Pharmacy regulation: change is coming

The new pharmacy watchdog will not lead to a total regulatory overhaul — but pharmacists cannot expect everything to remain exactly the same.

Francesca Rivers takes a closer look at the implications of the General Pharmaceutical Council’s current batch of standards out for consultation

Regulation of pharmacy under the General Pharmaceutical Council is not intended to be revolutionary. Nor is it intended to be unnecessarily onerous. But the new regulator for pharmacists, pharmacy technicians and pharmacy premises is being created with the aim of modernising and strengthening regulation, and putting patient trust and safety first. With that aim comes a number of changes that will affect the working lives of pharmacists and pharmacy technicians.

Change is not always necessary or appropriate, and is rarely welcome — but it is unavoidable. However, pharmacists and pharmacy technicians have the opportunity to put forward their penniesworth on what is in store for the profession.

Proposed regulatory standards, education procedures and registration criteria are currently open to examination, with a stream of further consultations planned for next year (see Panel 1).

Although many rules and practices will be carried forward unchanged from the Royal Pharmaceutical Society’s dynasty, there are some areas of the draft standards and education and registration requirements that are worthy of more considered evaluation and comment before the consultations — and the window of opportunity to have a say — close early next year.

The need to revisit the code of ethics only a few years after it was extensively revised is likely to be particularly controversial. In addition, there are other more specific points in the standards on which pharmacists will have views.

Tougher return to practice

In a profession comprised mainly of women, there is a proposal that means any career break longer than two years will involve a stark decision for the individual: either undertake more rigorous retraining than at present or leave the Register. This recommendation will have an impact on the wider workforce as well as those seeking to return to practice after an extended career break.

“The GPhC will expect registrants who have not practised for two years to return to practice or to leave the Register,” states the draft return-to-practice policy in the proposed regulatory standards.

Approach to registration

Those first entering the pharmacy profession will also be subject to new restrictions. Draft criteria for GPhC registration include a proposed eight-year time limit for successfully completing the MPharm, preregistration training and registration examination (or “registration assessment”, as it is to be dubbed under the new regulator). Pharmacy technicians will have to get on the Register within five years of embarking on one of the accredited training courses. The GPhC also wants to put an end to fourth attempts at registration (after appeal), limiting the number of times a student can take the registration assessment to three.

Some have argued that these restrictions are too lenient. The thinking behind the eight-year time allowance for becoming a registered pharmacist was to ensure the currency of new registrants’ knowledge and...
skills, while allowing time for the three permissible attempts at the registration exam. One comment made on PJ Online questioned whether those students whose training spans almost a decade can be considered to have sufficient skills and knowledge to begin pharmacy practice.

The consultation document itself casts doubt over whether a pharmacy student should be allowed three attempts at the examination. The proposals point out that the arrangements are more lenient than all other assessments in UK universities, where the norm is to allow only one attempt at a resit, and “a third attempt would be exceptional”.

Indeed, should the registration assessment continue to take the form of a multiple-choice test? That format is likely to remain for the next few years, but renaming the exam an “assessment” will allow future flexibility on the form the examination will take, the proposals reveal.

Involving character and conscience
Other proposals worthy of note include plans for preregistration applicants to undergo health and character checks, the results of which will be shared with preregistration employers and the board of registration examiners.

The continued inclusion of a clause in the standards for conduct, ethics and performance that allows pharmacists to withhold certain services on the basis of their personal beliefs (the “conscience clause”) has also been highlighted as a point worthy of debate (PJ, 21 November 2009, p564).

In addition, the acceptance of self-selection of pharmacy medicines, provided procedures are in place that protect patients, is suggested in the consultation.

Conspicuously absent in the GPhC proposals to date are any requirements vis-à-vis ensuring the language competence of pharmacy professionals (PJ, 22/29 August 2009, p204), or clauses to cater for the concerns raised by members of internet forum LocumVoice earlier this year — which included a call for standards for dispensary layout and design, and an effective mechanism for reporting concerns, which will guarantee whistle-blowers anonymity (PJ, 14 November 2009, p523).

Get views in while you can
Consultation on the draft standards closes on 12 January, with the consultation on proposed education procedures and registration criteria coming to an end a few weeks after that. Both documents will then be redrafted as necessary. Although the GPhC may wish to consult further once it is legally established, the rules and standards will be adopted by the regulator as it comes into force. Once the cogs of the new regulatory machine begin to turn, should members of the profession find the new system wanting they will find their power to influence change far diminished. Far better they engage with the proposals now, and express their views on the rules that will govern the profession in the future.

Panel 2: Getting the GPhC on its feet

The draft Pharmacy Order was laid before Scottish and English Parliaments on 11 November 2009. Approval is needed from Scottish Parliament and both houses of Westminster before the Order can go before the Privy Council.

Meetings of the Privy Council are held monthly, except in January. A Department of Health spokesman told The Journal that the DoH hopes the Order will go before the Privy Council as early as possible in the new year. On the advice of the Privy Council the draft Order will then be signed off by the Queen, making the General Pharmaceutical Council a legal entity.

As well as the consultation on standards, new rules will need to be implemented before the GPhC is ready to take over the regulation of the profession. If the parliamentary timetable cannot be met, or a general election is called, the projected launch of the GPhC in April may be delayed.

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