EXPLANATORY MEMORANDUM TO

THE GENERAL PHARMACEUTICAL COUNCIL (CONSTITUTION) ORDER 2010

2010 No. 300

AND

THE PHARMACY ORDER 2010 (COMMENCEMENT ORDER NO. 1) ORDER OF COUNCIL 2010

2010 No. 299 C. 24

1. This Explanatory Memorandum has been prepared by the Department of Health and is laid before Parliament and the Scottish Parliament by Command of Her Majesty.

2. Purpose of the instruments

- 2.1 The General Pharmaceutical Council (Constitution) Order 2010 ("the Constitution Order") is an order of the Privy Council made under article 4(2), and paragraph 2 of Schedule 1 to, the Pharmacy Order 2010. The Constitution Order makes provision for the constitution of the General Pharmaceutical Council (the GPhC), the new regulator for pharmacists, pharmacy technicians and registered pharmacies.
- 2.2 The Pharmacy Order 2010 (Commencement No.1) Order of Council 2010 ("The Commencement Order") is an order of the Privy Council that brings into force the amendment of Schedule 6 to the Health Act 2006 which is contained in paragraph 12(b) of Schedule 4 to the Pharmacy Order 2010. This amendment enables the Appointments Commission to exercise the Privy Council's functions under paragraph 1 (2) of Schedule 1 to the Pharmacy Order 2010 to appoint members of the GPhC.
- 3. Matters of special interest to the Joint Committee on Statutory Instruments
 - 3.1 None.

4. Legislative Context

4.1 The White Paper - *Trust, Assurance and Safety: the Regulation of Health Professionals in the 21st Century* (the White Paper) put forward a programme of reform to the regulation of the health care professions. The main emphasis of the reforms was to increase accountability of the health professions' regulators while at the same time increasing their independence from Government. One specific recommendation in the White Paper was the establishment of a new regulator for pharmacy to separate this function from that of professional leadership. Both functions are currently carried out by the Royal Pharmaceutical Society of Great Britain.

4.2 The Pharmacy Order 2010 establishes the GPhC as the new pharmacy regulator. The Constitution Order is an Order of the Privy Council made under article 4(2) of, and paragraph 2 of Schedule 1 to, the Pharmacy Order 2010 and sets out the detailed requirements for the constitution of the GPhC.

5. Territorial Extent and Application

5.1 Both the Constitution Order and the Commencement Order apply to Great Britain.

6. European Convention on Human Rights

The Constitution Order does not amend primary legislation, so no statement is required. The Commencement Order commences a provision in the Pharmacy Order 2010 that amends primary legislation, but the necessary statement was made in relation to the Pharmacy Order 2010.

7. Policy background

- What is being done and why
- 7.1 The Pharmacy Order 2010 takes forward recommendations in the White Paper which are designed to modernise and strengthen the regulation of healthcare professionals, to ensure patient, public and professional confidence in the regulatory bodies and make the protection of patients and the public a priority. It enables the constitutional arrangements for the GPhC to be set out in an order of the Privy Council.
- 7.2 The General Pharmaceutical Council (Constitution) Order 2010, sets out the details of the constitution of the GPhC. In particular it:
 - Establishes a Council of 14 members, 7 of whom are to be registrant and 7 lay members, the chair to be appointed by the Privy Council, within the overall membership of 14. The chair may be either a registrant or a lay person.
 - Enables the Privy Council to set the term of office of the chair and members of the Council on appointment and sets a maximum period of office which the chair and members of the Council may hold.
 - Sets out criteria for disqualification of people from appointment as members of the Council.
 - Sets out the circumstances in which a member of the Council or the chair may be suspended or removed from office.
 - Sets out deputising arrangements for the chair.
 - Sets out the quorum of the Council.

- Sets out the effect of Council vacancies on the validity of its proceedings.
- Provides that the Privy Council will appoint the first Chief Executive Officer of the GPhC.

• Consolidation

- 7.3 The General Pharmaceutical Council (Constitution) Order 2010 is self-standing and does not amend other legislation.
- 7.4 The Pharmacy Order 2010 (Commencement Order No. I) Order of Council 2010 brings into effect the amendment of Schedule 6 of the Health Act 2006 in paragraph 12(b) of Schedule 4 to the Pharmacy Order 2010. This enables the Appointments Commission to carry out the Privy Council's functions of appointing members of the GPhC.

8. Consultation outcome

- 8.1 The General Pharmaceutical Council (Constitution) Order 2010 was the subject of a joint public consultation, including on behalf of the Scottish Ministers, from 27 October to 25 November 2009. Ministers agreed to a shortened consultation period because of the similarity of the proposed constitutional arrangements for the GPhC to those of other health care regulators, the recent consultation on the draft Pharmacy Order 2010, which included some of the main features of the GPhC's constitution arrangements and the planned opening of the GPhC in spring 2010.
- 8.2 Eight responses to the consultation were received and the respondents represented a mix of pharmacy organisations. A copy of the report on the consultation is available at:

 http://www.dh.gov.uk/en/Consultations/Responsestoconsultations/DH_111013
 The constitution arrangements were generally welcomed and supported overall. However, the following areas of concern were raised:
 - In relation to the reasons for disqualification of a person from appointment to the Council there was concern from one respondent that there should not be discrimination against those who had committed a crime especially where it was a less severe offence.

 Another respondent was concerned that the individual concerned could be exonerated of a crime with which they were charged. A further respondent thought that the definition of lay was too narrowly drawn and other health professionals should be allowed to stand for appointment as lay members. After consideration of these points it has been decided to maintain the disqualifications as drafted as this is in line with arrangements being adopted across the health care regulators.
 - There was some concern expressed about the quorum arrangements. Two respondents were concerned that the parity between lay and professional members should be preserved within the quorum. The

reservation was noted but it has been decided that the stipulation for a quorum of 8 members with no specification of the make up between registrant and lay members should be adopted.

8.3 Although there have been no changes made to the Constitution Order as a direct result of the consultation exercise, article 5 of the Order has been revised to include a new ground for disqualification for appointment as a member of the Council (see article 5(g)). This is a technical change which has become necessary because of the commencement of changes made to the law on insolvency introduced by the Tribunals, Courts and Enforcement Act 2007.

9. Guidance

9.1 Neither the Department of Health nor the Scottish Government has issued any guidance in relation to these two Orders.

10. Impact

- 10.1 There is minimum impact on business, charities or voluntary bodies.
- An Impact Assessment was prepared for the consultation on the related Pharmacy Order 2010 and is available at www.opsi.gov.uk/si/si2010/draft/em/ukdsiem 9780111487358 en.pdf

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 This legislation will be subject to internal review by the Department of Health and the Scottish Government in 2011.

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.