

EXPLANATORY MEMORANDUM TO
THE PHARMACISTS AND PHARMACY TECHNICIANS ORDER 2007
2007 No.

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 Order sets out the arrangements for the professional regulation of pharmacists in Great Britain and of pharmacy technicians in England and Wales. The Order: introduces a 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.
3. **Matters of special interest to the Joint Committee on Statutory Instruments**
 - 3.1. None.
4. **Legislative Background**
 - 4.1. This Order in Council is one of a series of Orders that have been made under the powers given to her Majesty under sections 60 and 62(4) of the Health Act 1999 to modernise the regulation of health care professions. The arrangements for pharmacists replace those set out in the Pharmacy Act 1954, which is repealed. Statutory regulation of pharmacy technicians is introduced for the first time, although the Royal Pharmaceutical Society of Great Britain has been operating a voluntary register of pharmacy technicians since January 2005. The purpose of the Order is to give effect to the Government policies described in section 7.
5. **Extent**
 - 5.1. As regards the regulation of pharmacists, this Order applies to England and Wales and Scotland. As regards the regulation of pharmacy technicians, this Order applies to England and Wales only.
6. **European Convention on Human Rights**

6.1. The Minister of State for Delivery and Quality at the Department of Health, Andy Burnham MP has made the following statement regarding Human Rights:

“In my view the provisions of the Pharmacists and Pharmacy Technicians Order 2007 are compatible with the Convention rights.”

7. Policy background

Policy

7.1. This 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 in line with the Government’s policy to modernise the regulation of all health and social care professionals.

7.2. The major reforms proposed in the Pharmacists and pharmacy Technicians Order are:

- **Reform of the Society’s registration process including the statutory regulation of pharmacy technicians in England and Wales for the first time.**

7.2.1 The Order proposes that the register currently known as the “register of pharmaceutical chemists” should in future be called the “register of pharmacists”. The Order also provides, for the first time, for a statutory “register of pharmacy technicians” to be established for England and Wales. It also provides, for the first time, for the registers to be divided into two parts to distinguish between practising and non-practising registrants. The order proposes that those registrants on the practising part of one of the Society’s registers will be required regularly to demonstrate that they are maintaining continuing professional development and that their fitness to practise remains “unimpaired”. The Order also proposes provision be made for the Society’s registers to be published in such manner as the Registrar see fit (including on-line publication). The Order also proposes that all practising registrants should be covered by an adequate and appropriate indemnity/ insurance arrangement with regard to their professional liability.

- **An update of provisions for education and training, including statutory requirements for continuing professional development:**

7.2.2. The Order proposes that persons wishing to register as a pharmacist or pharmacy technician must satisfy the Society’s Registrar that they are appropriately qualified and that where necessary they have met such additional requirements as to education training and experience as are appropriate to their case. It will be for the Society to determine, subject to the requirements of European Community law, the nature of the knowledge and skills that will enable the Registrar to consider a person “appropriately qualified”. The Order also details the Society’s particular responsibilities in pursuit of its general

function of promoting high educational standards for pharmacists, pharmacy technicians and prospective registrants.

- **Provision of an increased emphasis on, and improved capacity to address, fitness to practise issues:**

7.2.3. In line with the process being undertaken by all other health and social care regulators, the opportunity is being taken by means of this Order to propose a comprehensive update of the fitness to practise provisions for pharmacists and pharmacy technicians. The existing requirement for a registrant to be “of good character” has been strengthened by adopting the concept of their remaining fit to practise. The order proposes additional powers for the Society to collect and disseminate fitness to practise information and, in the event of experiencing difficulties in securing the provision of legitimate information or documents, to have the option of applying for a court order to secure disclosure.

- **Reform of the Society’s statutory committee structure;**

7.2.4. The Order proposes a new structure to replace the Society’s current Statutory Committee with six statutory committees through which certain of its functions will be exercised and for the Society’s Council to make rules about the way these committees should be administered. The statutory committees proposed in the Order are the Continuing Professional Development Committee, the Disciplinary Committee, the Education Committee, the Health Committee, the Investigating Committee and the Registration Appeals Committee.

- **Provision of a clearer exposition of the Society’s responsibilities in protecting the public and its accountability in doing so.**

7.2.5. The Order proposes a general duty for the Society to protect, promote and maintain the health and safety of the public. It also proposes a formal requirement for the Society to cooperate so far as is appropriate and reasonably practicable with public authorities, other bodies and persons concerned with the education and training of registrants, prospective registrants and other healthcare professionals. Similarly, the Society is required to cooperate with bodies concerned with the regulation of health and social care professions or carrying out activities in connection with the regulation of the NHS. In addition, the Order proposes, for the first time, that the Society’s annual accounts and any report on them should be laid before each House of Parliament.

Consultation

7.2.6. Over 120 responses were received from organisations and individuals to the public consultation exercise that was conducted between 27 March and 19 June 2006. The large majority of responses were positive. There was widespread support (over 90% of those responding on the issues involved) for the proposal that practising pharmacists and pharmacy technicians should be

required to demonstrate regularly that they are keeping up to date, for the proposal to rename the Society's register "The Register of Pharmacists", and for the proposal to use the internet as the prime means of publishing the registers of pharmacists and of pharmacy technicians. There was a similar level of support for the emphasis in the Order on ensuring that registrants' fitness to practise is unimpaired.

7.2.7. There was also extensive support (over 75% of those responding on the issues involved) for the proposal to establish a group of new statutory committees to replace the existing Statutory Committee, including new Continuing Professional Development and Registration Appeals Committees. There were similar levels of agreement that the Order had captured all the significant elements of the Pharmacy Act 1954, for the proposal to establish a statutory register of pharmacy technicians for England and Wales, and for the Registrar to have the facility to refer cases directly to the Health and Disciplinary Committees for them to consider the issue of an interim order suspending or imposing restrictions on their registration in appropriate cases.

7.2.8. The majority of respondents (over 60% of those responding on the issues involved) supported the division of the Society's registers into two parts, covering practising and non-practising pharmacists and pharmacy technicians respectively, and the extension of the Society's powers to collect and disclose fitness to practise information, including the facility to apply for a court order to reinforce a request for information in certain circumstances.

7.2.9. Fuller details of the consultation exercise are contained in "*The Pharmacists and Pharmacy Technicians Order 2006: Report on consultation*", which is available on the Department of Health Website at: <http://www.dh.gov.uk/Consultations/ResponsesToConsultation/fs/en> .

8. Impact

8.1. A Regulatory Impact Assessment is attached to this memorandum at Annex A.

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.

Partial RIA – Pharmacists and Pharmacy Technicians Order 2006

1. Title of Proposal

The Pharmacists and Pharmacy Technicians Order 2006

2. Purpose and intended effect

• Objective

The Government's objective is to improve public safety, in particular by:

- Improving the system which ensures that pharmacists are fit to practise;
- Introducing a similar system to statutorily regulate pharmacy technicians; and
- Providing a mechanism to deal with health problems amongst registrants

• Background

Other major professional groups, such as doctors, dentists, opticians, nurses and the professions covered by the Health Professions Council have already undergone fitness to practise reforms.

The Government's aim in modernising health professional regulation is to increase public protection by making bodies:

- Smaller with more public and patient involvement;
- Have faster, fairer and more transparent procedures; and
- More accountable to the public and the health services.

The Royal Pharmaceutical Society of Great Britain, which is the body responsible for regulating the pharmacy professions, is governed by a Royal Charter and the Pharmacy Act 1954. Part of the modernisation of the Society was achieved in 2004 when the Society's 1953 Charter was replaced by a new supplemental Charter. The modernisation needs to be completed as soon as possible by means of the Pharmacists and Pharmacy Technicians Order that will use powers under section 60 of the Health Act 1999 to completely replace the Pharmacy Act 1954.

• Rationale for government intervention

The Government is committed to updating the regulations of healthcare professionals and several high profile regulatory problems have indicated how important effective regulation is if the public is to be adequately protected. The basic legislation governing the regulation of pharmacy professionals is

now over fifty years old and is in need of modernisation. There are key powers which the Royal Pharmaceutical Society has lacked which has hindered their ability effectively to regulate the profession in the way that is expected in the 21st Century. They have, for instance, had no adequate mechanism for dealing with regulatory issues that involved a health element, or for imposing interim measures while cases are being investigated. The Royal Pharmaceutical Society needs the Government's help to modernise the legislation on which their regulatory function rests.

3. Consultation

- **Within government**

Department of Health leads on the regulation of pharmacists for Great Britain (but not Northern Ireland). The regulation of pharmacists in Great Britain and of pharmacy technicians in England and Wales is reserved to Westminster. It is not proposed to regulate pharmacy technicians in Scotland, which is a devolved matter, in the current Order. We have been in regular contact with our colleagues in Scotland and have also consulted the health departments for Wales and Northern Ireland as necessary.

- **Public consultation**

RPSGB consulted its membership, and others, on its proposals for the future remit and functions of the Society in February 2002 and on professional leadership and development in September 2003.

A full statutory public consultation on the draft Pharmacists and Pharmacy Technicians Order was held between 27 March 2006 and 19 June 2006. A report has been prepared on the outcome of the public consultation and the draft Order has been amended in the light of responses to the consultation.

4. Options

(i) Do nothing. This is not an option. The Government is publicly committed to modernising the regulation of healthcare professions. It's programme is already well advanced. There would be inequity in a situation which failed to secure for the pharmacy professions improvements in regulatory practice which have already been delivered for many other healthcare professions.

(ii) Continue to work with the Pharmacy Act 1954 and commence the Pharmacists Fitness to Practise Act 1997. This would be better than option 1 and would provide at least some provision for a Health Committee for the Society. Thinking and practice on fitness to practise have moved forward considerably since 1997 and simply to commence what was agreed in 1997 would not put the Society on a par with the other regulators whose procedures have been updated by means of section 60 Orders. To commence the 1997

Act and then amend it would be more complicated and more time consuming than introducing the section 60 Pharmacists and Pharmacy Technicians Order proposed.

(iii) Introduce the reforms contained in the Order as planned. This provides the opportunity to completely overhaul and repeal the provisions of the Pharmacy Act 1954 to address the 21st Century context. It provides the opportunity for the Society, its structures and its regulatory functions to be fully aligned with latest health care regulation thinking and practice.

5. Costs and Benefits

• Sectors and groups affected

The Order will be of principal significance to pharmacy professionals and to the Royal Pharmaceutical Society itself. There will be a need to demonstrate, for instance, that practising pharmacists and pharmacy technicians are keeping up to date by means on Continuing Professional Development.

Reforms proposed to the Society's internal structure should ensure that disciplinary, and particularly health, issues will be handled in a more streamlined and effective way than has been possible in the past.

It will also affect patients and the public in terms of the additional assurances and protection it provides with regard to the competence of the pharmacy professionals with whom they are in contact.

We considered carefully whether there was any specific racial impact with regard to the Order and have concluded that there is none. Some respondents expressed a view that EEA graduates should be tested for proficiency in English as part of the registration process, as is the case for those who qualify outside of the EEA. This is, however, essentially outside the competence of this Order. The terms of the EEA mutual recognition directive (Directive 89/48/EEC) proscribe the language testing of exempt persons.

• Benefits

It is in the interests of all to ensure that registered pharmacists and pharmacy technicians are fit to practise and keeping up to date with developments within their profession. Members of the profession will appreciate the benefits of doing so and there is an obvious patient experience and public protection gain in addition.

As an increasing amount of clinical work is assigned to pharmacy technicians, sometimes replacing work once done by pharmacists, statutory regulation provides patients and healthcare employers with a necessary level of assurance that the people carrying out these roles are suitably qualified and meet necessary professional standards.

- **Costs**

It is not anticipated that there would be any significant public sector costs involved in the introduction of the Order. The Society is funded by registration/ retention fees and other income such as that derived from its publishing activities. The Society calculate there will be an uplift annually in their costs of approximately £600,000 on fitness to practise activity, which will include the new Health Committee, interim orders jurisdiction, performance powers and supervision and monitoring conditions. In addition, it is expected that there will be an uplift of around £400,000 a year for costs associated with the requirements for recording, reviewing and enforcing the new statutory CPD arrangements.

6. Small Firms Impact Test

As regards reforms to the regulation of pharmacists, it is not expected that any of the provisions of the Order will place any significant additional pressures on small businesses. The Order does contain a provision for mandatory indemnity/ insurance against claims for compensation due to negligence but such a provision is included in the Society's *Code of Ethics* and is regarded as normal good practice and, as such, should not represent a significant new burden.

The Order will make the registration of pharmacy technicians in England and Wales mandatory. Since January 2005 the Society has maintained a voluntary register of pharmacy technicians which currently contains 1,800 names, of which around 165 are in Scotland. When the Order comes into force this figure is expected to rise to 10,000, of which say 600 could be in Scotland. Scottish based pharmacy technicians will be allowed to apply for admission to the Society's statutory Register of Pharmacy Technicians, but it will not be mandatory for them to do so.

From October 2005 the Society has introduced a registration fee for pharmacy technicians based on whether the applicant is practising or non-practising. The fee also reflects whether the applicant is seeking entry by "the standard or grandparenting route (a)" (where no screening is required) or "the grandparenting route (b) or on the basis of a qualification gained outside the UK" (where screening is required). There are two elements to the registration fee - the one off application fee of £30, for standard applications, and £125, for those requiring scrutiny, together with a retention fee of £85. It is expected that these will be increased over time using an index linked to inflation. Whilst it is possible to predict with some degree of accuracy how many registered pharmacy technicians there will be who work in hospital pharmacy

(5,000), it is not so easy to predict how many registrants there will be from the community sector.

A 1998 mapping study of the pharmacy sector estimated the size of the pharmacy technician population within Great Britain to be about 15,000. The survey identified about 8,500 pharmacy technicians in the community sector, 5,000 in the hospital sector and the remainder working within primary care, industry, academia, prisons and the armed forces. Within the community sector there is no reliable data on the breakdown between numbers working for large chains (Boots, Lloyds, Alliance etc) and those working for independent contractors.

Of those who have joined the voluntary register and provided data to the RPSGB, 72% work in the community sector and 25% within hospitals. The indication so far is that while those who work in the hospital sector are expected to pay their own registration/ retention fee, many of those who work in the community are having it paid by their employer. Hence, the proportion of registrants from the community sector on the voluntary register is larger than would otherwise have been expected at this stage. Even assuming that all pharmacy technicians were working in small businesses, which is extremely unlikely, and that all those businesses were paying their technician's registration fees at the maximum possible level (i.e. involving scrutiny in every case), the cost at current prices would only be about £1.8m per year in total. In reality, it is likely to be considerably less and is unlikely to involve any single small business, which chooses to pay its technician's fee, in expenditure of more than £200 on first registration and £100 per annum thereafter.

7. Competition Assessment

It is not anticipated that the measures proposed will have any impact on the market for the provision of pharmaceutical services.

8. Enforcement, sanctions and monitoring

The Royal Pharmaceutical Society of Great Britain, like other professional regulators, sets out standards for registrants. In the past some of these were set out in Byelaws made under the Society's Charter and the Pharmacy Act 1954. In future, the proposal is that they will be set out in regulations made under the Charter or rules made under the Order, once it comes into force. The Society's Council is ultimately responsible for the enforcement of these rules and regulations.

Rules made under the proposed Order will be published for consultation for not less than 60 days before being submitted (other than those relating to fees) to the UK health departments and the Privy Council for approval .

The Council for Healthcare Regulatory Excellence, set up under the NHS Reform and Health Care Professions Act 2002, has a remit to report annually to Parliament on the effectiveness of professional regulation and to raise any matters it considers necessary with the Secretary of State and, where necessary, the devolved administrations.

9. Declaration and Publication

I have read the regulatory impact assessment and I am satisfied that the benefits justify the costs

Signed: Andy Burnham

Dated: 24th November 2006

Minister of State, Department of Health

10. Contact for further information

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