Revalidation:
Recommendations from the Task and Finish Group

Purpose
This paper provides a report on the work of the Revalidation Task and Finish Group (RG) and sets out a number of recommendations from the group which will underpin future work in this area.

Recommendations
The Revalidation Task and Finish Group recommends that Council agree, subject to minor additional drafting as may be required:

a. A draft definition as agreed by the RG;

b. The draft principles which will underpin future policy development in this area; and

c. Proposed next steps to take forward the work based on the draft principles and to develop proposals for further research.

1.0 Introduction, background and scope

1.1. The decision to establish a Revalidation Task and Finish Group was agreed by Council at its meeting on 10 February 2011. Council agreed that the key role of the group would be to advise Council on how best to take forward GPhC policy development in this area.
1.2. The Council agreed that the remit of the RG should be to:

   a. Consider the outputs of the RPSGB’s Revalidation Advisory Group report and the revalidation research commissioned by the RPSGB (funded by the DH) in 2009/2010;
   b. Consider the most appropriate terminology for what we are trying to achieve;
   c. Consider revalidation in the context of the risks in pharmacy practice;
   d. Consider approaches to revalidation being taken by other regulators in the context of the current political and economic climate;
   e. Make recommendations to the Council on the direction of GPhC revalidation policy.

1.3. The RG held three meetings in March, September and October. In addition a round-table event was convened in July with a range of external stakeholders to inform its discussions and test emerging thinking.

2.0 Revised remit of the Revalidation Task and Finish Group

2.1. The first meeting of the RG in March considered the draft remit from Council and agreed that before considering the key elements, such as risk profiling, the approach of other regulators and potential models for revalidation, it would be necessary for the group to consider and agree what it believed the purpose of revalidation should be for registered pharmacy professionals.

2.2. This stakeholder event in July and the subsequent RG meeting in September considered these issues in more detail. In particular the discussion at the stakeholder event heard from other regulatory bodies how a failure to define the ‘problem’ and to explain the purpose had undermined attempts to introduce revalidation across different professionals over the last decade and more.

3. Acknowledging ‘revalidation challenges’

3.1 As part of its consideration of the issues, the group looked in some detail at the challenges in relation to the introduction of revalidation, noting that the medical regulator was the most advanced in its preparations, but that it had taken over 12 years since medical revalidation was first proposed for the current model to be piloted and the roll-out process begun.

3.2 The group noted that some of the challenges were generic to all health professionals, while some were specific in relation to pharmacy. It noted that all would need to be addressed if some form of revalidation was to be introduced successfully by the GPhC:
• **Lack of clear purpose:** Over the last ten years, the impetus for revalidation has fluctuated between extremes; either as a perceived mechanism for identifying dangerous professionals (most notably in the aftermath of Shipman) or as a process to support continuing fitness to practise (as originally described in the Bristol Inquiry Report).

• **Problems of definition:** the word ‘revalidation’ means different things to different people and has, arguably, led to divergent expectations within professions, regulators and the public.

• **Risk appetite:** There has been little public discussion about the appropriate risk appetite (i.e. what revalidation cannot do, as opposed to what it will do) and as a result what the model could, or should, achieve.

• **Complexity:** Linked to the above challenges, proposed models for revalidation have been criticised as lacking credibility or robustness, or alternatively appearing to many as overly complex (and also costly). This is particularly a challenge in pharmacy where the majority of the workforce operates outside of the formal NHS managed environment and where a significant percentage of the workforce have multiple employers or act as locums.

• **Evidence:** Without detailed evidence about risk in pharmacy (and elsewhere), it has also proved challenging to answer the key question, ‘what is the problem we are looking to resolve’, or flowing from that, ‘will the revalidation model we are proposing, solve the problem we have identified?’

### 4.0 The case for revalidation

4.1 Despite the challenges set out above the group considered in some detail the arguments remaining for the introduction of revalidation. The group considered that the arguments remained compelling and that they should underpin the GPhC’s statement about purpose for revalidation. They are:

• Maintaining public confidence in the pharmacy professions (and the GPhC as the regulator) would be weakened by a failure to introduce revalidation, not least because opinion polling has repeatedly shown that the public believe health professionals are already subject to regular reviews or assessments of fitness to practise.

• The group reviewed arguments made previously about the need for assurance of continuing fitness to practise. Specifically they reviewed the case made in the
Bristol Inquiry Report\(^1\) for revalidation and concluded that the argument remains just as persuasive now, as they did then:

“For some, however, competence did (and does) not grow with experience. Others did (and do) not pay much attention to continuing professional development. And others tried their best but their competence diminished with time. Remarkably, there was no system in place to spot waning competence, to support these professionals and to protect patients. Only when things went dramatically wrong was action taken, and then, too often, it was too late for the patient and the professional.”

- As a professional regulator, we have a duty to assure fitness to practise of registrants from the point they come onto the register, to the point they leave, either by choice or because they are removed from it. As the Bristol Report argued (as above), waiting for things to go wrong does not protect patients adequately.

- The Bristol Inquiry asserted that there was evidence of sub-optimal performance within the medical profession. The report asserted that a lack of regulatory scrutiny – with a focus on either initial registration or when serious concerns were drawn to the regulators attention – was a cause for concern. Although the evidence about the levels of sub-optimal performance in pharmacy is limited (for example some evidence through fitness to practise determinations and some academic research) we can still assert with a reasonable level of confidence that, the pharmacy professions is unlikely to be very different in this regard to other professions and the arguments made in the Bristol Inquiry hold true.

- Although the recent UK government white paper, *Enabling Excellence*\(^2\), emphasises the case for a more flexible and tailored approach to revalidation, the government still expects health professional regulators to provide evidence on this subject and a clear direction of travel. This desire for a progress on revalidation is also the strongly held view of the Health Select Committee.

- Finally, there is an ongoing argument that for confidence to be maintained into the longer term of the concept of a regulated profession, a more explicit statement about the respective roles of individuals’ professionalism and the role of the regulator in assuring continuing fitness to practise of those on the register is required.

5.0 **Draft definition and principles for revalidation**


\(^2\) [www.dh.gov.uk](http://www.dh.gov.uk)
5.1 Having considered these and other issues in relation to revalidation, the group considered how best to define revalidation and the principles which should underpin future work on revalidation undertaken by the Executive on Council’s behalf.

5.2 The group agreed that a draft definition of revalidation be put to Council. It considered that revalidation should be described by the GPhC as:

‘The process by which assurance of continuing fitness to practise of registrants is provided and in a way which is aimed primarily at supporting and enhancing professional practice.’

5.3 The group acknowledged that although not the main purpose of any model, consideration should be given alongside any future model to additional measures which could or should be taken to identify those registrants who pose an immediate risk to patient safety.

5.4 The group further considered key principles it believed should underpin a future model of continuing assurance of fitness to practise. These principles were drafted to take into account the challenges set out in this paper as well as to go beyond the generic principles, set out in Annex B of this paper, of the Non-Medical Revalidation Working Group3, established by the previous government, and to recognise a future model will need to be appropriate to pharmacy.

5.5 The draft principles are set out in Annex A.

6.0 Next steps

6.1 If the draft definition and principles for continuing assurance of fitness to practise are agreed by Council, the group recommends that these principles be used as the basis for the development of external communications about Council’s support for the development of a model of revalidation for pharmacy and its purpose.

6.2 It is proposed that in addition to explaining them through media channels, the principles are tested with pharmacy professionals and their representative groups as well as patients and patient representative bodies.

6.3 In addition the group recommended that, should the draft principles be agreed by Council, the Executive would be asked to develop proposals for taking forward

further work, including research, to enable the development of suitable models and report back to Council on progress made.

7.0 **Equality and diversity implications**

7.1 Any future model of revalidation will need to take full account of equality and diversity issues and legislation. In particular care will need to be taken that any future risk–model does not disproportionately affect any minority group.

8.0 **Communications implications**

8.1 It is recommended that further external communications activities are undertaken to test and refine the draft principles.

8.2 Ongoing engagement will be needed with all groups in pharmacy including representative groups, employers, registrants as well as patients and the public.

9.0 **Risk implications**

9.1 Council needs to balance the need to ensure the continuing confidence of patients and professionals through the assurance that registrants continue to be up to date and fit to practise. Failure to do so carries a risk that confidence in the regulatory process is undermined.

9.2 Council will have to offset this risk against the danger than any future model does not meet the stated purpose and as such provides a regulatory burden without providing the enhanced assurance that the public expects.

9.3 These risks are reflected in the draft principles and will need to be mitigated by having robust research and engagement programmes in place.

**Recommendations**

The Revalidation Task and Finish Group recommends that Council agree, subject to minor additional drafting as may be required:

a. A draft definition as agreed by the RG;

b. The draft principles which will underpin future policy development in this area; and

c. Proposed next steps to take forward the work based on the draft principles and to develop proposals for further research.

Hugh Simpson, Director of Policy and Communications
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Appendix A

The continuing assurance of fitness to practise of pharmacists and pharmacy technicians: draft principles

1. The focus should be assurance of continuing fitness to practise and not a fixed point assessment
   This means that any model will have a positive impact on the development of professionals and will seek to enhance performance, rather than to identify and root out poor performers (although that may be a consequence). This would mean a periodic assessment, such as a post-registration examination, would not meet this principle.

2. The model should be consistent with the generic principles agreed by the NMRWG
   The proposed model will need to be tested against each of the twelve principles with specific consideration given to the need to command confidence of those undergoing revalidation as well as those in whose interests it is primarily aimed.

3. The model will need to consider more than one source of information
   The most challenging element to the development of any model will be identifying the most appropriate sources of information and using it appropriately to form judgement based on proper evidence and analysis. Information must be received from external sources and be related to current scope of practice. Although it could not be based solely on CPD, this would form a component of the model.

4. Some form of assessment will be required and will need to be made against a standard.
   For revalidation to have credibility, to be comparable across roles and to enable assessment to have meaning, standards to enable benchmarking will be required.

5. That standards should be based on the standards for conduct, ethics and performance which apply to all registrants.
   There has been much debate and confusion about what a revalidation ‘standard’ is and if it is the same thing as proficiency standards. Different regulators have taken a number of approaches, but we propose that developing a second set of core standards for pharmacists and technicians would be unhelpful and confusing and that the measurement for assessment should be based on the standards of Conduct, Ethics and Performance (although this may require an updated version to be developed, or an associated framework similar to that developed by the GMC to facilitate appraisal of doctors).

6. The model must take full account of the structure of the pharmacy workforce
   One of the major challenges in developing a model of revalidation in pharmacy is that it is a diverse workforce, operating in both NHS managed environments
(hospital), academic sectors as well as community pharmacy and industry. In addition to the diversity of the clinical / business environment, the workforce is diverse with many self employed, NHS employed, locums etc. This diversity in the workforce and in scopes of practice is another factor that supports the concept of revalidation standards based on standards that apply to all registrants.

7. *Any model would need to be appropriately costed and subject to testing including piloting.*
   It will be important that any proposed model is properly costed and has been subject to a robust piloting process and impact assessment.
### Appendix B

**Non-Medical Revalidation Working Group – Principles for Revalidation**

*Source: Department of Health Non-Medical Revalidation Working Group, November 2008*

<table>
<thead>
<tr>
<th>Principle</th>
<th>Theme</th>
<th>Summary Description</th>
</tr>
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<tbody>
<tr>
<td>Principle 1</td>
<td>Consistency</td>
<td>Models should be consistent with the Better Regulation Executive’s five principles of good regulation.</td>
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<tr>
<td>Principle 2</td>
<td>Professional Standards</td>
<td>The regulatory body for each profession should set out the contemporary professional standards, which registrants will have to meet in order to maintain registration.</td>
</tr>
<tr>
<td>Principle 3</td>
<td>Remediation</td>
<td>Where revalidation processes highlight performance concerns there should be scope for remediation of the professional but measures to secure public safety must remain paramount.</td>
</tr>
<tr>
<td>Principle 4</td>
<td>Patient and public involvement</td>
<td>A successful revalidation process must have the confidence of the public that it is appropriate, relevant and fit for purpose.</td>
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<tr>
<td>Principle 5</td>
<td>Continuing Professional Development (CPD)</td>
<td>This is the process by which individual registrants keep themselves up to date in order to maintain the highest standards of professional practice.</td>
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<tr>
<td>Principle 6</td>
<td>Quality Assurance</td>
<td>Quality assurance mechanisms must be built into revalidation processes.</td>
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<tr>
<td>Principle 7</td>
<td>Equality</td>
<td>Equality and diversity considerations must be evident in the development of systems and processes for revalidation.</td>
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<tr>
<td>Principle 8</td>
<td>Integration</td>
<td>Clinical governance frameworks yield information on professionals’ performance and practice. Where appropriate, effective connections need to be made between them and the system of revalidation.</td>
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<tr>
<td>Principle 9</td>
<td>UK-wide</td>
<td>Revalidation arrangements should be consistent in outcome across the United Kingdom.</td>
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<td>Principle 10</td>
<td>Demonstrating Benefits</td>
<td>The structures and processes of revalidation should be effective in confirming fitness to practise.</td>
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<tr>
<td>Principle 11</td>
<td>Information</td>
<td>The nature of the information required by each regulatory body will be based on their risk profiling of their registrant groups.</td>
</tr>
<tr>
<td>Principle 12</td>
<td>Incremental Introduction</td>
<td>The introduction of revalidation should be incremental.</td>
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