph (9)(a),

may appeal from that decision to the Statutory Committee which may decide the appeal.

(12) This Article does not apply to a person who is registered as a visiting pharmaceutical chemist from a relevant European State.”.

Transitional provisions

3.—(1) In this Article—

“the Council” means the Council of the Pharmaceutical Society of Northern Ireland;

“a pre-existing indemnity arrangement” means—

- (a) an adequate and appropriate indemnity arrangement commenced on or before the 24th October 2013; or
- (b) an adequate and appropriate insurance policy commenced on or before the 24th October 2013;

“registrar” means the registrar appointed under Article 9(1) of the principal Order;

“the transitional period” means the twelve month period that ends at the end of 24th October 2014.

(2) Subject to paragraph (4), the obligation in Article 11A(1) of the principal Order (*Indemnity arrangements*) for a registered person to have an appropriate indemnity arrangement in respect of liabilities which may be incurred in practising as a pharmaceutical chemist does not apply during the transitional period where there is a pre-existing indemnity arrangement in relation to that registered person.

(3) Where paragraph (2) applies, the registrar shall request in writing that a registered person who practises as a pharmaceutical chemist provides evidence of the pre-existing indemnity arrangement to him within such period as the registrar may specify.

(4) Nothing in paragraph (2) affects the duty of a registered person who practises as a pharmaceutical chemist—

- (a) before the end of the transitional period, to comply with the obligation in Article 11A(1) as it otherwise has effect on or before the expiry of the pre-existing indemnity arrangement; and
- (b) at or after the end of the transitional period.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on
XX October 2013

Joyce Cairns
A senior officer of the
Department of Health, Social Services and
Public Safety

EXPLANATORY NOTE

(This note is not part of the Order)

This Order makes amendments to the Pharmacy (Northern Ireland) Order 1976, which is the framework legislation for pharmacy within Northern Ireland. These changes reflect the requirements under Article 4(2)(d) of directive 2011/24/EU for a Member State of treatment to have in place systems of professional liability cover or similar.

The changes require registered persons to have appropriate cover under an indemnity arrangement in respect of liabilities which may be incurred in practising as a pharmaceutical chemist. The amendment also makes it clear that pharmaceutical chemists cannot practise unless there is an indemnity arrangement in operation in relation to that person. The amendments introduce enabling powers for the Council of the Pharmaceutical Society of Northern Ireland ('the Society') to make regulations requiring a pharmaceutical chemist to inform the registrar if their cover provided under an indemnity arrangement ceases to be in operation, and to inform the registrar if appropriate cover under an indemnity arrangement is provided by an employer. Failure to comply with the provisions can be dealt with as a ground on which registration as a pharmaceutical chemist may be withdrawn or refused by the registrar.

A Transposition Note in relation to this Order is annexed to the Explanatory Memorandum which is available alongside the Order on www.legislation.gov.uk.