Council meeting 11 April 2013

Public business

Registered pharmacies project

Purpose
To update the Council on the progress of the registered pharmacies project.

Recommendations:
The Council is asked to note the paper.

1.0 Project management overview and assurance

1.1 Significant progress has been made in our work to modernise pharmacy regulation. Following extensive engagement and consultation, new standards for registered pharmacy premises were approved and published in September 2012. Work continues at pace to develop the operational inspection model to provide assurance that the new premises standards are being met.

1.2 Whilst acknowledging the scope and major implications of this work our current focus is very much on identifying, planning and carrying out activities which will be required to achieve two key milestones: the implementation of the new inspection model; and the implementation, at a later date still to be determined, of the new enforcement regime, through statutory Rules. This work is wide-ranging and requires input and resource from across the organisation.

1.3 We are therefore using project management discipline to structure, plan and coordinate this work to ensure that collectively agreed priorities and aims are achieved.

2.0 Inspection Development Assurance Group

2.1 The first meeting of the Council member assurance group for the development of
the inspection model met at the end of January. Further meetings are scheduled for mid April and July.

2.2 The assurance group reviewed information around the overall development approach and plan, individual work streams, timelines and progress to date. In particular the group focussed in detail on:

- the inspection decision framework;
- engagement with sounding boards and patient and public involvement groups;
- the quality assurance approach; including
- developing the skills and knowledge matrix and training development programme for inspectors.

2.3 The assurance group endorsed the overall development approach and progress to date, whilst providing constructive challenge. Issues raised by the group for further consideration included:

- Ensuring further engagement arrangements sufficiently covered rank and file practising pharmacists and pharmacy technicians across the range of community pharmacy practice.
- Adding public health to knowledge categories of skills and knowledge matrix of inspectors.
- Ensuring the inspection model was flexible enough to apply to different delivery models and the changing health landscape.
- Reconsidering our use of the term “relationship management” of multiples, to ensure a proper focus on the accountability of owners, rather than the provision of service by the GPhC
- Risks to the project (please see also section 10 below).

2.4 The programme for the next assurance group meeting is being finalised, and will include the action learning testing plan and a greater focus on the relationship management approach as examples.
3.0 Inspection model

3.1 Work continues on the work streams comprising the development plan as set out below. A high level brief summary of progress of these work streams is set out below:

3.2 Registration of new pharmacy premises
- 2 stage process developed – eligibility check and compliance check with draft application form developed.
- Decision framework for inspectors drafted to aid decision making on whether the pharmacy is able to demonstrate it can meet our standards on day one of opening.
- Engagement with commissioners and sounding boards.

3.3 Proportionate regulation informed by risk
- Extensive engagement to understand what information / intelligence is available and readily accessible to inform scheduling of inspections.
- Pragmatic approach to assessing risk for scheduling purposes in draft for use in the interim, utilising inspectors’ knowledge and accessible information from others where available.

3.4 Pre-inspection preparation
- Information and documents that could be reviewed before the on-site
inspection have been identified, including tasks that could be carried out beforehand.

3.5 On-site inspection

- Extensive engagement on inspection decision framework and the examples of outcome indicators under “meeting minimum standards” and “consistently meeting good standards”.
- Criteria for minor and major non-compliance in place for a pharmacy that has not met our standards.
- Improvement and enforcement approach drafted with input from sounding boards and stakeholders.

3.6 Report writing

- Engagement with public and patient groups in England, Scotland and Wales and with practising pharmacy professionals through sounding boards to understand their requirements.
- Prototype high level public facing plain English summary reports drafted ready for further engagement.
- Prototype reports for pharmacy owner drafted ready for further engagement and testing.

3.7 Quality assurance

- Approach developed with accompanying skills and knowledge matrix for inspectors mapped against new premises standards.
- Inspectors assessed against skills and knowledge categories.
- Training and development plan in place.
- 1st development event held covering risk management arrangements in multiples and independents, hospital pharmacy, clinical governance, making judgements from observation, new medicines service and medicine use reviews.

3.8 Relationship management of multiples

- Outline approach for a more strategic approach to managing the performance picture of multiples against our premises standards, to enable more efficient and effective regulation and to better hold them to account.
• Clarification that this is intended to complement, not to replace, on-site inspection of pharmacies owned by large multiples.

• Job profile drafted.

• Testing multiples lined up.

3.9 IT

• Workflow of new inspection model mapped out and agreed.

• High level business requirements identified for an interim IT solution to support the deliverability of the new inspection model and external development capability identified.

3.10 The first phase of action learning testing is scheduled to commence at the end of April. Different aspects and ways of approaching the various different elements of the inspection model will be tested to inform our understanding of what works and what doesn’t on the ground. It will also identify what further changes are required to the model to ensure it is fit for purpose as well as identifying any further policy decisions that may be required to be made by Council.

4.0 Registered Pharmacies rules

4.1 Work is progressing on the development of the registered pharmacies rules, which will allow us to enforce the standards for registered pharmacies using powers not currently or previously available. These rules are relatively novel in nature, reflecting the GPhC’s unique functions as a system regulator and a professional regulator. As such, they need to be developed from scratch with no templates or precedents to follow.

4.2 When the standards were agreed in September 2012, the Council noted that they would not be fully enforced until the rules had come into effect. It was envisaged at that point that the rules could not conceivably be laid in the UK and Scottish Parliaments before October 2013; our expectation now is that the rules are not likely to be laid within 2013.

4.3 The fact that there will be a gap between implementation of the new inspection model and full implementation of the new rules-based enforcement regime will prove helpful, as stakeholders have indicated that they would like a longer period to prepare for implementation.

4.4 One of the novel aspects of these rules is that the registered pharmacies standards will themselves be incorporated into the rules, as required by article 7
of the Pharmacy Order 2010. The standards will therefore become part of the legislation. Council members will be aware that draft rules must be cleared by the Privy Council’s advisers before the Council makes the rules and that this will involve an iterative process to produce a final draft. A potential risk is that textual changes may be required which could work against the Council’s preferred approach of setting less detailed, outcome-focused standards. A meeting with the Department of Health has been scheduled to discuss and hopefully finalise the timetable for the rules, and the Council will be updated when more information is available.

5.0 Continuing policy and guidance development

5.1 Our approach
When Council approved the standards for registered pharmacies it was also provided with additional information about our plans for ‘Managing the transition’ (09.12/C/04) to full implementation of our new inspection model and enforcement powers. That paper set out the principles which would underpin that work which were:

- Commitment to full engagement
- Clear, transparent communications
- A supportive approach to compliance
- Working in partnership (with key interest groups and representative bodies)
- Maximise opportunities to test our approach

Our engagement activities and development of the new inspection decision framework is consistent with these principles.

5.2 Guidance
The Council also noted our commitment to developing guidance where required to help understanding of the new standards and provide further information to owners and superintendents. Our intention had been to develop guidance in three areas:

- Registered pharmacies who provide pharmacy services via the internet;
- Registered pharmacies manufacturing medicines under an exemption to MHRA licensing requirements; and
- Requirements for registered pharmacies wishing to enable self-selection of P category medicines.

5.3 Following internal analysis and some external feedback we are proposing to change the scope of two of these pieces of guidance. We are currently exploring amending the first bit of guidance to cover distance selling, rather than just internet pharmacy, to reflect the changing nature of models of service delivery already in existence and likely future trends. We have set up an internal working group to ensure suitable desk-based research is carried out, to manage external
engagement, and identify any legal analysis that is required and consultation processes. We have also confirmed that the third of the above pieces of guidance will cover safe supply of Pharmacy only medicines, rather than looking at one particular issue or model of supply.

5.4 The timetable for publication has changed to reflect the change in scope and the requirement to engage with those key groups who will use the guidance.

- Guidance for pharmacies manufacturing (section 10 exemption): we expect to share this draft guidance with the MHRA and others this Spring before publishing it for feedback.
- Guidance on pharmacies conducting distance selling: we are currently hoping to consult on draft guidance related to distance selling in the Autumn following advanced engagement and scoping work.
- Guidance on the supply of P medicines: we plan to finalise this guidance to coincide with the coming into force of our enforcement rules. (As previously agreed by Council in September 2012 no self-selection of P medicines will be permitted until both the Rules and the guidance are in place and prior notification to the GPhC will be required)

5.5 Further policy developments
In addition to the development of supplementary guidance, scoping of further policy development for a range of related issues is ongoing. This includes: data collection for new pharmacies and existing pharmacies; how we promote, manage and respond to concerns raised about standards of registered pharmacies in the future; developing systems for managing intelligence and information sharing; how we respond to innovation including new service models; and, wider issues of transparency, public and professional engagement and working with the new NHS systems in England as well as new regulatory structures in Scotland and Wales.

6.0 Supply of pharmacy medicines

6.1 In parallel with the work referred to above in relation to guidance, we have continued to engage constructively with stakeholders holding a range of views on detailed topics, including those with continuing concerns about the absence from the registered pharmacies standards of a blanket prohibition on the open display of Pharmacy medicines. For example, we have met at senior levels with the Royal Pharmaceutical Society and the Pharmacists Defence Association to discuss their concerns about this subject and the Council’s regulatory approach.

6.2 We have used these further opportunities to highlight the extent to which some negativity on this issue sits within an otherwise very positive context of widespread appreciation for the Council’s commitment to standards which focus on outcomes, and to using regulation strategically to:
• promote and encourage professionalism and a just culture in pharmacy;
• strengthen the accountability of pharmacy owners and superintendents in relation to matters more within their control than that of individual pharmacy professionals; and
• enable responsible innovation against a background of rapid change in the scope and impact of pharmacy services and in service delivery models.

6.3 We have also found it helpful, through ongoing discussions, to understand more fully some of the underlying concerns behind the positions taken by some on this issue, including:
• concerns about the education and training implications of the professional challenges for pharmacy professionals around clinical conversations relating to selection of Pharmacy medicines; and
• concerns about the relative lack of empowerment reportedly experienced by some pharmacy professionals providing a professional service in a commercial environment.

On both these topics we have sought to highlight the fact that the registered pharmacies standards themselves place relevant obligations on owners of pharmacies and superintendents. Likewise we have taken every opportunity to remind stakeholders, when necessary, that the law continues to require sales of Pharmacy medicines from registered pharmacies to be supervised by a pharmacist, and that the standards require risks to be managed appropriately, and supplies to be made safely. Additionally, we have taken steps to promote awareness of the additional safeguards agreed by Council (see para 5.4 above).

6.4 In response to questions and challenge about consultation, the approach we have taken is to point out how inappropriate it would have been – in the context of consulting on an outcomes-focused approach to standards for registered pharmacies – to include a specific question about a topic on which we were not proposing to prescribe an ‘input’ requirement or prohibition. In any event, given that the possibility of enabling open display was trailed in the consultation document (under the then heading of “compliance indicators”) consultees had the opportunity and prompt to give us their views on that topic, as indeed the RPS and the PDA did. We have been asked in recent discussions whether the Council would consider holding a further consultation specifically on this topic. We have shared our view that this appeared to be an unlikely course for the Council, given the strength of the case for maintaining the overall outcomes focused approach to the standards.
7.0 **Equality & Diversity implications**

7.1 Given the scale of this project a full Equality Impact Analysis is appropriate. One will be carried out and the results published, with any significant implications taken into account in our further planning and delivery work.

8.0 **Communications implications**

8.1 An extensive programme of engagement and communication forms an important strand of work in this project, both during the development, transition and implementation phases. Additional details can be provided to the Assurance Group, and to the Council as required.

9.0 **Resources implications**

9.1 The design and initial implementation work is resourced within current budgeting. As previously advised and considered by Council in relation to budgeting, the medium and longer term resource and cost implications of the new inspection model need to be kept under review. This is included within the overall project plan and will be evaluated following the testing phases of the new inspection model.

10.0 **Risk implications**

10.1 Risks are captured in the relevant Directorate risk registers and therefore feed in to our ongoing risk management activity. We will be exploring project risks in more detail with the Assurance Group.

**Recommendations**

The Council is asked to note the paper.

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