Consultation on the draft standards for registered pharmacies

Purpose
This paper seeks Council’s approval of the draft standards for registered pharmacies and the associated consultation document.

Recommendations
The Council is asked to consider and agree:

a. the consultation document (Annex A) including the draft standards for registered pharmacies; and

b. to delegate responsibility for approving final text of the document to the Chair of Council

1.0 Introduction

1.1. At its meeting in November, Council approved the proposed approach to the planned consultation on the regulation of pharmacy premises (Council Paper 11.11/C/02).

1.2. That paper set out the detailed preliminary work that has been undertaken since the Council took on responsibility for pharmacy regulation. In addition to work carried out by the executive, Council has considered in two workshop sessions a number of relevant issues including, but not limited to, the registration criteria, the content and format of the standards in this area as well as wider discussions about risk in pharmacy. Informed by Council's informally expressed views, and
by our pre-consultation engagement work, a set of draft standards and consultation document has been prepared and is attached in Annex A.

1.3. It is our intention, subject to Council’s approval, to finalise the consultation paper and commence a full public consultation and engagement exercise within the next few weeks.

2.0 **The structure of the consultation paper**

2.1. The draft consultation document is set out in three main sections. They are:

- **Introduction**: An introduction to our overall approach to regulation of registered pharmacy premises and how we link with other parts of the regulatory system. This material sets the scene for the consultation.

- **Registration and standards**: This is the core focus of the consultation document and where we will be seeking detailed input. It covers which premises we intend to register and why, as well as the draft standards we are proposing for registered pharmacies.

- **Compliance and enforcement**: How we plan to secure compliance against the proposed standards and our approach to enforcement activity. Clearly there will be further work to do on this front as the project progresses. As with the introduction, this material is principally contextual at this stage, to assist readers respond to the consultation on registration and standards by understanding how we expect to use the standards operationally in due course.

2.2. Some key elements are not included in the current draft either because they are unnecessary at this stage for the purpose of approval, such as the glossary of terms, or because it would be premature to do so in advance of Council’s consideration of the draft paper. These include:

- The Chair’s ‘foreword’

- The ‘box out’ section which will introduce and briefly summarise each of the three main sections

- The consultation questions

2.3. We want to ensure that the consultation questions are informed by Council’s debate and are drafted in a way which reflects best practice in holding consultations, as described, for example, by the Consultation Institute in their
‘Consultation Charter’ which sets out seven key principles.¹ We are seeking external advice and input into question design through the Consultation Institute to ensure a robust and effective process is put in place. Council will need to agree how best to ensure feedback is provided to the Chair to enable him to approve the final document including consultation questions.

3. **Key considerations**

3.1 Issues which have arisen as part of our pre-consultation engagement work include a desire for clarity in relation to the scope of the standards: to what and to whom do they apply.

3.2 We have concluded that the most accurate, as well as the most accessible description of the standards is ‘Standards for registered pharmacies’. A number of alternatives have been considered.

3.3 A key consideration has been to ensure that, in naming the standards, it is clear to those reading them that the standards include services provided by registered pharmacies both within the registered address, and also in other locations such as care homes. It is therefore proposed that the title for the standards avoids the use of the word ‘premises’ which could be misleading and is, arguably, unnecessary.

3.4 We also noted that the definition of a Retail Pharmacy Business, as set out in the Section 132 of the Medicines Act 1968² is limited to the sale or supply of Pharmacy (P) or Prescription Only Medicines (POMs), and therefore concluded that to describe the standards as for retail pharmacy business would be too narrow a definition.

3.5 In the introduction to the standards and elsewhere in the consultation document we make clear it is our view that the main accountability for meeting the standards lies with the pharmacy owner, except when the registered pharmacies is owned by a body corporate, in which case the superintendent pharmacist also carries responsibility.

3.5 However, we have reached the view that the standards should be about what they relate to and not those who will be principally responsible for meeting them. This both makes clear our focus on supporting compliance with the standards, rather than allocating blame, but also recognises the importance of making the document accessible to non-pharmacy audiences.

¹ [www.consultationinstitute.org/](http://www.consultationinstitute.org/)
² S132, Medicines Act 1968 (as amended): “... a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (whether medicinal products on such a list are sold in the course of that business or not);”
3.6 The draft standards have already been through a preliminary assessment and revision by the Word Centre to ensure that they are written in plain English.

3.7 We have also provisionally arranged to hold three small focus groups in advance of the launch of the consultation, one in each of England, Scotland and Wales and run by an external consultancy. The objective is to enable us to increase accessibility to the consultation process by receiving feedback from those who will have to meet the standards. We plan to review the design of our consultation events and communications materials on the basis of the feedback.

4.0 Consultation process

4.1 Subject to the approval of Council, it is our intention to hold a full twelve week consultation on the draft standards for registered pharmacies. This is provisionally scheduled to begin early in February. We are planning formal launch events in London, Edinburgh and Cardiff.

4.2 There will be specific activities aimed at each of our key audience groups including patients and the public, pharmacy professionals and their representative groups as well as government and those commissioners or providers of pharmacy services, including owners and employers. We will be inviting Council Members to observe consultation events.

4.3 In addition to events aimed at a larger audience, we have already been in contact with a range of stakeholder organisations to identify suitable opportunities during the consultation period to promote awareness of the consultation and to hear feedback at existing events. This includes attendance at Local Practice Forum and Local Practice Committee meetings. We have offered to host events where our consultation timetable does not fit with timetabled meetings.

4.4 We will promote the consultation extensively through media as well as our own registrant publication, *Regula+e* and our stakeholder e-bulletin, *Upda+e*. We will be using a dedicated email address and have set up a microsite to promote the consultation, to collect feedback and to report on that feedback. We will further promote the consultation using social media sites and techniques, in addition to traditional media.

4.5 All our activities will cover the whole of Great Britain with specific events planned for England, Scotland and Wales.
5.0 Equality and diversity implications

5.1 Following our pre-consultation engagement on this issue over the previous six to twelve months, we consider that the draft standards are consistent with the principles of equality and diversity. However, we will be considering further any impact on equality and diversity during the consultation process and will prepare a full Equality Impact Assessment which we will consult on later this year alongside the consultation on the draft Rules.

5.2 We will be actively promoting engagement with the consultation through our Equality, Diversity and Inclusion network.

6.0 Communications implications

6.1 The proposals contained in the consultation document represent a significant change in the way pharmacy regulation is carried out. We are fully committed to engaging in a meaningful way to ensure that the greatest confidence possible in both the standards for registered pharmacies as well as the proposed manner of securing compliance and decision-making process on enforcement.

6.2 We are putting significant further resources from the communications budget into the engagement process.

7.0 Risk implications

7.1 Having clear enforceable standards will contribute to safe and effective services at registered pharmacies.

7.2 There are significant risks if we fail to engage in meaningful engagement as part of the consultation process. By moving away from a rules-based approach to outcome focussed standards, it is important that we explain this change, what it means for superintendents, owners, pharmacy and pharmacy technician registrants and other pharmacy staff. This will include the development of compliance guidance, as mentioned in the consultation document itself.

7.2 We will also need to consider alongside the consultation process the development of appropriate operational systems to secure compliance with the standards or, if necessary, take enforcement activities.

7.2 Full and effective engagement will help to mitigate these risks.
Recommendations

The Council is asked to consider and agree:

a. the consultation document (Annex A) including the draft standards for registered pharmacies; and

b. to delegate responsibility for approving final text of the document to the Chair of Council.

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