EXPLANATORY MEMORANDUM TO

THE GENERAL PHARMACEUTICAL COUNCIL (REGISTRATION RULES) ORDER OF COUNCIL 2010

2010 No. 1617

AND

THE GENERAL PHARMACEUTICAL COUNCIL (STATUTORY COMMITTEES AND THEIR ADVISERS RULES) ORDER OF COUNCIL 2010

2010 No. 1616

AND

THE GENERAL PHARMACEUTICAL COUNCIL (FITNESS TO PRACTISE AND DISQUALIFICATION ETC. RULES) ORDER OF COUNCIL 2010

2010 No. 1615

AND

THE GENERAL PHARMACEUTICAL COUNCIL (APPEALS COMMITTEE RULES) ORDER OF COUNCIL 2010

2010 No. 1614

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 instrument

2.1 The Pharmacy Order 2010 (SI 2010/231) establishes a new regulator for pharmacy, the General Pharmaceutical Council (GPhC), and sets out the arrangements, in Great Britain, for the professional regulation of pharmacists, pharmacy technicians and registered pharmacy premises. The GPhC replaces the Royal Pharmaceutical Society of Great Britain (RPSGB) as the regulator for pharmacy in Great Britain. The RPSGB retains its other role as the professional body. The Rules scheduled to, and approved by, these four Orders of Council set out the details of the GPhC's arrangements in relation to the registration of pharmacists, pharmacy technicians and pharmacy premises; the composition, constitution and general procedures of the three statutory committees; the functions of legal, clinical and specialist advisers; the procedure for dealing with fitness to practise proceedings; and the procedure for dealing with appeals against decisions relating to registration.

2.2 The Rules scheduled to the General Pharmaceutical Council (Registration Rules) Order of Council 2010 ("the Registration Rules") are made under sections 74A(6) and (7), 74B(2), 74C(4), 74E(2), 74G(2) and 74I(3) of the Medicines Act 1968 and articles 19(3) and (4), 23(1), 25(3), 27(1), 28(1), 29(4), 30(2) and (4), 31(1), 36(1), 37(3) and 66(1) of the Pharmacy Order 2010. The Registration Rules set out matters relating to the register which the Registrar appointed by the GPhC is required to establish and maintain in relation to the registration of pharmacists, pharmacy technicians and premises at which a retail pharmacy business is to be carried on.("the Register").

2.3 The Rules scheduled to the General Pharmaceutical Council (Statutory Committees and their Advisers Rules) Order of Council 2010 ("the Statutory Committees Rules") are made under articles 18(2), 63(4), 64(8) and 66(1) of, and paragraph 5 of Schedule 1 to, the Pharmacy Order 2010. The Statutory Committees Rules set out matters relating to the constitution and composition of the three statutory committees of the GPhC and to the functions of advisers to the statutory committees and to other non-statutory committees of the GPhC.

2.4 The Rules scheduled to the General Pharmaceutical Council (Fitness to Practise and Disqualification etc. Rules) Order of Council 2010 ("the Fitness to Practise Rules") are made under articles 48(1)(b), 51(5), 52(1) and (2), 57(3), 61(1) to (3) and (6), 63(4), 64(8) and 66(1) of the Pharmacy Order 2010. The Fitness to Practise Rules set out matters relating to the procedures which will be followed by the GPhC when considering allegations that the fitness to practise of a registrant is impaired; allegations that a person should be disqualified from carrying on a retail pharmacy business and allegations of criminal conduct that the GPhC is under a duty to investigate.

2.5 The Rules scheduled to the General Pharmaceutical Council (Appeals Committee Rules) Order of Council 2010 ("the Appeals Committee Rules") are made under articles 61(1) to (3) and (6), 63(4), 64(8) and 66(1) of, and paragraph 5(1)(e) and (3)(d) of Schedule 1 to, the Pharmacy Order 2010. The Appeals Committee Rules provide for the functions of the Appeals Committee of the GPhC in respect of appeals relating to: the registration of pharmacists and pharmacy technicians; the provision of education, training tests or other means of assessment by institutions or other providers; or the registration of premises at which a retail pharmacy business is to be carried on, and for the procedures to be followed in proceeding before the Appeals Committee.

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 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 provision was for the

establishment of a new regulator for pharmacy to separate the regulatory function from that of 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. It enables details of processes for registering pharmacists, pharmacy technicians and pharmacy premises, the procedures to be followed by the statutory committees and procedures for appeals against appealable decisions, to be set out in Rules.

4.3 Operational transfer of the regulatory functions from the RPSGB to the GPhC will take place on 27 September 2010, once this suite of Rules is in place.

5. Territorial Extent and Application

5.1 These instruments apply to Great Britain.

6. European Convention on Human Rights

6.1 As these 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 designed to modernise and strengthen the regulation of healthcare professionals, to ensure patient, public and professional confidence in the regulatory bodies and to make the 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 suite of rules which are the subject of this Explanatory Memorandum, set out the GPhC's procedures in the following areas.

7.2 The Pharmacy Order 2010 provides for the Register to be in a number of parts. In particular, Part 1 is concerned with the registration of pharmacists, Part 2 with the registration of pharmacy technicians and Part 3 with the registration of pharmacy premises (registered pharmacies). Provision is also made for the registration of visiting pharmacists and pharmacy technicians in Parts 4 and 5 of the Register. The Registration Rules set out various matters relating to the Register including detailed provisions for the form and manner of applications relating to entry in the various Parts of the Register and for the renewal of entries. In particular the Registration Rules establish:-

- The ability of the Registrar, at his discretion, to waive fees prescribed in the Fees Rules, either completely or in part. This will allow the Registrar to make provision for low income fees. The Registration Rules also give the Registrar discretion, in specified circumstances, to offer payment of fees by direct debit in instalments, or otherwise.

Details of the operation of these arrangements are not specified in the Rules as they are an operational matter for the GPhC.

- The manner in which the Register is to be kept and maintained; that is in writing and securely, guarding against falsification;
- The content of the Register which will include, for registrants:
    - title and name under which they practise or intend to practise;
    - home address;
    - registration number
    - date of first and any subsequent entry in the Register;
    - period for which the entry is valid;
    - any annotations or specialisations;
    - any qualifications
    - date of review of CPD;
    - recording information in the Welsh language, where appropriate;
    - marking the Register to distinguish registrants who have temporary registration under the emergency registration provisions (article 34 of the Pharmacy Order 2010).

For registered pharmacies the Register will include:

- address of the premises;
- name and address of the person carrying on a retail pharmacy business at the premises;
- name under which the business trades;
- date of first and any subsequent entry in the Register;
- period for which the entry is valid;
- any conditions which attach to the entry;
- any annotations in respect of specialisations;
- where the owner of the business is a body corporate, the name and home address of the superintendent pharmacist;
- details of any improvement notices issued under article 13 of the Pharmacy Order 2010;
- recording information in the Welsh language, where appropriate;
- marking the Register to distinguish those premises which have temporary registration under to emergency registration provisions (section 74J of the Medicines Act 1968);

- Duty of registrants to notify the Registrar of changes to information in the Register;
- Detailed provision in relation to the form and manner of applications for entry in Parts 1, 2 or 3 of the Register. This includes
    - information to be provided by applicants for entry in the Register or for renewal of an entry and for recording of annotations. The provisions in relation to application forms of prospective pharmacists and pharmacy technicians for entry in the Register have been harmonised wherever possible;
    - countersignature of applications for registration may be by a pharmacists or pharmacy technicians;
    - the evidence to be provided in support of the application;
    - where the application is for registration in Parts 1 or 2 of the Register the Registrar, in making a decision about applicants'

good character, must have regard to the criteria for deciding whether fitness to practise is impaired that is specified in the Fitness to Practise Rules;

- For renewal of entries, the Registrar must give registrants at least 3 months' notice of the requirement to renew their entry in the Register and the registrant must make the application for renewal at least 2 months before the date on which their entry in the Register is due to expire. However, transitional arrangements are to be put in place in respect of the first renewal of entries transferred to the Register on the day appointed for the coming into force of article 19 of the Pharmacy Order 2010 ("the appointed day") (see below);
- The form of applications for recording annotations in respect of specialisations of registrants and renewal of such entries. The evidence to be submitted in support of applications and renewals is defined. The provisions have been broadly drafted to take into account possible future developments in specialisation within pharmacy. Currently the only specialisation recognised by the GPhC is pharmacist prescribing;
- The circumstances in which the Registrar may refuse applications for entry in the Register, applications for renewal of entries or the recording of annotations. 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 prescribed fee set out in rules made under article 36 of the Order or made arrangements with the Registrar to pay that fee;
- Procedure for the voluntary removal of entries or annotations from the Register and any subsequent restoration of these to the Register is also set out. In the case of registrants, restoration of an entry to the Register is not possible in cases where an application for renewal of an entry has not been made or has been made after the end of the prescribed time limit. In the case of pharmacy premises, applications for restoration can be made where the entry has been removed from the Register under article 14(4)(a)of the Order, section 74A(7) of the Medicines Act 1968, following an application for voluntary removal under section 74G of that Act, or where the entry of the premises in the Register has ceased to be valid because of a change of ownership of the retail pharmacy business carried on at the premises. In each case the Registrar has the right to refuse restoration if he considers that to do so would be prejudicial to the health, safety or well-being of the public;
- Applications to vary or revoke conditions of entry in the Register in respect of pharmacy premises for example where the registrant considers that the there are reasons why the conditions cannot be complied with, must be supported by documentation and evidence to enable the Registrar to determine the case. Where the Registrar grants an application he must ensure that the appropriate alteration is made to the Register. A fee may be charged in connection with the cost of making the alteration to the Register;

- Alterations to the Register, for example in the case of the registrants, change of name or to record determinations of the Investigating Committee or Fitness to Practise Committee;
- Where a prescribed fee is payable all applications must be accompanied by the relevant fee, and
- Procedure for dealing with incorrectly made or fraudulently procured entries. Before determining the matter the Registrar is required to serve a Notice of Intention to Remove. This may be followed by the registrant or, in the case of pharmacy premises, the person carrying on the retail pharmacy business, requesting a hearing before the Fitness to Practise Committee, or for the case to be determined without a hearing.
- The commencement of Rules 11 and 24, which cover the renewal of an entry in the Register, and Rules 13 and 26, which cover the renewal of an annotation made to an entry in the Register, is being delayed until the 4 January 2011. The purpose of this 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 by 31 December 2010. This will apply to all registrants transferring automatically from the registers held by the RPSGB to the GPhC Register. The delay in commencement enables alternative transitional measures to be put in place for the renewal of such entries and annotations by virtue of an Order of the Privy Council made under article 69(3) of the Pharmacy Order 2010 in connection with the commencement of Schedule 5 of that Order. These transitional measures set out an abridged procedure for renewing entries and annotations in the Register which will operate in respect of the first renewal of entries transferred to the Register on the appointed day. These measures will reduce the risk of registrants having their entries removed from the Register because of a failure to renew those entries before they cease to be valid by virtue of article 25 of the Order which makes provision regarding the duration of entries in the Register. Entries transferred to the Register on the appointed day are, by virtue of provision in paragraph 3 of Schedule 5 to the Pharmacy Order 2010, treated as having been made on 1 January 2010 and must therefore be renewed by the GPhC before the end of 31 December 2010 otherwise they will cease to be valid.

7.3 The Statutory Committees Rules set out various matters relating to the constitution and composition of the three statutory committees of the Council i.e. the Investigating Committee, the Fitness to Practise Committee and the Appeals Committee, and the function of the advisers to the statutory committees and other committees of the Council. In particular, these Rules set out the following:-

- The Appointments Committee (established by the Council using powers in article 4(7) of the Pharmacy Order 2010), will
    - select and appoint chairs, deputy chairs and other members of the statutory committees;
    - suspend or remove chairs, deputy chairs and other members from office where appropriate;
    - oversee training, development, performance review and appraisal of all statutory committee appointees;

- The grounds upon which a person will not be eligible for appointment to a statutory committee and make clear that, among others,
    - current members of the General Pharmaceutical Council;
    - employees of the GPhC;
    - members of other GPhC statutory committees

  are not eligible;
- The composition of the statutory committees in respect of lay and registrant members, including the requirement that chairs and deputy chairs be lay members and may be legally qualified;
- The Appointments Committee's role in advising the Council on the required competencies for appointments to the statutory committees. However, the Rules provide that the Council will determine the minimum competencies required for appointment as a member of a statutory committee;
- The standards expected of, and training to be undertaken by, members of the statutory committees and the requirement that their performance be appraised periodically in accordance with arrangements determined by the Appointments Committee;
- Terms of office of appointees will be four years but with a maximum period of eight years in any twenty year period for appointment to any one statutory committee;
- Procedures for resignation, removal or suspension of members from the statutory committees;
- A requirement for the Appointments Committee to maintain a reserve list of appropriate persons to serve as members of the statutory committees and procedures for filling vacancies on the statutory committees;
- The chair's power to co-opt members to the committee;
- Administrative arrangements for meetings of the statutory committees including;
    - the quorum and membership for particular meetings and hearings;
    - the appointment and duties of secretaries to the statutory committees;
    - decisions to be taken by a simple majority vote;
- The functions of legal, clinical and specialist advisers in relation to the statutory committees and other committees of the GPhC.

7.4 The Fitness to Practise Rules prescribe the procedures to be followed by the GPhC and its statutory committees (primarily the Investigating Committee and the Fitness to Practise Committee) when considering three types of allegation–

- That the fitness to practise of a registrant is impaired;
- That a body corporate should be disqualified from carrying on a retail pharmacy business, or
- That there has been criminal conduct which the GPhC is under a duty to investigate.

The Fitness to Practise Rules establish:-

- Provisions of general application relating to-

    - service of documents and venue of proceedings;
    - information which must be provided to the Registrar by a registrant in relation to matters which could affect their fitness to practise eg details of any criminal conviction or police caution; and
    - applications for restoration to the Register.
- Procedures to be followed by the Registrar and the Investigating Committee on receipt of allegations which cover, inter alia-
    - matters to be considered by the Registrar in determining whether an allegation is, or is not, to be referred and. if it is referred, the route by which the allegation will be considered;
    - matters to be considered by the Investigating Committee when determining whether or not it is appropriate for the allegation to be referred to the Fitness to Practise Committee or for criminal proceedings to be brought;
    - how the Investigating Committee is to consider allegations;
    - when the Investigating Committee can agree undertakings, and
    - when the Investigating Committee may reconsider an allegation;
- The criteria which the Fitness to Practise Committee is to have regard to in cases which have been referred to them when deciding whether or not the requirements as to fitness to practise are met in relation to registrants;
- Procedures to be followed by the Fitness to Practise Committee in cases referred to them which cover, inter alia, the following:
    - the type of hearing to be held;
    - case management including disclosure of evidence;
    - the conduct of the principal hearing;
    - how the Committee is to proceed where the person concerned is absent from the principal hearing;
    - cases which can be dealt with by agreement of undertakings or by the giving of advice or warnings and how alleged breaches of undertakings are to be dealt with;
    - postponements and adjournments;
    - witness evidence, including the identification and treatment of vulnerable witnesses at the hearing;
    - how any additional matters which may arise before or during hearings are to be dealt with;
    - how specified types of case which fall outside the standard arrangements are to be dealt with, eg where joinder is appropriate or where additional allegations or evidence arise at a late stage in proceedings; and
    - costs provisions.
- The notification of decisions both to the registrant concerned and to others where appropriate.

7.5 The Appeals Committee Rules set out the functions of the Appeals Committee and the procedures to be followed in proceedings before that committee. All decisions which are identified as appealable under the provisions of the Pharmacy Order 2010 (article 39) are covered by these rules. This covers appeals in relation to registered

pharmacy premises and educational institutions or providers as well as appeals by registrants. The Appeals Committee Rules establish:-

- The procedures for appeals including
  - the requirements for the Notice of Appeal;
  - action to be taken by the GPhC following receipt of a Notice of Appeal;
  - the requirements for the Notice of Hearing, in those cases where a hearing is requested;
- The holding of case management meetings and the procedures for these;
- The procedures and conduct of hearings before the Appeals Committee including -
  - rules of evidence for hearings;
  - circumstances where hearings, or parts of hearings, may be heard in private eg health related issues or matters where the interest of any person in maintaining their privacy as respects an issue outweighs the public interest of the hearing (or part of the hearing) being held in open session;
  - the procurement of advice from clinical, specialist and legal advisers;
  - obtaining advice from the Fitness to Practise Committee of the GPhC;
  - the burden and standard of proof;
  - representation by lawyers or others;
  - provision for consideration of appeals on the papers;
  - procedures for hearings, including witness evidence and the arrangements for vulnerable witnesses;
  - postponements and adjournments;
  - notification of decisions of the committee;
  - awarding of costs, and
  - notes and transcripts of hearings.

- ***Consolidation***

7.6 No consolidation is necessary as these Orders do not amend previous legislation.

8. Consultation outcome

8.1 The GPhC published the Rules, in draft, for public consultation across Great Britain on 16 February 2010. The consultation closed on 4 May 2010. 130 individuals and organisations replied to the consultation. The GPhC has since prepared a detailed response to the views expressed by those who replied. This "Consultation Report" was approved by the GPhC's Council on 3 June 2010 and is available on its website http://www.pharmacyregulation.org/getinvolved/consultations/index.aspx

8.2 Some of the responses to the consultation, particularly in relation to the Registration Rules, were concerned with matters which are set out in the Pharmacy Order 2010, such as the introduction of a rolling register and the procedure and

timetable for the renewal of entries in the Register. However, the Pharmacy Order 2010 has already been made any rules which are made under it must be consistent with, and made within the rule-making powers given in, the Order.

8.3 The need for good communications, particularly with regard to areas which differ from those in place for registration with the RPSGB, was highlighted by several respondents. This has been endorsed by the Council and an enhanced communications programme is to be developed.

8.4 In response to the consultation, the Statutory Committee Rules have been amended to clarify that a tied vote of the Fitness to Practise Committee, when considering whether or not a person's fitness to practise is impaired is to be taken as a decision in favour of the person concerned (Rule 20).

8.5 As a result of the consultation changes have been made to the fitness to practise criteria (Rule 5) of the Fitness to Practise Rules. The criteria which were consulted on generated a high volume of comment, both about whether the suggested approach was appropriate (in particular, the suggestion that the criteria were too detailed and should instead be drafted in the form of broad headings), and about individual criteria. This rule has been reframed so that it reflects broad principles rather than detailed criteria.

8.6 Other changes to the Fitness to Practice Rules which resulted from the consultation are -

- Removal of the requirement for the Registrar to make a referral directly to the Fitness to Practise Committee if he considers there is "likelihood" that this will result in the registrant being removed from the register. In such circumstances Rule 9(6)(b) would be invoked and, in the public interest, urgent consideration would be given to the allegation.
- The Investigating Committee may require a medical examination of a person who is the subject of a health allegation (Rule 9(5));
- The disclosure provisions (Rule 14) have been amended allow less complex cases to be dealt with more quickly and be supplemented with case management directions. The registrant concerned is now required to disclose their case no less than 28 days prior to the hearing.
- In the case of hearing bundles (Rule 18) the rules now clarify that a skeleton argument is required only where the case necessitates consideration of a point of law.
- The Investigating Committee may now agree to undertakings with the registrant where a registrant admits that his/her fitness to practise is impaired (Rule 10);
- An adjustment of the rules to allow the consideration of additional allegations at a hearing, where it is just to do so (Rule 29);
- Where a witnesses first language is not English the rules now permit the Committee to direct that his/her evidence be given through an interpreter (Rule 43);
- The requirement to serve and file a schedule of costs is now discretionary so that it would not be necessary if neither party was seeking a costs order (Rule 46).

8.7 The Appeals Committee Rules have been amended to remove the power for the Investigating Committee to advise the Appeals Committee, as this was judged to be unnecessary.

8.8 More detailed points raised by respondents to the consultation will be considered by the GPhC as it develops procedures under the rules.

9. Guidance

9.1 Neither the Department of Health nor the Scottish Government has issued guidance in relation to these four sets of rules. 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 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

10.3 Equality Impact Assessments has been prepared by the GPhC. This is a wide-ranging assessment which includes coverage of all the measures which are being brought in within the rules covered by this Explanatory Memorandum. These are available at http://www.pharmacyregulation.org/getinvolved/consultations/index.aspx

11. Regulating small business

11.1 The legislation applies to small business but adds no new burdens as it replaces existing legislation.

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.