Setting the standards for pharmacy

Professional standards for practising pharmacists and pharmacy technicians are going to be set in early 2010. The General Pharmaceutical Council is encouraging professionals to look at the drafts and send in their views this autumn.

Consultation on standards

The GPhC is required to consult on the new regulatory standards. In order to enable the GPhC to take up its regulatory functions from spring 2010, the consultation is being undertaken in parallel with the Parliamentary process to establish the GPhC. Consequently the consultation is being taken forward by the Council for Healthcare Regulatory Excellence (CHRE) — the independent body accountable to Parliament, that is responsible for scrutinising and overseeing the nine health profession regulators in the UK.

The consultation was launched on 21 October 2009 and runs until 12 January 2010.

Bob Nicholls, chairman designate of the GPhC, says: “This marks another important milestone in the establishment of the new pharmacy regulator.

“The standards reflect the input of a wide variety of stakeholders, including many members of the public, and I would like to thank those who have contributed via our workshops throughout 2009.

New regulatory standards — 10 key facts

1. The General Pharmaceutical Council will be introducing five new sets of standards.

2. Pharmacists, pharmacy technicians and pharmacy owners will be required to meet the standards as soon as they are in place — except for the premises standards where there is a two-year period to allow owners to make any improvements to existing pharmacy premises.

3. Some of the standards are supported by guidance, which is included in this consultation, and some will be in the form of legislative rules. The legislative rules will be consulted on separately, later in autumn 2009.

4. The development of the standards has been facilitated by the Department of Health in conjunction with stakeholders, including the public. This has been necessary because the GPhC has no legal status until the draft Pharmacy Order 2009 and the General Pharmaceutical Council (Constitution Order) 2009 become law in late 2009 or early 2010, Parliamentary timetable permitting.

5. There has been a series of workshops with professionals and patients and the public throughout summer 2009. The documents produced from the output of the workshops have been reviewed to ensure that the standards are workable across all sectors of practice.

6. Some standards build on existing work but others cover new areas. The new developments are:

- Standards for pharmacy owners and superintendent pharmacists
- Standards of proficiency for pharmacists and pharmacy technicians
- A change to statutory standards for continuing professional development for pharmacists and pharmacy technicians
- A shift in emphasis in the standards for conduct, ethics and performance for pharmacists and pharmacy technicians

7. There are new standards for owners of pharmacies and superintendent pharmacists in the following areas:

- Record keeping
- Policies and standard operating procedures
- Staff competence
- Arrangements for the obtaining, keeping, handling, use and security of medicinal products or medical devices
- Conditions in which medicines are stored
- Incident reporting mechanisms
- Condition of premises
- Availability or condition of facilities or equipment at the premises
- Management of waste
- The use of registered pharmacies as training establishments

8. In addition, it is expected that pharmacy owners and superintendent pharmacists will be subject to standards around:

- Operating registered pharmacies that offer internet services
- Arrangements for continuity of pharmacy services
- Staff recruitment
- Availability of resources to carry out professional duties

9. The new proficiency standards seek to ensure the safe and effective practice of pharmacy professionals and build on the Royal Pharmaceutical Society’s pharmacy practice framework. They set out the minimum standards considered necessary to protect members of the public and are the standards to be met by pharmacy professionals when they are first registered. After that pharmacists and pharmacy technicians must continue to meet the standards of proficiency relevant to their scope of practice.

10. The standards for conduct, ethics and performance will set out the behaviours, attitudes and values expected of pharmacy professionals and will apply to anyone who registers with the GPhC, including registrants who are not involved in direct patient care. Although these standards will not necessarily place “new” professional requirements on pharmacists and pharmacy technicians, there will be a change in emphasis to ensure that the standards of conduct, ethics and performance are outcome-focused and relevant to the wide range of roles that pharmacy professionals undertake.
“I encourage all pharmacists, pharmacy technicians and pharmacy owners, and patients and the public, to read the standards and to let us have any comments they wish to make. We will listen to their views and consider how we can incorporate them.”

Standards development

The development of the draft standards has been facilitated by the Department of Health through a series of stakeholder workshops involving pharmacy professionals and patients and the public. The drafts have been reviewed to help ensure they are relevant for all sectors.

The standards are intended to be proportionate to current risks. They set out minimum regulatory requirements and the intention is to use them as a key tool in the delivery of pharmacy regulation.

The aim is that they are broad and flexible, in order to enable innovation, rather than specific and directive. The development of a flexible standards framework, rather than the specific and directive. The development of a flexible standards framework, rather than the use of further secondary legislation, will ensure the GPhC can be responsive to change and able to react quickly to new developments in pharmacy practice in the future.

Duncan Rudkin, chief executive designate of the GPhC, says: “This consultation is important for every pharmacist and pharmacy technician who intends to remain registered, or to newly register, with the GPhC. The standards will affect the working lives of all registrants and, ultimately, the quality of services they provide to the public on a day to day basis. We are very keen to hear people’s views to ensure we get this right for the public and for professionals who deliver these important services.”

Guidance and rules

Draft guidance has been produced for some of the standards. Although there is no statutory obligation to consult on guidance, the opportunity is being taken to seek views on the draft guidance as part of the standards consultation. In addition, there will be a separate statutory consultation on the legislative rules for the GPhC later in autumn 2009.

Education procedures consultation

Further consultation, on the GPhC’s educational procedures, is due to be launched in November 2009. This is not a statutory consultation, it will be important since it impacts on arrangements for the preregistration programme and registration examination.

Next steps on standards

Following the formal consultation on the standards, they will be redrafted, where necessary. Once it has legal status, the GPhC will further engage with stakeholders to determine any additional amendments before the adoption of the standards by the council in time for the spring 2010 opening (Parliamentary timetable permitting).

Although establishing standards is an early priority for the GPhC, this is just the beginning. Once established, the GPhC will need to be forward looking and responsive to change in pharmacy practice. It will need continually to ensure that the standards support professional development. Therefore, the standards that are agreed for 2010 will be the foundation that the GPhC will build on as pharmacy becomes an increasingly clinical profession.

What the public said

Members of the public were involved in the standards development through focus groups held across in England, Scotland and Wales. These involved approximately 150 members of the public. There was a clear call from the patients and the public for pharmacy premises:

- To be secure and safe for both patients and staff
- To have facilities to ensure privacy and confidentiality
- To be clean and hygienic
- To be easily accessible
- To have certain information available, eg, complaints procedure, waiting times and opening hours

They took the view that standards for owners of pharmacies and superintendent pharmacists should focus on:

- Safe practice
- Staff recruitment
- Obligations that ensure that the focus is on quality of service provision
- Managerial responsibilities

Patients and the public expressed views on the types of conduct and behaviour they would expect from pharmacy professionals and said that pharmacy professionals should:

- Not discriminate on grounds of race, religion, etc
- Respect confidentiality and privacy, and apply discretion
- Act with compassion and dignity
- Put patient safety above protecting a colleague or themselves
- Have good manners, be friendly, respectful and polite, but not overstep professional boundaries
- Have an up-to-date knowledge of medicines
- Not allow their personal views to interfere with good practice
- Listen to patients and members of the public and involve them in their care
- Raise concerns if a colleague is not fit to practise or if policies or systems compromise patient care.

The outcome of these workshops has been taken into account in the draft standards.

How to respond to the consultation

Online To view the consultation document and send comments go to the CHRE website at www.chre.org.uk/consultation/175/.

Comments must be received no later than 12 January 2010

www.pharmacyregulation.org
What Council members designate say

Cathryn Brown
Pharmacist, based in Lancashire; pharmacy manager with the Co-operative Pharmacy “I would urge every pharmacist and pharmacy technician to take part in the standards consultation. Now is your chance to help shape the standards that will shape our future practice.”

Sarah Brown
Lay member, based in Kent; chairman of the audit and risk committee for the Revenue and Customs Prosecutions Office; member of the Bar Standards Board and Accountancy and Actuarial Discipline Board “The standards will provide a framework for the practice of pharmacy and will be central to the work of the new GPhC. By adopting a principles-based approach, they will encourage pharmacists to think about the underlying needs of patients and the public rather than merely seeking to comply with detailed rules which may not be relevant in a particular situation. Getting the standards right is crucial for achieving safe and effective practice, and I hope that patients and the public, as well as pharmacists and their employers, will read the draft proposals and let us have their comments.”

Celia Davies
Lay member, based in Oxfordshire; professor emerita at The Open University “Clearly written and easily accessible standards, created from a real dialogue between all parties, backed up with guidance and support, and open to modification and further development: these are what both the public and the professionals deserve and expect from a responsive, modern regulator. This consultation is a first step for the new council in ensuring that it gets stakeholder engagement right and acknowledges and balances the interests of all concerned.”

Soraya Dhillon
Pharmacist, based in Hertfordshire; foundation professor and head of the School of Pharmacy at the University of Hertfordshire “The GPhC is a landmark change in pharmacy, which I believe will, through robust, supportive, regulatory processes, enhance the profession’s ability to protect patients and deliver high quality, safe patient care. The educational standards provide a clear framework to enable individual practitioners and organisations to deliver high quality pharmaceutical services. Engagement on these processes from all sectors of the profession is crucial to ensure the right balance is achieved in the standards for effective regulation and quality improvement.”

John Flook
Lay member, based in County Durham; director of John Flook Coaching and Consultancy Ltd; chairman of the audit committee at Darlington Primary Care Trust; non-executive director and chairman of the audit committee of NHS Professionals Special Health Authority; health policy adviser to the NHS Confederation “We are interested to hear from professionals who work in pharmacy, people who own pharmacies, those in pharmacy education, students and people who develop and work with pharmaceutical products. We also want to hear from people who regularly use pharmacy services, particularly those with any special needs. As a regulator we need to hear the many different voices so we can balance the needs of professionals and the public and ensure the standards are effective, but also fair and proportionate.”

Christina Funnell
Lay member, based in North Yorkshire; City of York councillor; patient engagement consultant with Patient Opinion; trustee of the Pharmacy Practice Research Trust “Setting standards for any profession is one of the key roles for the professional regulatory body. The health professional regulatory bodies have all undergone major change to their governance structures so that they all have lay members on their boards. Involvement of patients, carers, service users and customers in setting standards, working alongside the profession, is vitally important if we are to have a 21st century health service. I hope that patient groups, charities, consumer groups and members of the public will actively participate in this consultation so that the GPhC can have the benefit of their comments, observations and suggestions about the vital role that pharmacists play in their health and social care.”

Kirstie Hepburn
Pharmacist, based in Glasgow; regional director for Lloydspharmacy “The development of the draft standards framework for pharmacists, pharmacy technicians, owners and superintendents, has been ongoing since November 2008, through a series of stakeholder workshops. The next stage in the process, wider consultation, creates the opportunity to have your views represented in the future standards for the profession. I would encourage everyone to get involved — speak up and influence the change that you want to see.”

Ray Jobling
Lay member, based in Cambridgeshire; fellow and lecturer in sociology at St John’s College, Cambridge; trustee of the Pharmacy Practice Research Trust; chairman of Pharmacy Health Link “This is an important and exciting time in the development of pharmacy as a profession, and in the services professionals provide to the community. The future will involve pharmacists and pharmacy technicians becoming even more closely involved in direct clinical engagement with patients. New standards for education and training are therefore essential to ensuring competent practice and patient safety, all the way from the early stages of professional education, into preregistration training.”
practice-based training and on to more specialised professional development. It is crucially important that the public and patients who rely upon pharmacy for sound and safe information, advice, supply and, increasingly, the prescription of medicines, should contribute to the consultation on the new standards.”

Elizabeth Kay
Pharmacist, based in West Yorkshire; clinical director, medicines management and pharmacy services, at Leeds Teaching Hospitals NHS Trust; visiting professor of pharmaceutical care at the University of Leeds “Professionals have an opportunity now to shape the future of professional practice by pharmacists and pharmacy technicians and the standards of our pharmacy premises. These new standards, prepared with public and patient involvement, are intended to be outcome-focused and relevant to the wide ranging roles undertaken by pharmacy professionals. The standards will affect the way in which pharmacy professionals are educated and trained, our continuing professional development and, later, the premises from which pharmacy is practised. I urge all pharmacy professionals to read the draft standards, and feedback comments, thoughts and ideas.”

Lesley Morgan
Pharmacy technician, based in Gwent; recently retired as director of the Welsh Centre for Pharmacy Professional Education “The establishment of the GPhC has provided pharmacy with the opportunity to review its operational standards. The standards for pharmacy technicians mark the start of a new era. They make up the first set of national standards that cover this area of practice. A good sound base for the development of pharmacy services that put the patient first is important. The national standards will support both service and staff development and comments and views of all pharmacy practitioners are vital in the setting of standards that are ‘fit for purpose’.”

Keith Wilson
Pharmacist, based in West Midlands; deputy dean of the School of Life and Health Sciences and professor of pharmacy at Aston University “This is a time of unparalleled opportunity to develop pharmacy services for patients. As the new regulator, the GPhC will set the standards for the pharmacy professions which will be critical for the development of pharmacy services. The consultation on standards provides all pharmacists and pharmacy technicians with a real opportunity to input to the development of these standards so that they do reflect professional practice.”

Peter Wilson
Pharmacist, based in Hertfordshire; shortly to retire as head of education development at the Royal Pharmaceutical Society “The new standards take a fresh look at our profession, from the education and training needed to qualify as a member of the profession, to the standards for pharmacy owners and superintendents and new standards for CPD. We need to know the views of the profession because the standards will affect the way pharmacy is practised and regulated. Are the standards realistic and practical for you and your role as a pharmacy professional? The standards for CPD expect every registrant to keep a CPD record that reflects their scope of practice, safe and effective practice and the standards of conduct, ethics and performance for the profession. Are they realistic and practical for you and your role as a pharmacy professional keeping a CPD record? Respond to the consultation and let us know: it’s important that we get it right.”

Judith Worthington
Lay member, based in Leicestershire; non-executive director at University Hospitals of Leicester NHS Trust; member of the General Chiropractic Council; chairman of the General Medical Council fitness to practise panels; member of the Taxation Disciplinary Board Investigation Committee, the Bar Standards Board Complaints Committee, and the Appointments Board at the Nursing and Midwifery Council “Developing the new standards is a key first step in the work of the GPhC in ensuring that its focus is on improving the quality of care for patients. The standards must provide clarity for the profession and a clear framework for the delivery of a quality service that is safe and effective at a time when professional roles are developing and expanding into new and exciting areas. This consultation is an opportunity for the profession and the public to influence the standards so that they are right — the right level of detail and content, and able to be understood by the public as well as the profession.”