Managing the transition: Working towards implementation of the standards for registered pharmacies

Purpose
To provide assurance to Council on our planning to ensure we effectively manage the transition to the new model for regulation of registered pharmacies.

Recommendations
The Council is asked to note this paper and provide feedback on our proposed approach to managing the transition phase and required work in advance of full implementation.

1.0 Introduction

1.1. Council has been asked to approve draft standards for registered pharmacies but as previously noted, the approval and subsequent publication of approved standards is only one phase in a much wider project to implement a new modern regulatory framework for pharmacy.

1.2. This paper outlines the approach and steps we propose to take, as we carry out the extensive work required to work towards full implementation.

1.3. Implementation is used to describe the point at which the standards are in Rules, following Privy Council approval, and have been laid before the UK and Scottish Parliaments. At that stage we will have the full range of powers to secure
compliance at our disposal and, if necessary, take enforcement action. **We do not expect this point to be reached before October 2013.**

1.4. Some of the steps described below may change as we listen to feedback and amend our proposals for transition. However, our work towards implementation will require us to carry out the following seven key steps:

i) Agreement of key principles which will underpin our policy, operational and engagement work during transition

ii) Publication of the new standards, once approved, and key statements on any significant consequential changes from the interim standards

iii) Establishment of formal and informal engagement channels

iv) Engagement on, and development of, specific pieces of guidance to support compliance with our standards

v) Development, testing and then publication of the ‘GPhC inspection decision framework’

vi) Further development of our new inspection model including testing, training of the inspection team and refinement of the model

vii) Consultation on and approval of the Rules.

1.5. **Principles which will underpin our transition work**

1.6. We have already demonstrated, through our consultation, *Modernising Pharmacy Regulation*, our commitment to an inclusive, open and transparent consultation and engagement process.

1.7. We recognise that our regulatory development work is more likely to enhance patient safety and meet our commitments to good regulation, including Hampton principles on inspection and enforcement, if we engage fully with those subject to our regulation and the public and pharmacy services users, in whose interests we operate.

1.8. With this in mind, we intend to follow the underpinning principles set out below as we take forward the necessary work to manage the transition towards full implementation.

i) **Commitment to full engagement:** We will adopt a similarly extensive approach to engagement with stakeholder organisations, pharmacy professionals and patients and public during the transition phase as we did in developing our proposals
ii) **Clear, transparent communications:** Individuals and organisations are entitled to know which standards they are required to comply with and how we, as the regulator, will make decisions. We will therefore be clear throughout the transition phase about the development of our approach to securing compliance and enforcement and the standards that should be applied.

iii) **A supportive approach to compliance:** During the transition phase, our key aim will be to support familiarisation with the new standards for registered pharmacies and development of additional tools such as the GPhC inspection decision framework, subject to an overriding commitment to take action if we believe patient safety is at risk.

iv) **Working in partnership:** Delivery of a new approach to modernising pharmacy regulation requires collaboration between the GPhC and other organisations. We are committed to working in partnership with other organisations to make sure that pharmacy professionals are properly supported and patients fully involved.

v) **Maximise opportunities to test our approach:** We will use the transitional phase to properly test our new inspection model as well as guidance that we are committed to produce.

### 2.0 **Publication of new standards for registered pharmacies**

2.1. It is our intention, subject to approval of Council, to publish approved standards on our website once they have been finalised, including final design and layout completed. At this point we would remove the interim standards for superintendents and owners from our website and any references to them in other documents.

2.2. We plan to post hard copies of the new standards to all registrants, including superintendents, alongside a special edition of Regula+e in October. We will also be seeking to notify all non-registrant owners.

### 3.0 **Establishment of formal and informal engagement channels**

3.1. We are planning a number of formal engagement meetings with key stakeholder organisations to develop further the partnership approach throughout the transition phase.

3.2. We have also sent invitations to a random sample of over 10,000 recipients, including pharmacists, superintendent pharmacists and more than 1,500 owners, to ask them for expressions of interest in joining a ‘sounding board’. The aim of the sounding board is to enable us to consult on development of the GPhC inspection decision framework.
3.3. We have had a very positive response to this request with over 1,000 recipients expressing interest with specific applications from over 100 recipients. The sounding board will cover England, Scotland and Wales.

3.4. We have also developed plans for an informal patient and public reference group to support further work, including the development of a patient-friendly guide to the standards.

4.0 Development of specific pieces of guidance to support compliance with our standards

4.1. We have set out our intention to prepare guidance to support compliance with our standards in a number of areas. The three areas identified thus far are:

i) Registered pharmacies who provide pharmacy services via the internet

ii) Registered pharmacies manufacturing medicines under an exemption to MHRA licensing requirements

iii) Requirements for registered pharmacies wishing to enable self-selection of P category medicines

5.0 Clarification on issues no longer specified in standards

5.1. The GPhC’s interim standards for owners and superintendents set out a legal requirement that medicines with a marketing authorisation (a licensed medicine) should be supplied where one exists, in preference to one without a relevant marketing authorisation (an unlicensed medicine).

5.2. The GPhC carried over, from previous RPSGB standards and guidance, an ‘exemption’ to this requirement for the supply of extemporaneously prepared methadone which is an unlicensed product.

5.3. As part of our work to clarify various legal requirements in relation to medicines legislation, we have reviewed relevant European and UK law. In particular we have looked at EU Directive 2001/83/EC, on the Community code relating to medicinal products for human use, and the Human Medicines Regulations 2012. We have also reviewed the recent European Court of Justice determination in relation to Commission v Poland which provides additional clarity in relation to the provision of medicines without a relevant marketing authorisation.
5.4. Our conclusion is that a decision to supply (unlicensed) extemporaneously prepared methadone, in preference to an available licensed alternative, is not compatible with the law in this area.

5.5. It is our intention to work with all relevant organisations, including representative bodies, patient groups (including methadone user groups) and the MHRA to identify the implications, and potential impact on patient care, of this legal clarification.

5.6. We will ensure there is a carefully managed period of transition reflecting the need to act in a way which is both consistent with the legal framework as well as the wider public interest.

5.7. We are committed to working with other regulatory bodies, including the MHRA and fellow health professional regulators, to ensure there is consistent guidance on related matters for registered health professionals.

6.0 Development, testing and then publication of the ‘GPhC inspection decision framework’

6.1. Resources are currently being focussed on developing the new inspection model and associated decision framework. The GPhC inspection decision framework is the key document which will be used by our inspectors to support consistent decision making about how well registered pharmacies have met the standards.

6.2. It will incorporate the draft 'compliance indicators' which were proposed in the draft standards for consultation. These will be expanded upon and are likely to be called 'outcome indicators'. Although each indicator is unlikely to have a further level of detail, we would expect there to be more indicators in this document and further contextual information about how they will be used by inspectors. As mentioned in our report on the consultation, we believe that this enhanced information will be welcomed by those who, in their consultation responses, expressed a wish for more information on this area, but without going beyond the outcomes approach into prescriptive detail.

6.3. We have already invited pharmacists and superintendent pharmacists to become part of a consultative sounding board to help us through the development phase. We have had a positive response to this request and, as set out in the appendix, work has already begun on the drafting of this document and we would expect to undertake a testing phase in the New Year.

6.4. We currently expect the GPhC inspection decision framework to include:

   i) An overview to the decision framework and how it should be used
ii) Compliance / outcome indicators for each principle describing examples of the sorts of outcomes we would expect

iii) Clarity on how decisions will be taken

7.0 **Further development of our new inspection model including testing, training of the inspection team and refinement of the model**

7.1. This process will be linked to the development of our decision framework and is well underway. We have established internal, multi-disciplinary work stream groups. We will also be using members of the external sounding boards from pharmacy and the public and patient reference group to help us test and refine our proposals.

8.0 **Consultation on and approval of the Rules**

8.1. The Pharmacy Order 2010 requires the Council to make provision in rules about the standards that are to be met in connection with the carrying on of a retail pharmacy business at a registered pharmacy.

8.2. The indicative timetable is subject to change due to our reliance on Department of Health and Privy Council resources being made available.

8.3. We are hoping to consult on the draft Rules in early 2013 and have them laid before the Scottish and UK Parliaments around October 2013. We have, however, identified this as a key risk to the transition timetable.

9.0 **Communications implications**

9.1. We have acknowledged that the significance of the proposed changes require us to communicate effectively to all those with an interest in the new standards for registered pharmacies.

9.2. We intend to promote the new standards and other key information, such as our intention to have a year-long transition phase.

9.3. We have also set up a dedicated page on our website to host the new standards and all related information including: key information; frequently asked questions; and, key statements on related high-profile issues.

9.4. A detailed operational communications plan has been developed to ensure the timing and content of all proposed changes is publicised.
10.0 Equality and diversity implications

9.1 We are currently drafting an equalities impact assessment consistent with our responsibilities as set out in the Equalities Act 2010 and will continue to monitor any emerging implications.

11.0 Resource implications

10.1 We have allocated significant staff time and budget resources to developing the new standards and inspection model. These were accounted for in the budget planning for 2012/13. There are no new additional financial requirements although as part of ongoing business planning we will continue to monitor and report to Council should this change.

12.0 Risk implications

12.1. There are a number of risks associated with the plans set out in this paper. If we fail to communicate effectively our proposals, and engage key interest groups in the development of the new inspection model, we risk either losing confidence of patients and professionals, or developing a model which is not proportionate to risk. We have set out a number of activities to mitigate this risk.

12.2. As mentioned above, there is a risk to the timetable as we are reliant on the Department of Health and Privy Council being able to allocate resources if the Rules are to be laid before the UK and Scottish Parliaments within the indicated timetable.

Recommendations

The Council is asked to note this paper and provide feedback on our proposed approach to managing the transition phase and required work in advance of full implementation.

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