Report on the GPhC consultation ‘Modernising Pharmacy Regulation’

Purpose
To present a final Report on our consultation Modernising Pharmacy Regulation for consideration and approval

Recommendations

The Council is asked to consider a draft Report on our consultation including ‘our response’ to issues raised.

The Council is asked to agree:

i) our response to the issues identified, and agreed by Council, as requiring further consideration

ii) the consultation Report for publication

1.0 Introduction

1.1. At its meeting in June 2012, Council approved a consultation summary report on, Modernising Pharmacy Regulation: draft standards for registered pharmacies.

1.2. That paper set out in some detail the extensive activities which were undertaken as part of the consultation process as well as setting out the methodology used to collect and analyse the responses.
1.3. Although the feedback on each of the proposals within the three main sections of the consultation document is positive, the scale of the feedback – with over 456 formal responses – was such that Council agreed to defer final conclusions and to agree a final report, including our response to questions or issues raised by respondents.

2.0 How we collated the feedback and analysed the responses

2.1. We utilised best practice in managing consultation responses. Our approach has been informed by guidance from the Consultation Institute and recognises that it is important that all feedback, whether it be from an individual or a large representative organisation is given full consideration. Steps we have taken to ensure the process is robust include:

- presenting the statistics in a clear and consistent manner throughout the summary report
- ensuring that these statistics include both online and paper based responses
- that those who were reviewing and coding responses were from a different policy team to those responsible for drafting the consultation document
- reviewing all the responses to the qualitative, open questions so that each response was coded in order to identify themes
- following this coding approach consistently for all responses received which either didn’t seek to answer questions directly or included more discursive feedback. This approach allows us to highlight recurrent themes which emerged in response to each question.
- all comments, including those from individuals and not part of a wider theme have been captured for further consideration as part of our review of the draft standards as has feedback from all of the consultation events.

2.2. We have attempted to listen to, and where possible capture, informal feedback received during and outside the consultation period. This has included monitoring print, online and social media. We have not, however, recorded this in the consultation report to avoid distorting the statistical analysis.

3.0 What we heard during the consultation process

3.1. However, there are certain issues which we have already identified as needing further consideration before the standards are finalised and can be presented for approval to Council.

4.0 Issues which required further consideration
4.1. At the Council meeting in June, we set out a number of issues which we felt required further consideration before presenting a response for Council to consider.

4.2. We are now in a position to present a draft response to Council for consideration. A draft response to each of these specific issues raised is provided, although Council will wish to note feedback is provided in the Report on a much larger number of points and feedback received.

4.3. The specific issues we committed to providing a response on were: clarification on the registration criteria; how the standards were presented and drafting suggestions; the need to work with other regulators; feedback on how professional duties and regulatory requirements in relation to medicines legislation can best be met.

4.4. Our draft response is set out in the sections below.

5.0 Registration criteria

5.1. A number of responses raised questions about the registration criteria and our interpretation of the relevant sections of the Medicines Act 1968 (now the Human Medicines Regulations 2012). We have received and considered the external legal advice to ensure the registration criteria reflects the law in this area.

5.2. We are now clear that the follow criteria must be used when both determining eligibility and requirements to register:

We will only register a pharmacy where the service model includes the retail sale of Pharmacy (P) medicines, the retail sale of Prescription only medicines (POMs) or the supply of Ps and POMs in circumstances corresponding to retail sale. Therefore the service model must include one of the following:

1. The sale of Pharmacy (P) medicines

2. The supply of P medicines or Prescription Only Medicines (PoMs) against prescriptions

3. The supply of P medicines or Prescription Only Medicines (PoMs) against prescriptions written by a veterinary practitioner for the treatment of an animal.

5.3. As a result, for example, a veterinary pharmacy will be eligible and required to register if its service model includes the supply of pharmacy (P) medicines or Prescription Only Medicines (PoMs) against prescriptions written by a veterinary practitioner for the treatment of an animal. This is a change from our previous
interpretation which was that the medicines would have to be human medicines for use by human patients.

5.4. We have already identified further guidance required to sit alongside the proposed standards; further communications will be required as this is drafted and finalised.

5.5. Finally, the standards for registered pharmacies, as set out in the Pharmacy Order 2010, will also need to be set out in rules. There are further statutory obligations to consult on these rules.

6.0 How the standards are presented and drafting suggestions

6.1 We received a range of suggestions about the presentation and drafting of the standards and compliance indicators which highlighted to us the need to make changes to assist both clarity about the standards themselves, but also a desire for further information about how we would inspect against the standards and how the compliance indicators would be used. We have listed to this feedback and made a number of proposed changes as set out below:

We have reviewed the drafting of the standards to make them clearer. This has included merging some of the standards to avoid duplication. This will make the standards shorter and, we hope, clearer.

Having reviewed all the feedback about compliance indicators associated with the draft standards, we are proposing to remove them from the standards document. Having reflected on the feedback we feel that this kind of information should form part of the decision framework inspectors will use in assessing how well a pharmacy meets our standards. This will be a public document, accessible to all, which will be used by our inspectors, to assist them in reaching decisions about whether owners and superintendents have complied with the standards.

We will be publishing further information about our plans to develop further our decision framework and associated communications alongside publication of the finalised and agreed standards.

7.0 How we work with other regulators

7.1 Consistent with principles of good regulation and the Hampton principles, we are committed to working closely with other regulators to ensure we are avoiding unnecessary duplication and identify any key gaps in regulation.

7.2 We have established good working relationships with the key ‘system’ regulatory bodies in each country of Great Britain, the Care Quality Commission, Healthcare Inspectorate Wales and Healthcare Improvement Scotland. We also
continue to work closely with other health professional regulations. As our response in the report states:

*We are working with the key regulatory bodies and health organisations (including commissioners) in England, Scotland and Wales to identify areas of duplication and overlap in requests for information from pharmacies. This includes exploring any wider opportunities to share performance monitoring information where relevant to help inform a more focused and proportionate regulatory approach.*

8.0 **Feedback on how professional duties and regulatory requirements in relation to medicines legislation can best be met.**

8.1 One of the main issues raised requiring further consideration relates to self-selection of P medicines.

8.2 A number of responses from pharmacy representative bodies and pharmacists argued that the prohibition, previously set out in the interim standards for superintendents and owners, on pharmacies having P category medicines available for self-selection by patients and the public should be re-inserted into the proposed standards.

8.3 In our deliberative events with patients and the public there was a divergence of view, with arguments both for and against enabling P medicines, in certain circumstances, to be available to select.

8.4 We have listened to the feedback and recognise the genuine concern of some within pharmacy about how this can be implemented safely, and in particular how to ensure pharmacists meet their ongoing legal requirement to supervise all sales of P medicines.

8.5 In developing a response to the concerns raised we have sought to balance Council’s commitment to outcome-focussed standards and our desire, widely supported, to enable professionals to use their judgement, against arguments about potential risks. This paper does not seek to summarise those arguments but we have been particularly mindful of the concerns expressed by the leadership body for the profession, the Royal Pharmaceutical Society, particularly in relation to difficulties it believes its members may experience when trying to communicate or discuss risks in relation to P category medicines once a patient has already selected it and fears about commercial pressures driving decisions, rather than patient safety.

*Options considered*
8.6 We have considered retaining the position as set out in the draft standards and remaining silent on the issue of self-selection. We do not believe, given the concerns raised, that this position would be appropriate.

8.7 We have also considered the option proposed by the Royal Pharmaceutical Society and others of inserting a rule in the standards prohibiting self-selection of P medicines. We do not think this approach is in the interests of good regulation; we wish to support pharmacy professionals in making decisions in the best interests of patients and the public, consistent with medicines legislation and other legal and professional regulatory obligations.

8.8 As the consultation report states, it is our intention to retain our outcome focussed approach in the standards. We do not recommend a rule be inserted in the standards which would prohibit self-selection of P category medicines under any circumstances. We do, however, agree with the proposal of the Royal Pharmaceutical Society that if there is no specific standard on this issue, the GPhC should produce guidance to support compliance with the standards. Further detail on the proposed timing for development of this guidance is set out in the council paper, *Managing the transition*.

8.9 We also think that further requirements should be put in place before self-selection of P medicines can take place within registered pharmacies. Should Council agree with the recommendation as set out below, we propose to make a wider communication clarifying the following key preconditions before self-selection could be enabled:

i) Specific guidance from the GPhC on this issue would need to be in place, having been developed in consultation with a wider range of stakeholders

ii) We would require advance notification of any intention to enable self-selection. This would be to ensure we are able to monitor developments through collection of necessary information. This requirement would be set out in rules.

iii) These rules would need to have been approved by the Privy Council and laid before the UK and Scottish Parliaments. We do not expect this process to be completed before October 2013.

8.10 The recommended response, as set out in the draft Consultation Report, for Council to consider is below:

*On the basis of the arguments presented, we do not think that self-selection could never be done in a safe way, involving a constructive and informed discussion with patients. It remains a legal requirement under the Human Medicines Regulations 2012 for pharmacists to supervise all sales of Pharmacy Medicines.*
The GPhC remains committed to outcome focussed standards but on the basis of the feedback received we do not propose to allow self-selection of P category medicines to occur before further work is completed and before we have our enforcement processes in place.

We are therefore proposing to develop specific guidance on requirements which would need to be in place before self-selection can occur and to make clear owners and superintendents must not permit self-selection until guidance has been published and our enforcement powers are enacted by Parliament, probably not before October 2013.

9.0 Communications implications

9.1. As set out in the Consultation Report, we undertook widespread and thorough consultation and engagement activities.

9.2. We also recognise that this represented only one phase of the engagement required and we are committed to continuing this approach as we develop further guidance required as well as the Decision Framework.

9.3. Further detail on some of the communications activities planned are set out in the associated Council Paper, Managing the transition: Implementation of the standards for registered pharmacies.

9.4. This paper confirms that the standards for registered pharmacies, as required by the Pharmacy Order 2010, will also need to be set out in rules. There are further statutory obligations to consult on these rules which we plan to do in 2013.

10.0 Equality and diversity implications

8.1 We have already consulted and met with a wide a range of audiences including those from hard to reach groups. Activities included working with patient representative groups as well as deliberative events with the public. We are currently developing an equalities impact assessment consistent with our responsibilities as set out in the Equalities Act 2010 which we expect to publish as the new inspection model is finalised.

11.0 Resource implications

9.1 There are limited resource implications associated with the publication of the final Report on the consultation. However, we will required some additional resource to enable the development of identified guidance and communications activities. These can be met from within existing budgets.

12.0 Risk implications
12.1. We have mitigated some of the risks associated with the implementation of a new approach to regulation by holding such a thorough and wide-ranging consultation.

12.2. Some risk was also mitigated by seeking further legal advice in relation to the registration criteria which has allowed us to amend and clarify our proposals.

12.3. There are further reputation risks if we do not communicate clearly and effectively both the timing for implementation, recognising we do not expect to enforce fully the standards until the late summer/autumn 2013 and involve key stakeholders in the development of supplementary documentation including the GPhC Inspection Decision Framework. Further details are set out in the associated paper, Managing the transition.

12.4. We should acknowledge that

Recommendations

The Council is asked to consider a draft Report on our consultation including ‘our response’ to issues raised.

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i) the consultation Report for publication

ii) our response to the issues identified, and agreed by Council, as requiring further consideration.

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