

EXPLANATORY MEMORANDUM TO

Pharmaceutical Services (Amendment) Regulations (Northern Ireland) 2009

S.R. 2009 No. 320

1. Introduction

- 1.1. This Explanatory Memorandum has been prepared by the Department of Health, Social Services and Public Safety to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.
- 1.2. The Statutory Rule is made under the Health and Personal Social Services (Northern Ireland) Order 1972 and is subject to the negative resolution procedure.

2. Purpose

- 2.1. These Regulations further amend the Pharmaceutical Services Regulations (Northern Ireland) 1997.
- 2.2. They contain measures enabling temporary emergency changes to the arrangements for the provision of pharmaceutical services in the event of an emergency arising out of a threat to human welfare which is caused or which may be caused by human illness (for example, pandemic influenza).
- 2.3. In the case of such an emergency, arrangements are put in place to enable community pharmacies to relocate temporarily or take on additional premises and services (such as supplying domiciliary oxygen services) without needing to go through the normal applications process – and to enable doctors who provide pharmaceutical services to provide pharmaceutical services to patients who are not on their normal patient list.
- 2.4. Community pharmacies included in a pharmaceutical list, whose opening hours are subject to detailed provisions in the Pharmaceutical Regulations, are given additional flexibilities to allow them to make emergency changes to their opening hours and to close premises, where it is reasonable to do so.
- 2.5. Community pharmacies and doctors who provide pharmaceutical services will revert to their normal arrangements with the Regional Board after the emergency, unless these have been changed in the mean time via the normal applications process.

3. Background

- 3.1. Due to the current pandemic threat this Department needs to make changes to the Pharmaceutical Services Regulations (NI) 1997. These changes will relax certain regulatory requirements and contractual terms and conditions during the course of a pandemic. They are designed to be temporary measures to give both the Health Service and providers of pharmaceutical services flexibility to enable them, wherever possible, to maintain maximum services locally. The changes would be triggered, if required, by means of Directions and they mirror changes being introduced by the Department of Health.

- 3.2. These amendments will allow for flexibility within community pharmacy during periods of inadequate staffing, safety concerns or the inability to operate efficiently. They could also facilitate longer opening hours to deal with increased demand for services, or relocation particularly if other providers have to close.

4. Consultation

- 4.1. These proposals have already been subject to UK wide consultation in early 2009 when the Medical and Healthcare Products Regulatory Agency/Department of Health/Home Office consulted on proposed legislative changes for planning in the event of pandemic flu. Respondents to that consultation, including the Pharmaceutical Society of Northern Ireland, were in favour of the proposed changes.

5. Equality Impact

- 5.1. As the measure has no adverse impact on Section 75 groups the Department has concluded it is not necessary to submit this measure to a full EQIA.

6. Regulatory Impact

- 6.1. A Regulatory Impact Assessment is not considered necessary as the impact of the reductions will not have an adverse impact on business, charities, social enterprise or voluntary bodies.

7. Financial Implications

- 7.1. None

8. Section 24 of the Northern Ireland Act 1998

- 8.1. The proposed legislation is considered compatible with section 24 of the Northern Ireland Act 1998.

9. EU Implications

- 9.1. Not applicable

10. Parity or Replicatory Measure

- 10.1. Similar legislation has been made in the rest of the UK.

11. Additional Information

- 11.1. None.