EXPLANATORY MEMORANDUM TO

THE MEDICINES ACT 1968 (PHARMACY) ORDER 2011

2011 No. 2647

1. This Explanatory Memorandum has been prepared by the Department of Health and the Department of Health, Social Services and Public Safety, Northern Ireland and is laid by Command of Her Majesty.

2. Purpose of the instrument

2.1 The purpose of this Order is to remove the restriction (contained in sections 70(5) and 71(5) of the Medicines Act 1968 ("the Act")) which is placed on pharmacists who are, by virtue of a pharmacy qualification awarded by European Union (EU) Member States, apart from the United Kingdom, or by Iceland, Norway, Liechtenstein or Switzerland ("relevant European states"), entitled to practise as a pharmacist in Great Britain (GB) by virtue being entered in Part 1 or Part 4 of the register established and maintained by the General Pharmaceutical Council under article 19 of the Pharmacy Order 2010 ("the register"), from being a responsible pharmacist in charge of a newly established pharmacy. For these purposes, a "newly established pharmacy" is a pharmacy premises in Great Britain (GB) that has been a registered pharmacy for less than 3 years. This restriction is commonly known as "the 3 year rule".

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 This Order will come into force on 4th November 2011. It is removing a restriction in the Medicines Act 1968 and does not therefore require any steps to be taken by persons in order to comply with it. The purpose of removing the restriction is to put pharmacists registered in GB under the European mutual arrangements for the recognition of professional qualifications on a par with pharmacists who were awarded their pharmacy qualification in GB. Its immediate removal has the support of both the pharmacy profession and representative organisations for pharmacy.

4. Legislative Context

4.1 This Order is made jointly by the Secretary of State for Health and the Minister for Health, Social Services and Public Safety under section 73 of the Act. It removes the restriction currently contained in sections 70(5) and 71(5) of the Act.

5. Territorial Extent and Application

5.1 The Order applies to the United Kingdom (UK) although the provisions of the Act which are being revoked do not have effect in relation to pharmacy premises in Northern Ireland.

6. European Convention on Human Rights

Earl Howe, the Parliamentary Under Secretary of State for Quality – Lords, has made the following statement regarding Human Rights:

"In my view the provisions of the Medicines Act 1968 (Pharmacy) Order 2011 are compatible with the Convention rights".

7. Policy background

7.1 All pharmacists practising in GB must be entered in the register as must all pharmacy premises. Some pharmacists are entitled to practise in GB, because of arrangements which are in place for the mutual recognition of pharmacy qualifications awarded outside of the UK.

7.2 EU Member States can, under EC Directive 85/433 (now Directive 2005/36), put restrictions on the recognition of pharmacy qualifications awarded outside of their territories. In GB there is a restriction imposed on pharmacists who were awarded their pharmacy qualification in a "relevant European State" (which is defined in the Act as being an EU Member State, apart from the United Kingdom, or Iceland, Norway, Liechtenstein or Switzerland) and who are entitled to practise in GB. These pharmacists cannot be the pharmacist in charge (the "responsible pharmacist") of a newly established pharmacy which is a pharmacy that has been a registered pharmacy for less than three years. This restriction is known as the "the 3 year rule".

7.3 The proposal to remove the restriction is as the result of changes in the domestic environment for pharmaceutical services provision as well as increasing relaxation on rules of pharmacy ownership in EEA countries. The restriction was originally put in place for economic reasons, because pharmacy owners in GB felt that they were not in a comparable position to those in other parts of the EU.

7.4 The removal of the restriction does not give rise to a need to consolidate the legislation amended by this Order

8. Consultation outcome

8.1 A public consultation was held on the proposal to remove the restriction on pharmacists, registered in GB by virtue of a qualification awarded by a relevant European State, being in charge of a pharmacy, which has been a registered pharmacy for less than 3 years. The consultation was published on the Department of Health website on 12 January 2011 and closed on 7 April 2011. Thirty five responses were returned from a mix of organisations and individuals.

8.2 A report of the consultation has been prepared and is being laid before Parliament alongside this Order. Copies of the document *Recognition of pharmacist qualifications awarded in the European Economic Area and Switzerland: removing the "3 year rule"*

from new pharmacies. Consultation report is available on the Department of Health website at http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

8.3 There was a high level of support (80%) from respondents for the overall proposal to remove the restriction and more respondents identified benefits from the removal (57%) than identified risks (20%). In particular, respondents identified benefits

- for patients
  - improved continuity of care;
- for pharmacists
  - putting all pharmacists registered to practise in GB on a level footing;
  - wider job opportunities
- for employers
  - a wider pool of potential employees
  - a reduction in bureaucracy for filling vacancies, both permanent posts and locums
  - cost savings resulting from reduced bureaucracy

8.4 Risks identified were mainly concerned with the experience of the pharmacist and their familiarity with practice in GB. This was considered in the report of the consultation – paragraphs 4.7 to 4.15.

8.5 Based on the response to the consultation it was proposed to proceed to remove the restriction for pharmacists registered by virtue of a qualification awarded by a relevant European State, from being the responsible pharmacist in a pharmacy which has been registered for less than 3 years. This is being achieved through an order under section 73 of the Act.

9. Guidance

9.1 The Department of Health have not issued any guidance in relation to this Order.

10. Impact

10.1 The impact on business, charities or voluntary bodies is minimal in terms of its monetary implications. These and the more general impact issues arising out of this Order are discussed in the attached Impact Assessment.

10.2 The impact on the public sector is zero.

10.3 An Impact Assessment is attached to this memorandum and will be published alongside the Explanatory Memorandum on www.legislation.gov.uk.

11. Regulating small business

11.1 The legislation applies to small business. However as an existing restriction is being removed the impact on small business is likely to be positive.

12. Monitoring & review

12.1 The legislation will be subject to review by the Department of Health in 2014.

13. Contact

Diana Kenworthy at the Department of Health Tel: 020 7972 2820 or email diana.kenworthy@dh.gsi.gov.uk can answer any queries regarding the instrument.