



Response to

**The Pharmacy Order 2009
The General Pharmaceutical Council
Setting Standards
Proposals for Consultation**

as taken forward by the Council for Healthcare Regulatory Excellence

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Healthcare and Associated Professions, The Pharmacy Order 2009 The General Pharmaceutical Council - Setting Standards - Proposals for Consultation

Who we are

Community Pharmacy Scotland (formerly known as the Scottish Pharmaceutical General Council) is the body recognised to represent the pharmacy contractors who own Scotland's 1212 community pharmacies in negotiations with the Scottish Government on remuneration and terms of service relating to the provision of NHS pharmaceutical care services. Within our membership we represent all types of pharmacy, multiple or independent, situated throughout Scotland including a number of pharmacies in remote and rural locations.

Our prime focus in recent years has been the development of a new contract for pharmacy contractors, one which will call for the delivery of new services, potentially in novel ways, but continuing to place emphasis on the opportunity which community pharmacy offers in terms of access for patients to healthcare services. Scottish pharmacy contractors employ large numbers of pharmacists who will be required to register with the General Pharmaceutical Council (GPhC), and a number of support staff who could be eligible for registration as pharmacy technicians.

Pharmacy contractors currently dispense in excess of 80million prescriptions per year, offer a range of public health initiatives to promote well-being, provide consultations, treatment and/or referrals through the Minor Ailment Service plus offer access for patients with health problems when other health professionals are unavailable.

Significant investment has been made by contractors in recent years to ensure that premises are fit for purpose, the training needs of staff are addressed and that an appropriate IT infrastructure is in place. Community Pharmacy Scotland is now considering how it may reinforce the quality element within the contract and ensure that it sits comfortably within the overall health quality strategy.

General Comments

We are confident that our members and the staff they employ are well placed to deliver for patients and the public in Scotland. In preparing our response to the draft standards we have looked to see whether the standards do reflect an outcome and patient focused approach and if they will help the regulator to:

- develop trust and confidence with all parties
- sustain, assure and improve standards and quality
- command the respect of the profession
- look to improve working lives

We have also examined the standards to see if they are appropriate in terms of the delivery of health care in Scotland where practice within the NHS has started to diverge from the rest of GB. Our scrutiny reflects our concern that it is inadequate for the GPhC to have only one member who must live or work wholly or mainly in Scotland.

The draft standards have been developed through a process led by the Department of Health, with considerable input from pharmacists who are employed by the current regulatory body. We were disappointed that it was not thought necessary for any of the standards workshops to take place

outside London. The resulting consultation document was subsequently only published on the website of the Council for Healthcare Regulatory Excellence and stakeholders did not receive any formal notification of the consultation process. That is in contrast to the procedures adopted by the existing regulator where formal contact was made with key stakeholders.

The time period allocated for the consultation is 12 weeks and it spans the Christmas/New Year holiday period. Given the breadth of the areas covered by the consultation and the lack of previous widespread debate in certain areas that consultation period appears rather abbreviated.

The rationale for the procedure adopted is that until the GPhC is formally established it could not carry out such development work. However the existing pharmacy regulator has received a satisfactory report from CHRE for the past two years, i.e. there did not appear to be evidence of substantial risks to patients and the public. There were existing standards which built from a recently revised Code of Ethics in which the need to make the care of patients the prime concern was clearly stated.

Our view is that the process adopted has not been helpful to the perception of GPhC held by stakeholders. In turn that perception may delay progress towards developing the trust and confidence of all parties. Community Pharmacy Scotland has an expectation that GPhC will come back to stakeholders once it has had time to consider the feedback to this consultation.

The consultation questions follow a similar format to that used in many previous DH consultations. They are leading rather than open-ended and create the feeling that any responses will be largely ignored. Again it doesn't seem to sit well with developing trust and confidence for all parties and is an area which might usefully be changed in future consultation work.

DRAFT STANDARDS - GENERAL PRINCIPLES

In the document the general principles behind the standards are stated to be that:

The standards should link to safe and effective practice

The standards should be patient and outcome focused

The standards should be broad and flexible

The standards should be consistent in terms of language and terminology

Question 1

Do you agree that overall the standards adequately reflect an outcome and patient focused broad and flexible approach?

Yes they reflect an outcome and patient focused approach. We have concerns that they appear to be overly prescriptive and do not accord with a broad and flexible approach. By being overly prescriptive they may actually cause professionals to become more defensive in their practice to avoid negative patient outcomes.

The links to safe and effective practice for pharmacy technicians are not yet explicit given the lack of a practice framework for technicians.

The emphasis in the standards on patient and outcome focus appears to have come at the expense of being standards which are readily interpretable by pharmacists or perhaps even by patients and the public. The presentation is not particularly accessible and in certain drafts it is not clear what is expected of the professional, e.g. in Annex C which deals with proficiency. It seems unlikely that in the first instance they will be seen in any way as improving working lives.

Question 2

Do you agree with the use and definition of the term patients and public?

We agree that an attempt should be made to define the recipients of services but our view of what constitutes patients and the public may not coincide with how patients and the public see themselves.

Question 3

The GPhC is committed to embedding Equality and Diversity at the heart of everything it does. Do you think that the draft standards support this commitment?

We cannot see anything to suggest otherwise.

ANNEX A – DRAFT STANDARDS – OWNERS AND SUPERINTENDENT PHARMACISTS

Question 4

Do you think that the draft standards for owners of pharmacies and superintendent pharmacists are proportionate to the benefit they bring and the risk they are guarding against?

We do not feel we can answer that question until we are able to assess the way in which performance against the standards is assessed and then the outcomes achieved. In our opinion many of these standards already exist but are perhaps not as visible to the public and patients as the regulator expects. The draft standards are very detailed rather than broad and flexible.

As stated previously much effort has already gone into improving standards in pharmacy premises in Scotland and to changing the way practice occurs. We see it to be important that the regulator should expect adherence to the standards in order to avoid risk to the patient. Adherence should not be expected to meet the convenience of the public.

We welcome the fact that there will be a period of two years for implementation and we would expect the process of implementation by the Inspectors to be subject to regular review to ensure that it is happening appropriately. Community Pharmacy Scotland is keen and willing to work collaboratively with the GPhC to facilitate delivery.

We will also need to assess the costs to owners of meeting these new regulatory burdens. For most pharmacies the bulk of their activity relates to the provision of NHS services and therefore it will be necessary to enter into negotiations with the Scottish Government on how these additional costs are to be met. If new funds are not forthcoming, then that could impact upon the range and availability of services available, outcomes which do not seem to be in the best interests of patients and the public.

Question 5

Should there be specific standards for the systems in place within registered pharmacies to control and prevent healthcare related infections?

Regulation is intended to be targeted and proportionate to risk so before a specific standard is developed we would like to see the evidence to back up that requirement. If the intention is to bring in specific standards whenever a new risk is identified it seems unlikely that the draft standards have been developed to be broad and flexible.

Question 6

There is no explicit prohibition on owners of pharmacies and superintendent pharmacists offering medicines for self-selection. Instead there is a general requirement that systems are in place to ensure the safe supply of medicines to patients and the public in a manner that promotes safe and effective use and appropriateness. Do you agree with this approach?

We are content that there should be a general requirement as it will be for the owners and superintendents to determine the best approach in their particular set of premises.

ANNEX B – DRAFT STANDARDS – CONDUCT, ETHICS AND PERFORMANCE

Question 7

Do you think that the draft code of conduct ethics and performance adequately applies to registered pharmacists and pharmacy technicians in all sectors of practice?

In comparison with the previous Code of Ethics, which was developed after an extensive consultation period, this code is over-long, repetitive and user-unfriendly. The workshop members also do not seem to be overly representative of diversity within the profession.

It is also contradictory – if all standards are equal why are they then numbered? If the standards are intended to be patient and outcome focused, we don't understand the departure from the idea of making care of patients the first concern and then grouping other relevant standards below that. That would fit better with both with a principle-based approach and the practitioner using professional judgement to determine how to proceed in the best interests of the patient and public.

The Code is very much geared to patient outcomes. Some pharmacists because of the diversity of employment within the profession have very little patient contact and will find it more difficult to relate to sections of the Code. There will be a need for the regulator to support its introduction for these pharmacists.

We cannot comment on whether the code applies adequately to registered pharmacy technicians given the lack of a practice framework.

This is the third code on conduct, ethics and performance produced in almost as many years. We see it as vital that GPhC adopts a supportive approach to its introduction.

It would also be helpful if GPhC were to consider introducing its standards in a different format. For example, the Good Medical Practice booklet issued by GMC is much more accessible and understandable.

Question 8

Do you agree that there should be provision within the Code which allows personal beliefs of registrants to prevent them from providing a particular professional service? Subject to ensuring that patients and the public are referred to alternative providers of the service they require?

Yes but only for services where there is a particular moral or religious reason. Pharmacist should not be able to opt out of service provision where they have a political objection to the care mechanism.

ANNEX C – DRAFT STANDARDS – PROFICIENCY

Question 9

Do you think that the proficiency standards for pharmacists and pharmacy technicians are sufficient to ensure that they are able to practise safely lawfully and effectively?

No. In our view the draft proficiency standards are insufficiently developed. They do not make clear how the proficiency of a registrant who has been practising for a number of years will be gauged. The concept of advanced and specialist practice is not being taken forward in Scotland in the same way as in England and any change to the draft standards will need to reflect that fact.

Taken together Annexes C, D and E2 still appear like work in progress.

The concept of proficiency will be new to many registrants. The process to develop this set of standards has been restricted to those with particular knowledge of the subject and a few invited participants. The finalised standards document will need to bring out more clearly exactly what it is trying to achieve.

It should not be necessary to duplicate within this document the contents of the standards on conduct, ethics and performance, which in our view it does.

The relevance of Part 2 which appears to have been taken from another document is also unclear.

The relevance of Part 3 to daily practice and patient outcomes needs to be brought out more.

The links between the education standards, the practice framework and proficiency standards, the standards for CPD and then Back to Practice need to be clarified and made visible for all registrants in a form which is consistent, straightforward, doesn't suffer from duplication of information and is practical to use.

We would strongly suggest that more work is needed on this section and that appropriate consultation takes place.

Question 10

Do you agree that the standards of proficiency for pharmacy technicians should require a broader range of knowledge and understanding?

It is essential to have a clearer definition of practice for pharmacy technicians (PTs) before a decision is taken on what the proficiency standards should be. However, certain aspects of the proposed proficiencies are no longer relevant in Scotland e.g. small scale pharmaceutical production where such activity is increasingly being centralised.

Our view is that we must have an open debate on whether what is currently being proposed for pharmacy will deliver for patients and the public in Scotland. We have no clear picture of what PTs themselves want and the perception from some of our members is that the staff currently employed show little appetite for regulation.

The current learning requirements for PTs are already very extensive but rarely used in practice due to the need to work under supervision. The breadth of knowledge rather than the application of skills was the only reason the current course was able to secure the Level 6 on the SQA framework.

If there is an intention to increase the level of knowledge required then the extra time and cost involved will also have to be factored into any decision on whether to employ PTs and put them through courses.

Question 11

Do you agree with the distinctions between the proficiencies of pharmacists and pharmacy technicians?

Yes. At present it is the responsibility of a pharmacist to secure the safe and effective running of a community pharmacy in Scotland and for the dispensing of NHS prescriptions to take place under direct supervision. Many of the proficiencies shown are not required at present by technicians working in the community and we need to have more debate on what is expected of the technicians before we decided if the standards are adequate.

ANNEX D DRAFT STANDARDS – EDUCATION AND TRAINING

Question 12

Do you agree that the knowledge programmes for pharmacy technicians may continue to be delivered outside national frameworks provided that they have been accredited by the GPhC as delivering equivalent outcomes?

If knowledge programmes for pharmacy technicians were to be delivered solely within national frameworks it then becomes easier to ensure the qualifications gained are transferable, particularly when new skills are developed.

The current accredited providers' material is widely used in the community. We would not want to see that source removed unless we were confident that alternative methods of provision were adequate.

Question 13

Do you agree that pharmacy technicians must be able to apply a general knowledge of clinical and pharmaceutical science?

We come back to the point that there is a need for clarity on what pharmacy technicians are being expected to deliver. There is already concern that the S/NVQ framework is not delivering technicians with appropriate skills. The standards proposed are knowledge-heavy and certain aspects are irrelevant to Scotland where small scale pharmaceutical production and the manufacturing process have been centralised. The current regulator has therefore already agreed that the new S/NVQ Level 3 frameworks can be different. We would like to see GPhC acknowledge that the underpinning knowledge programme developed in Scotland should be reflective of practice and useful to practice. As an example, the risk for patients from aseptic dispensing in the community is non-existent so we do not understand why all technicians need to show that learning outcome. In an emergency a pharmacist would manage that risk.

Regulation is meant to be proportionate to risk and targeted – the draft standards do not appear to fulfil these criteria. If regulation is to be targeted, then it has to relate to current practice, not to the way technicians worked previously.

Secondly we do not understand the increased focus on chemistry in the draft standards including the structure and classification of inorganic chemicals. The standards proposed for chemistry are in excess of the requirements within the National Occupational Standards recently developed. Pharmacy is moving towards pharmaceutical care, involving greater interaction with the patient, so the standards should be providing for the development of relevant skills.

Thirdly, the draft standards do not recognise in the indicative syllabus that it will not be possible to accommodate all the proposed learning outcomes within the Scottish Qualification Credit Framework for a National Certificate. If new units have to be written to deliver the outcomes then a new award will need to be created and more time will be necessary to get new courses up and running. The existing courses have already exceeded their life span. It would be helpful for GPhC to take on board that education as well as health is devolved and educational grants or apprenticeships in Scotland will often be linked to a candidate undertaking a Scottish qualification.

The breadth of the proposed syllabus could mean an increase in the time when the student needs to be released for college or distance learning. There is a cost attached to that and if the content of the course is not seen to be relevant, and of no practical use then uptake is unlikely to be high.

The standards state that candidates on the programme should also receive a minimum of 250 hours of off-workstation learning across the duration of the programme. It is hard to see how this can be accommodated in pharmacy premises. This is a requirement for Modern Apprenticeships in England and Wales but is not a specified requirement in Scotland.

Our main concern here is that work is already underway to deliver the new S/NVQ Level 3 courses. Any further delay might mean the new knowledge programmes will not be validated by summer 2010. We do not want to end up in a situation where no accredited courses are available. It would be helpful if GPhC were to sanction completion of the work already done on the new S/NVQs as an interim measure. That will then allow time for a full debate on the role of the pharmacy technician and its relevance to current practice. As the representative of pharmacy contractors we can input our views on a practice framework for support staff which is relevant to the safe practice of pharmacy. As professionals subject to regulation it would also be helpful to hear from PTs on how they see their role developing.

Question 14

Do you agree that undergraduate education and pre-registration should be integrated?

We see the need to look at this but it will take time and the necessary support/funding will have to be put into place. As an example how will tutors develop the skills to mentor students at different stages of their undergraduate training? Who would co-ordinate placements?

In Scotland the arrangements for delivery of the pre-registration year are co-ordinated by the Pharmacy Division within NHS Education for Scotland (NES). Next year an impact assessment of the process will be available to inform where change might be needed.

There has been little discussion on how integration of the pre-registration year might happen and to date the only mention we have seen of it appeared in the English White Paper.

We will be happy to consider this further once a more detailed consultation including the Scottish perspective is made available.

Question 15

Do you agree that the standards should be based on an increased clinical role for pharmacists?

No. We agree that there should be strong emphasis on the clinical role in the standards but not all pharmacists practise in a patient-facing role. The standards should reflect the diversity of occupations within the profession or the alternative is that many pharmacists may choose to leave the register and their input will be lost from practice in that area.

There is also the issue around securing sufficient funds to provide the training to accommodate the increased clinical role.

Question 16

Do you agree that delivering these standards will require changes to assessment at undergraduate level?

No. The Schools of Pharmacy have already made changes to their assessment procedures to reflect the increasing clinical content of the course.

We want to see undergraduate courses continue to deliver graduates who are able to adapt to changes within practice and divergence of practice across Great Britain. We want to see assessment procedures in place which are capable of delivering graduates who are able to undertake work across many areas. We do not see it as helpful to be too rigid at the end of the undergraduate course. Where practice moves on with new skills being developed then the opportunity is there to assess and monitor through the proficiency and CPD requirements. It would only be for instances where there is a demonstrable risk to the patient and public that there should be a need for assessment of that particular skill.

ANNEX E – DRAFT STANDARDS – CONTINUING PROFESSIONAL DEVELOPMENT

Question 17

Do you agree that together, the standards and framework provide a comprehensive approach to CPD, in line with the draft Pharmacy order requirements?

The Draft Pharmacy Order requirements are:

- the amount and type of CPD that a registrant is expected to undertake
- the information to be provided by a registrant about the CPD and the form and manner
- the times at which information about CPD undertaken is to be provided
- the keeping of records

The standards and framework appear to provide a comprehensive approach to the recording of CPD but how effective that approach will be to maintaining competence remains to be seen.

Question 18

Do you agree that registrants, irrespective of their scope of practice should record some CPD that relates to their ability to practise according to the GPhC standards of conduct, ethics and performance?

In order to practise registrants have to keep their knowledge and skills up to date. It is therefore a given that they have to record some CPD and that CPD should obviously be relevant to the area in which they practise or where a change to the scope of practice is being made. The draft standards again seem to be showing areas of duplication.

We see it is suggested that entries should be made on a continuous and timely to date basis – we'd suggest that there should be scope to update entries if new learnings occur relevant to the previous work rather than start a whole new entry.

Annex E2 – Draft Standards - Return to Practice

Question 19

Do you agree that there should be a return to practice requirement after two years out of practice?

No. The figure of two years appears to be arbitrary. As regulation is meant to be proportionate to the risk we would like to see evidence presented on what the levels of risk are.

Question 20

Do you agree with the proposed return to practice and updating requirements?

Courses are already available for back to practice. The difference being proposed is the period of supervised practice and it is not clear how this is to be achieved (given that we also have to consider integrating the pre-registration year and extended training for PTs). As already stated we see the standards for proficiency as unfinished so without them it will be impossible to make any assessment of competence.

A supporting framework would be needed and this would have to be discussed with the health departments. It should not be anticipated that employers will be able to pick up the burden of supervised practice without support.

There is a case to be made for supporting people to remain in practice rather than dropping out. The number of female registrants is increasing and learnings from the GP retainer scheme (which is funded by Government) could provide pointers for pharmacy.

If the return to practice requirements become too difficult to achieve then the likelihood is there will be a fall in registrant numbers which will not secure the best outcomes for patients and the public.

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