Public business

Priority changes to the Pharmacy Order 2010

Purpose
To ensure that the GPhC is prepared for any opportunity which may arise for changes to the Pharmacy Order 2010.

Action required
The Council is asked to confirm the list of items summarised in paragraph 2.5 of this paper as desirable priority changes to the Pharmacy Order 2010.

1.0 Introduction

1.1 The Law Commission is conducting a review of the legislative framework for health professions regulation and expects to issue proposals for consultation in 2012. This exercise was announced in Enabling Excellence:

“The Government has asked the Law Commission to undertake a simplification review of the existing legislative framework and to develop a draft Bill for consultation. This will be a substantial body of work which will take some time to complete, but the intention would be to introduce legislation towards the end of the current Parliament.”¹

The GPhC has identified influencing the design and implementation of a new legislative framework as a priority in our Strategic Plan 2012-2015, and we continue to be very actively and positively engaged in the Commission’s work.

¹ Enabling Excellence: autonomy and accountability for health and social care staff, Department of Health, London, February 2011
1.2 Officials have indicated the possibility of an Order (a “section 60 Order”) to make amendments to existing health professions regulation legislation, following publication of a consultation and draft Bill by the Commission and early results of the efficiency and effectiveness review being carried out by the Council for Healthcare Regulatory Excellence. It would be prudent to identify any Pharmacy Order changes which the GPhC should press for.

2.0 Key Considerations

2.1 Candidates for inclusion in a section 60 Order will be assessed by reference to the following criteria:

- The amendments are required to protect patients and the public
- The amendments will improve the efficiency and effectiveness of the regulatory body
- The amendments are consistent with overall Government policy
- The amendments do not pre-empt or contradict any proposals from the Law Commission.

2.2 The Pharmacy Order 2010 is the newest of the legislative frameworks for the regulation of the health professions and in many ways it represents an advance on previous legislation. The consultation on the draft Pharmacy Order took place between December 2008 and March 2009 (which of course was before the GPhC Council and executive were identified and appointed). Since that time policy has moved on considerably, and we have over a year’s worth of experience of operating the Order, which does provide a basis for identifying desirable changes.

2.3 In making these recommendations, the executive has excluded a number of potential changes which ought to be considered in due course but which are not thought to meet the priority criteria summarised in paragraph 2.1. Equally, this paper does not seek to address longer term potential future developments which would more appropriately be taken forward in the context of the Law Commission’s work.

2.4 The changes being proposed are explained in detail in the appendix to this paper with, in each case, a summary of the proposed change, the rationale for it, the benefits it would bring and an account of why it meets the priority criteria in paragraph 2.1.

2.5 The proposed changes which Council is asked to support are:

a. Enable the GPhC to require evidence of English language competence from EEA applicants for registration
b. Remove the prescriptive detail which specifies registration expiry dates in legislation; and enable the Council to deal with these matters (including the ‘rolling register’) in rules, following consultation.

c. Changes to the Fitness to Practise provisions in the Pharmacy Order to increase the flexibility and efficiency of the initial stages of the procedure.

d. Enable the GPhC to work in a more “joined-up” way with other regulators and authorities (eg. police forces), by requiring third parties to provide information about applicants for registration, as well as information about current registrants.

e. Clarify that the GPhC is able to require certain European pharmacist applicants and all European pharmacy technician applicants to meet the standards of proficiency for safe and effective practice of pharmacy prior to registration.

f. Facilitate the development of a risk-based and proportionate approach to premises regulation by removing the requirements to specify the intervals for routine inspections, and the circumstances for special inspections and other visits, in rules.

GPhC recommendations on legal change will be just that: recommendations. Implementation of any change is subject to the relevant public policy, legal and parliamentary scrutiny and decision-making processes.

3.0 Equality and diversity implications

3.1 Equality and diversity implications of each proposed change are addressed in the appendix.

4.0 Communications implications

4.1 Advancing the case for each of these changes (if agreed) would create a positive opportunity to illustrate and demonstrate the Council’s commitment to proportionate and cost-effective regulation.

4.2 If these changes were proposed in a draft section 60 Order they would undergo statutory consultation as part of the full public consultation to which all section 60 Orders are subject. It would not be necessary for the GPhC to consult on the proposals themselves, therefore, although some of the implementation would in due course require GPhC consultation, for example in relation to changes to rules.
4.3 There are some specific communications implications in each case which are highlighted in the appendix.

5.0 Resource implications

5.1 The implementation of these amendments can be made within existing resources. Any specific issues are identified in the appendix. All the proposed changes would improve the effectiveness and/or efficiency of pharmacy regulation.

6.0 Risk implications

6.1 This paper seeks to mitigate the risk that the GPhC misses an opportunity to make useful amendments to the Pharmacy Order in advance of potential future over-arching legal reform.

Action required

The Council is asked to confirm the list of items summarised in paragraph 2.5 of this paper as desirable priority changes to the Pharmacy Order 2010.

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3 January 2012
Appendix 1

a. Enable the GPhC to require evidence of English language competence from EEA applicants for registration

1.0 Proposed change

1.1 Amend the Pharmacy Order so that the GPhC is entitled to require evidence of English language competence from EEA applicants for registration.

1.2 The purpose of this change is to improve public protection and patient safety in pharmacy. Relying exclusively on employers to assess language competence as an aspect of fitness for purpose in a particular job role does not provide adequate public protection in a profession many of whose members work outside managed NHS environments, on a self-employed basis, or are employed in small private businesses, and/or work as locums.

1.3 In order to ensure proportionality in the implementation of the change, the proposal does not extend to mandatory blanket language testing. The change would be designed to enable evidence to be required when considered necessary; the criteria and process for determining necessity and for considering evidence would need to be developed, and should not in any event be specified in detail in amending legislation.

2.0 Equality and diversity

2.1 The change would raise equality and discrimination issues; these could and should be safely addressed through the production of criteria and a fair implementation process.

3.0 Communications

3.1 The planning for the introduction of the change would necessitate policy and legal communications with DH and the devolved authorities, and with the European Commission, in order to ensure compatibility with relevant European law. Implementation would involve operational communications with applicants and with employers.

4.0 Resources

4.1 With the change framed in terms of a right for the GPhC to require evidence, rather than to conduct tests, the onus of providing evidence of English language competence when necessary, as an aspect of an individual’s fitness to practise in pharmacy, would rest on the applicant. The GPhC would undertake additional administrative activity in some cases in requesting and evaluating the evidence. No major resource implications have been identified.
b. Remove the prescriptive detail which specifies registration expiry dates in legislation; and enable the Council to deal with these matters in rules, following consultation

1.0 Proposed change

1.1 Amend the Pharmacy Order so that the GPhC Council can make provision in rules as to the length of registration periods and expiry dates.

1.2 The purpose of this change is to reduce cost, improve efficiency and reduce disproportionate regulatory burdens.

1.3 The effect of the amount of detail in the Pharmacy Order registration provisions is that for registrants and premises joining the register since September 2010, registration expires automatically on the anniversary of their registration. This has required the GPhC therefore to introduce and maintain the so-called rolling register.

1.4 Many pharmacy stakeholders, including but not limited to companies with multiple premises and numerous registrant members of staff have found that this increases substantially their governance and compliance burden. The proposed change would enable the Council to legislate for these matters and thus alternative approaches could be discussed with stakeholders. Provided registrations are renewed in a timely fashion before they expire (however that is determined) there are no safety and standards issues or risks from the public point of view.

2.0 Equality and diversity

2.1 The change would not have any equality and diversity impact.

3.0 Communications

3.1 Communication of the rolling register, in parallel with the bulk renewal for transferred registrants, represents a continued challenge for the GPhC and pharmacy stakeholders.

3.2 The planning for the introduction of any eventual change would necessitate consultation in due course, as well as policy and legal communications with DH and the devolved authorities in relation to new GPhC rules. Implementation would involve operational communications with applicants, registrants and with employers.

4.0 Resources

4.1 Whereas in theory the spreading out of the renewal workload over the year could have been expected to ease resource pressures for the regulator, in practice (on the basis that we have two registration and renewal dates per month plus the bulk renewal for transferred registrants) we now have to conduct
27 renewal rounds annually rather than the one which would be necessary if all registrations expired at the same time. The impact on the GPhC IT system would need to be identified and managed.
c. Changes to the Fitness to Practise provisions in the Pharmacy Order to increase the flexibility and efficiency of the initial stages of the procedure

1.0 Proposed changes

1.1 Within the current overall legislative context of Fitness to Practise, and in advance of the Law Commission’s proposals, it may still be possible to identify desirable changes to the detail of GPhC current legislation.

1.2 Assuming that any fundamental re-design of the overall architecture of the FTP procedure is a matter for the Law Commission’s review and would not be considered by way of a priority change, we should explore the scope for interim changes to:
   - maximise the utility of the registrar function in less serious cases (i.e. those in which a sanction short of suspension or removal is in order), for example by empowering the registrar to issue warnings subject to adequate safeguards and/or by enabling more efficient and effective imposition and management of conditions on registration
   - enhance the scope of the Council’s power to issue criteria to guide referrals to and by the Investigating Committee.

With both these types of changes we will put in place both appropriate quality control in decision-making and robust quality assurance. The detail of changes will need to be subject to detailed discussion with officials and GPhC and government legal advisers.

2.0 Equality and diversity

2.1 Increased flexibility and greater use of administrative decision-making have the potential for unfairness; these risks need to be mitigated by working accountably (eg. subject to audit) within transparent policies and decision-making frameworks.

3.0 Communications

3.1 Early engagement with stakeholders to explain the case for interim changes, and to understand any concerns they may have, will help to ensure that the detailed changes which emerge are well-thought through and appropriate.

4.0 Resources

4.1 The sorts of changes being explored would reduce the workload of the Investigating Committee, which is proportionately a costly form of decision-making process.
d. Enable the GPhC to work in a more “joined-up” way with other regulators and authorities (eg. police forces), by requiring third parties to provide information about applicants for registration, as well as information about current registrants

1.0 Proposed change

1.1 Obstacles to effective information-sharing between regulators and public authorities (eg. police forces) can put the public at unnecessary risk.

1.2 The purpose of this change is to improve public protection; ensuring the fitness to practise of those applying for registration is just as important in public protection terms as ensuring the continuing fitness to practise of those who are already registered. We have experienced difficulties in particular cases in obtaining necessary information; this is an actual rather than a hypothetical problem.

1.3 The Order gives the GPhC power to require third parties to supply information about the fitness to practise of registrants. This can be backed up, if necessary, by Court Order. The purpose for which information can be required should be extended to include information which would inform our assessment of applicants’ fitness to practise.

2.0 Equality and diversity

2.1 The change would not have any equality and diversity impact directly. The use of the widened power would of course need to be non-discriminatory.

3.0 Communications

3.1 Operational communications with those applying for registration (web pages, application forms, guidance notes) would need to make it clear that we might seek, and be entitled to compel, third parties with relevant information to provide it to us.

4.0 Resources

4.1 This change would not have any significant resource implications.
e. Clarify that the GPhC is able to require certain European pharmacist applicants and all European pharmacy technician applicants to meet the standards of proficiency for safe and effective practice of pharmacy prior to registration.

1.0 Proposed change

1.1 The Order requires the GPhC to set standards of proficiency for the safe and effective practice of pharmacy which it is necessary for a person to reach before being registered as a pharmacist or pharmacy technician but specifically excludes all European qualified pharmacists or pharmacy technicians from being required to meet these standards prior to registration.

1.2 The Directive recognition procedures for European pharmacists in certain circumstances and for all European pharmacy technicians require the GPhC to assess an applicant’s qualifications and work experience against the national requirements for registration. The GPhC’s application procedures comply with the Directive. The proposed change is to clarify that the exclusion in the Pharmacy Order only applies to European pharmacists under the automatic route to the register where the assurance of proficiency is provided by the ‘home’ member state.

1.3 The purpose of this change is to improve the effectiveness of public protection.

2.0 Equality and diversity

2.1 The change would not have any equality and diversity impact.

3.0 Communications

3.1 There are no significant communications implications beyond explaining the rationale for the change to interested parties.

4.0 Resources

4.1 There are no resource implications; the clarification would not involve any reduction or increase in activity.
f. Facilitate the development of a risk-based and proportionate approach to premises regulation by removing the requirements to specify the intervals for routine inspections, and the circumstances for special inspections and other visits, in rules.

1.0 Proposed change

1.1 The Order (article 9) requires the GPhC to make rules relating to the intervals at which inspectors may conduct routine inspections of pharmacies, and the circumstances in which inspectors may conduct special investigations of, and other visits to, pharmacies.

1.2 The GPhC aims to ensure that regulation is fair and proportionate – in line with the level of risk posed to public health, safety and wellbeing – and not over-burdensome. We want it to be flexible enough to respond to the changing demands made of the profession and to allow for innovation at the same time as maintaining high-quality practice. The level of detail required in rules under the Order would make it more difficult for us to target resources at the areas of highest perceived risk.

1.3 The purpose of this change is to enable an efficient and effective approach to premises regulation.

2.0 Equality and diversity

2.1 The change would not have any equality and diversity impact.

3.0 Communications

3.1 There are no significant communications implications beyond explaining the rationale for the change to interested parties.

4.0 Resources

4.1 There are no resource implications of this change, as there are currently no rules governing the intervals at which routine inspections may take place or the circumstances in which other visits to pharmacies may be made. Avoiding the need to make such rules would avoid the need for inspectors to make visits which were not considered necessary in order to comply with the detail prescribed in rules.