EXPLANATORY MEMORANDUM TO

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN (REGISTRATION RULES) ORDER OF COUNCIL 2007

2007 No. 441

AND

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN (FITNESS TO PRACTISE AND DISQUALIFICATION ETC. RULES) ORDER OF COUNCIL 2007

2007 No.442

AND

THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN (FITNESS TO PRACTISE AND REGISTRATION APPEALS COMMITTEES AND THEIR ADVISERS RULES) ORDER OF COUNCIL 2007

2007 No. 561

1. This explanatory memorandum has been prepared by Department of Health and is laid before Parliament by Command of Her Majesty.

2. Description

- 2.1. The three Orders approve a linked set of rules made by the Royal Pharmaceutical Society of Great Britain (the "Society") relating to:
 - the registration of pharmacists and pharmacy technicians, in particular the application process and the provisions relating to appeals against some decisions to the Society's Registration Appeals Committee,
 - the procedures to be followed when considering three types of allegations: allegations that the fitness to practise of an individual registered pharmacist or pharmacy technician is impaired; allegations that a person (which may be a company) should be disqualified from inclusion in the register of pharmacy retail business premises kept by the Society; and allegations of criminal conduct that the Society is under a duty to investigate, and
 - the constitution of, and the advisers to, four of the Society's statutory committees: the Investigating Committee, the Health Committee, the Disciplinary Committee and the Registration Appeals Committee.
- 3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1. None.

4. Legislative Background

- 4.1. The Rules that are approved by these Orders, and the approval Orders themselves, are the first occasion for the use of a number of powers contained in the Pharmacists and Pharmacy Technicians Order 2007 ("the 2007 Order"). The Rules are linked to the new arrangements for the registration and fitness to practise of pharmacists which are set out in the 2007 Order and which are also to come into force on 30th March 2007.
- 4.2 The 2007 Order establishes a framework for the professional regulation of pharmacists within Great Britain and pharmacy technicians in England and Wales. As regards pharmacists, the 2007 Order replaces the provisions of the Pharmacy Act 1954, which it repeals. The updating of the framework legislation for the regulation of pharmacists was necessary, in part, to provide an increased emphasis on, and improve the Society's capacity to address, fitness to practise issues. It also provided an opportunity to reform the Society's registration procedures, including by the establishment of its Registration Appeals Committee.

5. Extent

5.1. This instrument applies to Great Britain.

6. European Convention on Human Rights

6.1. As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required

7. Policy background

Policy

- 7.1 These Rules comprise part of the implementation programme for the 2007 Order. The main features of the 2007 Order are that it:
 - introduces reform of the Society's registration process, including bringing pharmacy technicians in England and Wales into statutory regulation for the first time;
 - updates provisions for education and training, including statutory requirements for continuing professional development;
 - provides an increased emphasis on, and improved capacity to address, fitness to practise issues;
 - reforms the Society's statutory committee structure; and
 - provides a clearer exposition of the Society's responsibilities in protecting the public and its accountability in doing so.

The Order continues the reform of the regulation of pharmacy professionals started with the granting of the Royal Pharmaceutical

Society of Great Britain's new supplemental Royal Charter in December 2004. These reforms are part of the Government's policy to modernise the regulation of all health and social care professionals.

7.2 The main aims of the three sets of Rules that these approval Orders approve are as follows:

• Registration Rules

7.2.1 These Rules provide for the necessary detail to enable the Society to operate its registration system effectively. They include necessary detail to deal with: the form and keeping of the Society's register of pharmacists (and will in due course also apply to the Society's register of pharmacy technicians); processing applications for registration in, and retention in, the register; investigating and taking action where registration may have been fraudulently procured or incorrectly obtained, or where the registrant's fitness to practise was impaired at the time of registration but this was not declared; and the appeals procedures for a range of appealable registration decisions.

• Fitness to Practise and Disqualification etc. Rules

7.2.2 These Rules provide the necessary detail to enable the Society to operate its new fitness to practise procedures effectively. The 2007 Order gives it powers, for the first time, to deal with impaired fitness to practise on the grounds of physical or mental health, and there are detailed arrangements for how the new Health Committee is to deal with these cases. A new Disciplinary Committee is to deal with the Society's other fitness to practise cases, and also with cases of disqualification from the Society's register of retail pharmacy premises. The Disciplinary Committee replaces the Society's old Statutory Committee and, alongside the Health Committee, has powers to investigate a broader range of matters than the old Statutory Committee and impose a broader range of sanctions. The Rules contain the necessary detail for the new procedures, and includes provisions with regard to: the initial consideration of allegations by the Society's Registrar; consideration, where appropriate, of allegations by the Society's Investigating Committee; consideration by its Health or Disciplinary Committees, including with regard to the interim measures (the imposing of temporary sanctions pending the principal hearing); procedures for case management meetings and for the principal hearings (and any subsequent review hearings); and ancillary matters such as the arrangements for witnesses and the standard of proof to be applied.

• Fitness to Practise and Registration Appeals Committees and their Advisers Rules

7.2.3 As a consequence of the reform of the Society's committee structure, there are now four statutory committees that deal with the Society's registration and fitness to practise processes: the Investigating Committee, the Health Committee, the Disciplinary Committee and the Registration Appeals Committee. These Rules contain the necessary detail with respect to the constitution of those committees and the functions of their professional

advisers. They include provisions that deal with: matters relating to the appointment and removal of committee members and their professional advisers; provisions relating to meetings and hearings, including a requirement for each of the committees to have a secretary; and the functions of legal, clinical and other specialist advisers.

Consultation

The RPSGB carried out a consultation on its proposals amongst registrants and stakeholders for rules covering registration, including fees, and fitness to practise. This consultation ran from 3 July 2006 until 22 September 2006. A total of fifty four responses were received, forty-eight of which were on the questionnaire the remainder general comments, and most were supportive of the proposals. Only three questions on the questionnaire received a majority of responses against the proposed arrangements. These were the issues of:

- automatic removal from the Register for non payment of the annual retention fee (41% in favour 50% against);
- requirements for applicants for registration to provide a certificate issued by a medical practitioner to confirm their good health (6% in favour 79% against); and
- whether the costs of a hearing should include the costs of medical examination, performance assessments and associated reports (20% in favour 48% against)

As a result of the consultation the RPSGB amended the draft rules to:

- include the requirement for the registrar to send a reminder to the registrant before removing them from the register,
- allow registrants to self certify their good health, and
- limit the costs provisions so that they relate exclusively to the main hearings (principal hearings, hearings where the directions issued at principal hearings are reviewed, and restoration hearings) and not to the preliminary investigations of the Society. The award of costs is at the discretion of the Committee before which the hearing is held.

8. Impact

- 8.1. A Regulatory Impact Assessment has not been prepared for these instruments as their impact on business, charities or voluntary bodies is negligible. They are essentially about process issues and matters internal to the Society.
- 8.2 There are no identified costs to either the public or the Exchequer arising from this Instrument.

9. Contact

Stephen Arthur Deputy Project Manager, Professional Regulation Branch at the Department of Health; Tel: 0113 254 5789 or email Stephen.arthur@dh.gsi.gov.uk can reply to any queries regarding this instrument.