

**EXPLANATORY MEMORANDUM TO
THE GENERAL PHARMACEUTICAL COUNCIL (TRANSFER OF PROPERTY,
RIGHTS AND LIABILITIES, FEES AND GRANTS) ORDER 2010**

2010 No. 1618

AND

**THE PHARMACY ORDER 2010 (APPROVED EUROPEAN PHARMACY
QUALIFICATIONS) ORDER 2010**

2010 No. 1620

AND

**THE PHARMACY ORDER 2010 (COMMENCEMENT ORDER NO. 2) ORDER OF
COUNCIL 2010**

2010 No. 1621 (C.85)

AND

**THE PHARMACY ORDER 2010 (REGISTRATION – TRANSITIONAL
PROVISIONS) ORDER 2010**

2010 No. 1619

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

2. **Purpose of the instruments**

2.1 The General Pharmaceutical Council (Transfer of Property, Rights and Liabilities, Fees and Grants) Order 2010 (“the Transfer Order”) sets out the property, rights and liabilities of the Royal Pharmaceutical Society of Great Britain (RPSGB) which will transfer to the General Pharmaceutical Council (GPhC) on the appointed day. It is made under the powers conferred by paragraphs 17 of Schedule 5 to the Pharmacy Order 2010 (“the Pharmacy Order 2010”) (SI 2010/231).

2.2 The Pharmacy Order 2010 (Approved European Pharmacy Qualifications) Order 2010 (“the Approved European Pharmacy Qualifications Order”) provides for the recognition, within Great Britain of certain pharmacy qualifications awarded in Switzerland and in EEA States, other than the United Kingdom. It is made under powers conferred by article 21(1)(b) and (3) of the Pharmacy Order 2010.

2.3 The Pharmacy Order 2010 (Commencement Order No. 2) Order of Council 2010 (“the Commencement Order No. 2) is an order of the Privy Council that is made under the power conferred by article 1(5) of the Pharmacy Order 2010. It makes provision for the coming into force of the Order, except in so far as it is already in force.

2.4 The Pharmacy Order 2010 (Registration – Transitional Provisions) Order 2010 (“the Transitional Provisions Order”) sets out, for transitional purposes, the procedures relating to the first renewal of entries made in the Register and the first renewal of annotations made to such entries. It is made under the powers conferred by article 69(3) of the Pharmacy Order 2010 in connection with the commencement of Schedule 5 to that Order.

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

3.1 None.

4. Legislative Context

4.1 The Health and Social Care Act 2008 set out a series of provisions to reform the regulation of health care professionals. 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 provision enabled the establishment of a new regulator for pharmacy to separate regulation from professional leadership, both of these functions being currently carried out by the RPSGB.

4.2 The Pharmacy Order 2010 establishes the GPhC as the new pharmacy regulator. There is provision within that Order to enable the transfer of relevant property, rights and liabilities in connection with RPSGB regulatory functions and the transfer of relevant staff. from the RPSGB to the GPhC, to enable the GPhC to undertake its regulatory role. Operational transfer of the regulatory functions from the RPSGB to the GPhC will take place on 27 September 2010, once the necessary Rules, which set out in more detail the procedures and operation of the GPhC, are in place.

4.3 Under the provisions of the Pharmacy Order 2010, all Commencement Orders are subject to negative resolution procedure. The Commencement Order No. 2 is therefore brought to the attention of the Joint Committee on Statutory Instruments.

5. Territorial Extent and Application

5.1 These instruments apply to Great Britain.

6. European Convention on Human Rights

6.1 As the instruments are subject to negative resolution procedure and do not amend primary legislation, no statement is required.

7. Policy background

- *What is being done and why*

7.1 The Health and Social Care Act 2008 included provisions which are designed to modernise and strengthen the regulation of health care professionals, to ensure patient, public and professional confidence in the regulatory bodies and make protection of patients and the public a priority. The Pharmacy Order 2010 was made under the Health Act 1999 as amended by the Health and Social Care Act 2008, to establish the GPhC as the new regulator for pharmacy, in place of the RPSGB.

The Transfer Order

7.2 To enable the GPhC to assume responsibility for the regulation of pharmacy, the Transfer Order establishes those material and non-material items transferring from the current to the new regulator in order to effect a seamless transition of regulation. Article 1 of the Transfer Order makes provision for citation, the commencement and interpretation.

7.3 Article 2 of the Transfer Order specifies the property, rights and liabilities of the RPSGB which will be transferred to the GPhC on the day the regulatory activities are transferred (“the transfer date”). Schedule 1 to the Transfer Order provides detail of ;

- furniture, fittings, plant, equipment and machinery which the RPSGB has and, because of their use by or in connection with the regulatory activity of the RPSGB, will pass to the GPhC. These comprise -
 - software, data and hardware relating to the 2007 Registers and the premises Registers (“the Concept system”);
 - information relating to the inspection of registered pharmacies in Great Britain and the Isle of Man which contained in the Inspectors Record of Visits (“the IROV Database”);
 - the database relating to the Case Managements System and the information contained in that database;
 - all computers, mobile telephones, data cards and electronic instruments used by the relevant staff;
 - all office furniture used by the relevant staff;
 - all goods, stocks, inventory, stores and raw materials used by or in connection with the RPSGB’s regulatory activity; and
 - all assets, tangible or intangible, purchased through money supplied by way of grants made by the Department of Health to the RPSGB in relation to the RPSGB’s work in preparing for the establishment of the GPhC;
- contracts and agreements relating to the maintenance of the computer systems, cars and electronic equipment which is being transferred. These are -
 - maintenance contracts in respect of the Concept system;
 - operating leases and maintenance contracts for cars, photocopiers, printers and other electronic equipment used by relevant staff;
 - insurance policies relating to regulatory activities being transferred; and

- all other contracts, agreements, arrangements, engagements, assignments and orders which relate to the RPSGB's regulatory activity.
- intellectual property rights which the RPSGB has and which relate to regulatory activity including -
 - all books, records and other documents, including documents and records held on computer or other electronic device, relating to
 - information contained in the 2007 registers and the premises register;
 - persons who are or have been entered in the 2007 registers as a practising pharmacist or pharmacy technician;
 - pre-registration students who have applied for entry in the 2007 registers as a practising pharmacist or pharmacy technician;
 - registered pharmacies entered in the premises register.
 - all records and evidence held by the RPSGB relating to
 - any investigation or proceedings conducted by the RPSGB against a person carrying on a retail pharmacy business at a registered pharmacy; and
 - any inspection conducted by an inspector on behalf or in conjunction with a relevant UK regulatory body which does not relate to the regulatory activity of the RPSGB.
 - records relating to the pre-registration exam and pre-registration students including questions set in previous exams or prepared for future exams;
 - records and other data relating to the quality assurance of education and training provision;
 - employment records of relevant staff transferring to the GPhC;
 - domain names registered by the RPSGB in respect of the GPhC; and,
 - all authorisations and quality assurance markings held by the RPSGB in connection with the regulation of retail pharmacy business carried on by registered pharmacies over the internet.

7.4 Article 2 also details the rights and liabilities relating to any relevant staff, who are named in a list compiled by the GPhC of staff whose employment with the RPSGB is to transfer to the GPhC on the transfer date. The liability comprises -

- all salaries, wages and emoluments;
- all statutory contributions;
- all income tax deductible under PAYE;
- all employer's contributions; and
- any other employment costs.

7.5 In Article 3 certain specific liabilities which will not transfer from the RPSGB to the GPhC are set out. This includes -

- any liability in tort in relation to claims of damages for death or personal injury caused or alleged to have been caused before the transfer date;
- any liability in relation to which the Secretary of State has given an indemnity to the RPSGB; and
- any liability arising in respect of the Royal Pharmaceutical Society of Great Britain Staff Pension Scheme.

7.6 Article 4 details the amount of the regulatory fees, collected by the RPSGB in respect of persons entered in the 2007 Registers and pharmacies entered in the premises register for the year 2010, which will be transferred to the GPhC.

7.7 Article 5 makes provision for the amount of money which will be transferred from the RPSGB to the GPhC in respect of the remainder of grants, which have been made to the RPSGB. These are listed in Schedule 2 as the grants made by

- the Department of Health in England in connection with costs incurred in preparing for the establishment of the GPhC;
- the Departments of Health in England in respect of the monitoring of controlled drugs; and
- the Department of Health in England in respect of research into and development of revalidation standards.

7.8 The final article of the Transfer Order is concerned with general supplementary provisions in relation to things which have been done by or in respect of the property, rights or liabilities which are being transferred from the RPSGB to the GPhC, including -

- activities in process (such as legal proceedings) to have effect as if done by, or in relation to, and may be continued by or in relation to the GPhC,
- references to the RPSGB contained in any agreement (written or un-written) or instrument or other document to be treated as references to the GPhC;
- rights to terminate or vary a contract, arrangement or instrument are not to be triggered because of its transfer to the GPhC;
- transfers which take place as a result of the transfer Order do not require consent, which might otherwise apply or whether they would otherwise be capable of being transferred; and
- the responsibility of the Clerk to the Privy Council for issuing a certificate, after consultation with the RPSGB and the GPhC, which pronounces on the effect of the Transfer Order.

The Approved European Pharmacy Qualifications Order

7.9 This Order provides, in Article 2, for the recognition of appropriate diplomas which were awarded by Switzerland and EEA States, other than the United Kingdom, which are considered as being approved qualifications for the purposes of entry in Part 1 of the Register. Pharmacists who are appropriately qualified in accordance with the provisions of this Order, once registered by the GPhC, may then practice as pharmacists in Great Britain, provided their fitness to practise is not impaired and they have paid the appropriate fee.

7.10 Article 3 sets out certain conditions which relate to the recognition of such diplomas. These include -

- for diplomas which are listed by name in Annex V, point 5.6.2 of the Directive (“Annex V of the Directive”) the Registrar is satisfied that the diploma guarantees the holder’s training meets requirements set out in Article 44 of the Directive and the diploma is accompanied by any certificates which are appropriate;
- for diplomas which are not listed by name in Annex V of the Directive the diploma is accompanied by a certificate from the competent authority of the relevant European State which attests that the diploma is evidence of training which satisfies the requirements of Article 44 of the Directive and is treated by the competent authority of the relevant European State in which it was awarded as being equivalent to a diploma listed in relation to that State in Annex V of the Directive; and,
- whichever of the above points apply the competent authorities of the relevant European State must provide a certificate, which is made available to the Registrar, stating that the holder of the diploma has been effectively and lawfully engaged in the practice of an activity which is open to pharmacists in that State for at least three consecutive years during the five years preceding the date of the certificate.

7.11 Article 4 sets out the conditions relating to old diplomas granted in respect of training commenced in the former Czechoslovakia, the former Soviet Union or the former Yugoslavia where it is required that a certificate is made available to the Registrar stating that the competent authorities of the relevant European State have certified that -

- the diploma has, on its territory, the same legal validity as regards access to the practice of pharmacy as the diploma listed in Annex V of the Directive in respect of their State;
- the holder of the diploma has been effectively and lawfully engaged in the practice of an activity which is open to pharmacists in that State for at least three consecutive years during the five years preceding the date of the certificate.

7.12 Article 5 relates to the conditions concerning old diplomas granted in respect of training commenced in the former German Democratic Republic. This is considered an appropriate European diploma if -

- the diploma entitles the holder to practise pharmacy throughout the territory of Germany on the same conditions as those applying to the holder of a diploma listed in Annex V of the Directive in respect of Germany; and
- a certificate is made available to the Registrar from the competent authorities in Germany certifying that the holder of the diploma has been effectively and lawfully engaged in the practice of an activity which is open to pharmacists in Germany for at least three consecutive years during the five years preceding the date of the certificate.

7.13 Article 6 sets out the conditions relating to new diplomas, which are not listed in Annex V of the Directive. It requires that the Registrar has made available to him a certificate from the competent authority in the relevant European State which has awarded the diploma stating that the diploma is -

- evidence of training that satisfies the requirements of Article 44 of the Directive; and
- treated by them as equivalent to a diploma listed in Annex V of the Directive in respect of that State.

7.14 Article 7 establishes that where the GPhC, including the Registrar, has justified doubts about the evidence which is presented but the relevant competent authority has provided confirmation of authenticity then the diploma may be accepted.

The Commencement Order No. 2

7.15 The Commencement Order No. 2 sets 27 September 2010 as the appointed day for the coming into force of the following provisions of the Pharmacy Order 2010 for all purposes-

- Part 2 and Schedule 1 relating to the Council and its Committees;
- Part 3 relating to standards in retail pharmacies;
- Part 4 relating to registration;
- Part 5 relating to education, training and continuing professional development;
- Part 6 relating to fitness to practise;
- Part 7 relating to proceedings;
- Part 8 , except as already in force;
- Schedule 2 relating to visiting practitioners from relevant European States;
- Schedule 3 relating to The Directive: Designation of competent authority etc.; and
- Schedule 4 Part 1 except as already in force and Part 2 relating to amendments to primary and secondary legislation.

7.16 The Commencement Order No.2 also sets the 4 January 2010 as the appointed day for the coming into force of provisions relating to the renewal of entries in Part 1, Part 2 and Part 3 of the Register and renewal of annotations in the Register, namely

- paragraphs (6) to (10) of article 24 of the Pharmacy Order 2010; and
- paragraph (2) of article 40 of the Pharmacy Order 2010 in so far as it relates to paragraphs (6) to (10) of article 24 of that Order.

The Transitional Provisions Order

7.17 This Order sets out the arrangements for renewal of entries to the Register which are due to cease to be valid on 31 December 2010 unless renewed. The purpose of the Order is to enable the GPhC, as it assumes responsibility for registration, to give adequate notice to registrants who are required to renew their entries and annotations in the Register. This applies to all registrants transferring automatically from the registers held by the RPSGB to the GPhC Register. In particular it provides

- that the Registrar must send out the relevant application forms for renewal of entries in Part 1, Part 2 or Part 3 of the Register and renewal of annotations at least 2 months prior to 31 December 2010;
- that registrants who have not received an application form for renewal of entries in the Register, or renewal of annotations, two months prior to 31 December 2010 must notify the Registrar accordingly;
- the form and manner of applications for renewal of entries in Parts 1, 2 or 3 of the Register and any supporting documents, information or evidence;
- the circumstances in which the Registrar must refuse applications for renewal of registration. These include where the application is not made within the prescribed time limit, or is not accompanied by the required supporting documentation, information and/or evidence which is mentioned in the application form or where an applicant has not paid the appropriate fee or made arrangements with the Registrar to pay the relevant fee;
- the circumstances in which the Registrar may not remove a registrant's entry from Part 1 or 2 of the Register, that is where there is an ongoing fitness to practice investigation or proceedings and the registrant has not made an application for renewal, except where the Registrar considers that the public interest would be best served by so doing;
- the form of applications for renewal of entries recording annotations in respect of specialisations. The evidence to be submitted in support of renewals is set out. Currently the only specialisation recognised by the GPhC is pharmacist prescribing; and
- Where a fee is payable all applications must be accompanied by the relevant fee.

Consolidation

7.18 No consolidation is necessary as neither the Transfer Order, the Approved European Pharmacy Qualifications Order nor the Transitional Provisions Order amend previous legislation.

7.19 The Pharmacy Order 2010 (Commencement Order No. 2) Order of Council 2010 brings into the effect all of the provisions of the Pharmacy Order 2010 for all purposes, except for those provisions which were previously brought into effect by article 1(2) of the Pharmacy Order 2010 and The Pharmacy Order 2010 (Commencement Order No.1) Order of Council 2010. No consolidation is therefore required.

8. Consultation outcome

8.1 The Transfer Order has not been the subject of consultation. However, the Chief Executives and Registrars of the RPSGB and the GPhC have written to the Department of Health to confirm their agreement to the provisions set out in the Transfer Order.

8.2 The Approved Pharmacy Qualification Order and the Pharmacy Order 2010, under which it was made, contain the legislative measures necessary for implementing

Council Directive 2005/36/EC concerning the co-ordination of provisions laid down by law, regulation and administrative action in respect of certain activities in the field of pharmacy for the mutual recognition of diplomas, certificates and other evidence of formal qualifications in pharmacy. A consultation was not required.

8.3 The procedures for renewal of registration formed part of the consultation which the GPhC undertook in respect of its proposed Rules. The consultation was carried out across Great Britain between 16 February and 2 May 2010. The GPhC has prepared a detailed response to the views expressed by those who replied to the consultation. This “Consultation Report” was approved by the GPhC’s Council on 3 June 2010 and is available on its website at <http://www.pharmacyregulation.org/getinvolved/consultations/index.aspx>. However transitional provisions were needed in respect of the first renewal of entries made in the register on the day appointed for the coming into force of article 19 of the pharmacy Order. There has therefore not been any consultation on the procedure for the initial renewals which are set out in the Transfer Order although these provisions are to a large extent modelled on similar provisions contained in the Registration Rules.

9. Guidance

9.1 Neither the Department of Health nor the Scottish Government has issued guidance in relation to these three Orders. However, it is expected that the GPhC will be providing guidance for registrants.

10. Impact

10.1 There is minimum impact on business, charities or voluntary bodies..

10.2 There is no impact on the public sector.

10.3 An Impact Assessment was prepared for the related Pharmacy Order 2010 (SI 2010/231) and is available as part of the Explanatory Memorandum at <http://www.opsi.gov.uk/si/si201002>

11. Regulating small business

11.1 The legislation does not apply to small business.

12. Monitoring & review

12.1 This legislation, as part of the Professional Standards Programme, will be subject to 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.