An approach to assuring continuing fitness to practise based on right-touch regulation principles

November 2012
About CHRE
The Council for Healthcare Regulatory Excellence promotes the health and well-being of patients and the public in the regulation of health professionals. We scrutinise and oversee the work of the nine regulatory bodies\(^1\) that set standards for training and conduct of health professionals.

We share good practice and knowledge with the regulatory bodies, conduct research and introduce new ideas about regulation to the sector. We monitor policy in the UK and Europe and advise the four UK government health departments on issues relating to the regulation of health professionals. We are an independent body accountable to the UK Parliament.

CHRE will become the Professional Standards Authority for Health and Social Care during 2012.

Our aims
CHRE aims to promote the health, safety and well-being of patients and other members of the public and to be a strong, independent voice for patients in the regulation of health professionals throughout the UK.

Our values
Our values act as a framework for our decision making. They are at the heart of who we are and how we would like to be seen by our partners. We are committed to being:

- Focused on the public interest
- Independent
- Fair
- Transparent
- Proportionate.

Right-touch regulation
Right-touch regulation\(^2\) means always asking what risk we are trying to regulate, being proportionate and targeted in regulating that risk or finding ways other than regulation to promote good practice and high-quality healthcare. It is the minimum regulatory force required to achieve the desired result.

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1 General Chiropractic Council (GCC), General Dental Council (GDC), General Medical Council (GMC), General Optical Council (GOC), General Osteopathic Council (GOsC), General Pharmaceutical Council (GPhC), Health Professions Council (HPC), Nursing and Midwifery Council (NMC), Pharmaceutical Society of Northern Ireland (PSNI)

Contents

1. Executive Summary ...........................................................................................................1
2. Introduction ..........................................................................................................................3
3. The purpose and scope of continuing fitness to practise .................................................5
4. Towards a risk-based approach .........................................................................................10
5. Developing effective and proportionate continuing fitness to practise measures ..........16
6. Conclusion ..........................................................................................................................19
7. Annex 1: health and care regulators’ plans for continuing fitness to practise ...............20
1. Executive Summary

1.1 This paper looks at the role that professional regulation plays in supporting registrants to demonstrate that they are fit to practise throughout their practising lives. Right-touch regulation\(^3\), published in August 2010, sets out the principles that we believe should apply to regulation. It presents a risk-based approach, and argues that regulators should apply only the regulatory force that is necessary to achieve the desired result. We have used these principles to structure our thoughts on continuing fitness to practise.

1.2 In our view, the primary role of continuing fitness to practise should be that of reaffirming that registrants continue to meet the regulator’s core standards. Evidence considered in this report suggests that standards of conduct as well as competence should form the backbone of continuing fitness to practise requirements.

1.3 In order to be fit to practise, a professional must practise in accordance with the regulator’s standards, including requirements relating to the maintenance of professional skills and knowledge, however, compliance with input-based continuing professional development requirements is not of itself a demonstration of continuing fitness to practise.

1.4 Other regulatory functions can help support the outcomes of the dedicated continuing fitness to practise function. Registration, fitness to practise and education can all contribute in different ways.

1.5 Right-touch regulation recommends taking a risk-based approach to regulatory decisions: mechanisms for assuring continuing fitness to practise should mitigate risks in a manner that is proportionate. Gaining a clear understanding of what registrants do and of the context in which they do it will help to understand and quantify the risks presented by the regulated groups. We should take a broad view of risk and of its causes and consider their impact on both competence and conduct.

1.6 The severity and prevalence of risks should guide decision-making about the regulatory force that is needed to address them. We have found it helpful to think of the range of possible continuing fitness to practise frameworks on a risk-based continuum, with those providing the highest levels of assurance (for the highest-risk professions) at the top of the scale, and decreasing levels of assurance as the risk decreases.

1.7 The information derived from quantifying risks can also allow continuing fitness to practise measures to focus on the practice areas or groups that present the greatest risks, for example the tools used to collect evidence of continuing fitness to practise can be used to gather information about specific areas of performance or conduct; some methods of collecting evidence of continuing fitness to practise can by their very nature help to mitigate certain risks.

\(^3\) CHRE, August 2010. Right-touch regulation. Available at: www.professionalstandards.org.uk
1.8 Right-touch regulation also suggests that we should make use of any existing local or national mechanisms that can help with the delivery of their regulatory aims. The challenge will be to ensure that any mechanisms which are chosen to support the delivery of continuing fitness to practise are fit for their purposes.

1.9 In applying right-touch regulation, we found the concept of reliability was a useful way of thinking about the levels of assurance that different continuing fitness to practise measures can provide. By reliability, we mean the extent to which a regulator’s test of continuing fitness to practise accurately identifies as ‘passes’ the individuals who continue to meet their standards and as ‘fails’ those who do not. Some measures will be more reliable than others, and we suggest this variation should influence the design of each regulator’s continuing fitness to practise mechanisms.

1.10 Following the principle of proportionality, the level of risk should determine how reliable a response needs to be. On that basis, the question of whether a continuing fitness to practise framework is effective should be decided by whether it is as reliable as it needs to be to mitigate the risks presented by the profession.

1.11 Finally, we feel it is important that the public understands the levels of assurance these mechanisms can provide, and there should be transparency about what lies behind these decisions that determine how much regulatory force is needed to mitigate identified risks.
2. Introduction

2.1 This paper addresses the question of how the public can be assured that their health or care professional is always fit to care for them. More specifically, it looks at the role that regulation plays in supporting registrants to demonstrate that they are fit to practise throughout their practising lives.

2.2 We recognise that professionalism is key to keeping patients and service users safe and maintaining the quality of their care. Professionals, professional bodies, employers and regulators should all do what they can to encourage and embed professional attitudes and behaviour. When it comes to supporting practitioners to remain safe and competent over time, professionalism has an important part to play.

2.3 Regulators also have a duty to ensure that the people on their register are fit to remain registered – they need to have answers to the question: ‘how can I know that the professional looking after me is up to date and fit to practise?’ There needn’t be a tension between regulation and professionalism here. In developing mechanisms that enable them to periodically assure themselves of the fitness to practise of their registrants, regulators can provide an answer to this question, and in doing so support a culture of continuous learning and improvement.

2.4 Just how regulators choose to gain these assurances will depend on the groups they regulate, and on the context in which their registrants work. Continuing fitness to practise mechanisms should be proportionate to the risks posed by their registrants, and are therefore likely to vary between professions. Revalidation will not be an appropriate response for all professions, but for high-risk professions it may be. We find it helpful to think of the regulatory responses as sitting on a risk-based continuum, with revalidation at one end, and the auditing of self-reported, input based continuing professional development (CPD) at the other. What should be common to all responses is the monitoring of their effectiveness and of the transparency around these arrangements – over time regulators will need to be able to demonstrate that these mechanisms are achieving what they set out to achieve.

2.5 This paper sets out some broad guidance for regulators in the development and ongoing improvement of their continuing fitness to practise frameworks. We hope it will support regulators in taking a thoughtful and flexible approach to the challenge of assuring continuing fitness to practise.

About our approach

2.6 Throughout this paper we refer to regulators assessing continuing fitness to practise (rather than the term revalidation) because it describes the intended outcome, the purpose of the activity. As discussed above, revalidation is one way of demonstrating continuing fitness to practise. We distinguish between the regulators’ responsibility for assuring themselves that registrants continue to be fit to practise – complying with their codes of practice; and the registrants’ own responsibility for
continuing professional development which includes but may extend beyond the regulatory components of fitness to practise.

2.7 *Right-touch regulation*\(^4\), published in August 2010, sets out the principles that we believe should apply to regulation. It presents a risk-based approach, and argues that regulators should apply only the regulatory force that is necessary to achieve the desired result. It also stresses that the responsibility for assuring the quality of healthcare needs to be shared among regulators, employers, professionals, the law, and the people who use services. Right-touch regulation, we say, 'is based on a proper evaluation of risk, is proportionate and outcome focussed; it creates a framework in which professionalism can flourish and organisations can be excellent.'

2.8 In order to apply right-touch regulation to continuing fitness to practise in this paper, we begin by defining the problem – setting out the purpose and scope of continuing fitness to practise. We go on to look at the sorts of risks associated with continuing fitness to practise, and how quantifications of risk should influence the design of continuing fitness to practise mechanisms to ensure that they are proportionate and targeted. Finally, we explain how, by taking into account both reliability and risk, these mechanisms can achieve what they were designed to achieve.

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\(^4\) CHRE, August 2010. *Right-touch regulation*. Available at: www.professionalstandards.org.uk
3. The purpose and scope of continuing fitness to practise

3.1 This section explores some key questions about the regulator’s role in supporting its registrants to demonstrate their ongoing fitness to be on the register.

3.2 In the years following the publication of the report of the Shipman Inquiry\(^5\), there was much debate about the purpose of medical revalidation: was it to root out poorly performing doctors or to reconfirm their fitness to practise? In 2008, the Department of Health published a progress report on medical revalidation\(^6\) in which it was stated, broadly, that the purpose of revalidation was to confirm the fitness to practise of registrants, take remedial action where standards appeared to have been breached, and remove from the register the small proportion of registrants for whom remediation has been unsuccessful.

3.3 In the Command Paper *Enabling Excellence*\(^7\), published in February 2011, the Government made clear that while the development by the GMC of revalidation for doctors should continue as planned, proposals for revalidation for other professions must demonstrate ‘significant added value in terms of increased safety or quality of care for users of health care services’. The other regulators have responded to this by taking stock of their work on revalidation and by commissioning research, notably on the risks of the professions they regulate. A summary of the position of each regulator in relation to continuing fitness to practise is available at Annex 1.

3.4 Our last Performance Review\(^8\) stated that the outcome of revalidation or equivalent schemes should be that registrants could demonstrate they were safe and fit to practise. This continues to be our view, as does its corollary that regulators should be able to provide assurances of the continuing fitness to practise of its registrants. We propose that this can be and, in most cases, should be achieved by means other than formal revalidation\(^9\). This paper sets out this position in more detail, using the principles of right-touch regulation.

**What is the purpose of assuring continuing fitness to practise?**

3.5 In its paper on continuing fitness to practise published in 2008\(^10\), the Health Professions Council\(^11\) (HPC) touched on an important distinction relating to the purpose of revalidation, between ‘quality control’ which is aimed at ensuring that...
professional standards are met, and ‘quality improvement’ which aims to improve standards of care generally. They found that proposals for revalidation were often unclear in what they were trying to achieve.

3.6 This distinction had already been touched on in the 2006 Department of Health publication, The Regulation of the Non-medical Healthcare Professions. The report stated that a balance needed to be struck between compliance and improvement, and that a framework focusing on both was more likely to ‘motivate and engage with the majority who always aim to practise safely’12.

3.7 More recently, in Enabling Excellence, Government stated they would consider proposals for revalidation where ‘there [was] evidence to suggest significant added value in terms of increased safety or quality of care’13. We can interpret ‘increased safety’ as the quality control option, and ‘increased […] quality of care’ as the quality improvement option.

3.8 Using research into models in Canada, New Zealand and the UK, the World Health Organization’s (WHO) European Observatory on Health Systems and Policies14 identified a similar classification of two types of model for assessing the competence of physicians:

- The learning model, that rewards activities that improve quality such as attendance at CPD events, self-assessment of learning needs, patient feedback, academic activities and audits, and

- The assessment model in which performance is assessed either reactively, periodically, through systematic screening or through screening of high-risk groups.

3.9 The learning model is input-based, and therefore cannot be said to assure fitness to practise. The assessment model on the other hand aims to assess the fitness to practise of professionals and is therefore output-based, and should, if effectively implemented, be more reliable than the learning model.

3.10 The two options are not mutually exclusive however. Indeed the WHO research identified that where the assessment model was used, it was always in conjunction with the learning model, although the latter model on its own was most prevalent. Under the WHO definitions, the learning requirements are seen as providing the knowledge and improvements needed to allow registrants to succeed under the assessment requirements.

3.11 We feel that quality improvement can likely be achieved through considered and intelligent use of quality control mechanisms: using their various regulatory levers, professional regulators can support and encourage quality improvement. However,

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13 The Authority’s italics.

professional regulators remain the guardians of minimum standards of conduct and competence, and have a duty to protect the public.

3.12 Therefore, in our view, the primary (though not necessary only) role of continuing fitness to practise should be that of reaffirming that registrants continue to meet the core standards of competence and behaviour.

What is the scope of continuing fitness to practise?

3.13 It is important to view continuing fitness to practise in relation to the full range of factors that define fitness to practise. All nine regulators have a legal duty to ensure that their registrants are fit to be on their register. How this duty is described varies between regulators in its wording but always consists of a competence element and a conduct element. Whichever model or combination of models is used to assess continuing fitness to practise it is clear that it must encompass both conduct and competence.

3.14 The HPC identified, from an analysis of the outcomes of its fitness to practise cases from 2006 to 2008, that conduct was the predominant risk posed by the professions it regulated\(^\text{15}\). Research published by the General Social Care Council in June 2012\(^\text{16}\) also showed that 79% of its cases involved unacceptable behaviour, with only 29% of those cases involving both unacceptable behaviour and poor practice.

3.15 Other fitness to practise statistics back this up, for instance the General Dental Council found that 50 of the 171 issues considered by its Professional Conduct Committee in 2010 concerned either fraud and/or dishonesty, convictions or cautions, personal behaviour, or indecent assault or inappropriate sexual behaviour\(^\text{17}\).

3.16 Evidence from the National Clinical Assessment Service (NCAS), the NHS body that looks into concerns about the performance of dentists, doctors and pharmacists in England, Wales and Northern Ireland, also shows that a significant proportion of cases (44% of the cases they dealt with between December 2007 and March 2009) involved concerns about conduct.

3.17 Failings of conduct therefore seem to represent a high proportion of identified failings in fitness to practise.

3.18 Competence is the other essential component of fitness to practise. Competence issues accounted for 50% of the issues considered by the GDC’s Professional Conduct Committee in 2010\(^\text{18}\), 42% of cases considered by the GSCC (including

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\(^\text{15}\) Health Professions Council, October 2008, Continuing Fitness to Practise, Towards an evidence-based approach to revalidation; section 5.1.1, page 21
\(^\text{18}\) Taking the data from the GDC Annual Report, CHRE has classified the following as competence issues: poor treatment, poor practice management, failure to obtain consent/explain treatment, failure to take appropriate radiographs, and prescribing issues.
the 29% of cases that concerned both conduct and competence), and 54% of cases reported by NCAS\textsuperscript{19}.

3.19 The NCAS research into the cases it considered between 2001 and 2008\textsuperscript{20} suggests that clinical difficulties are more common in the older age groups (although the figures are not statistically significant). This could be symptomatic of the challenge that professionals face in remaining up to date throughout their professional career. In order to remain fit to practise, practitioners have to keep up with developments in the technical aspects of their practice, as well as with workplace practices and cultural norms. This is reflected in the regulators’ standards, which all include a requirement to maintain professional skills and knowledge. The evidence suggests that standards of conduct as well as competence should therefore form the backbone of continuing fitness to practise requirements.

3.20 Competence is assured at the point of entry on the register through the approval or recognition of pre-qualifying training provision. Once on the register, registrants must at the very least maintain the threshold level of competence, by which we mean the ‘contemporary’ standard of registration. For activities where practice and technique evolve over time practitioners must also keep up-to-date, meaning that just to maintain a minimum level of competence, they need to be continually developing their skills and knowledge.

3.21 Revalidation is often referred to, as it was in \textit{Trust, Assurance and Safety}, as a means of ensuring that professionals are both fit to practise and up-to-date. These two things are complementary – being up-to-date is a component of fitness to practise. In order to be fit to practise, a professional must practise in accordance with the regulator’s standards, including requirements relating to the maintenance of professional skills and knowledge.

3.22 For the purposes of assuring continuing fitness to practise, regulators may choose to translate their generic requirements about keeping up to date into something more specific about how much and what sorts of training and learning professionals should undertake, or how they should demonstrate that they have stayed in touch with new developments. However, we caution that compliance with continuing professional development requirements, while it may be a helpful measure to some extent, is not of itself a demonstration of continuing fitness to practise.

\textbf{How does continuing fitness to practise fit with other regulatory functions?}

3.23 Other regulatory functions can support the dedicated continuing fitness to practise function in providing assurances to the public of registrants' fitness to practise.

3.24 Registration and, where applicable, licensing, form an integral part of continuing fitness to practise mechanisms. Registers are the regulator’s public-facing record of who is and continues to be fit to practise, and exclusion or suspension from the

\textsuperscript{19} National Clinical Assessment Service, September 2009. \textit{NCAS Casework, The first eight years}. Available at \url{http://www.ncas.nhs.uk/publications/}; accessed 18/06/12

\textsuperscript{20} National Clinical Assessment Service, September 2009. \textit{NCAS Casework: The first eight years}. Table 3.2 – concerns by practitioner group. Available at \url{http://www.ncas.nhs.uk/publications/}; accessed 18/06/12
register means exclusion or suspension from the profession. Re-registration and re-licensing schemes give the regulators the opportunity to periodically assure themselves and therefore the public of their registrants’ fitness to practise.

3.25 Education and training functions can help reduce the numbers of registrants whose conduct and competence fall below acceptable standards later in their careers. This can be achieved not only by maintaining the quality of pre- and post-qualifying education, but also by ensuring that accredited training programmes produce professionals who understand the importance of professionalism and of keeping up to date and fit to practise throughout their careers.

3.26 Fitness to practise mechanisms can also play a part in supporting continuing fitness to practise, by providing valuable information about who is failing to meet standards, which standards are most frequently breached, and how the standards apply in different situations. This information can then be used to help registrants stay above the line, and to inform the design of mechanisms that contribute to mitigating these risks.

In summary

3.27 In this section, we have established that assuring continuing fitness to practise is about reaffirming that registrants continue to meet minimum professional standards of conduct and competence. We have explained that this can be achieved not only by introducing dedicated continuing fitness to practise mechanisms, but also by ensuring that all other functions contribute to this overarching aim.
4. Towards a risk-based approach

4.1 In accordance with the principles of right-touch regulation, we consider in the following section how regulators could use the quantification of risk so that their approach and methods of assessing continuing fitness to practise are targeted and proportionate.

Understanding and quantifying the risks presented by a profession

4.2 Developing ways of assuring continuing fitness to practise that are proportionate and effective at mitigating risks will require a clear understanding of what professionals do, and of the context in which they do it. Some regulators have commissioned research in this area, which we have sought to consolidate in the following paragraphs, in order to get a broad understanding of range of issues that regulators are considering.

4.3 The General Optical Council (GOC) commissioned Europe Economics to determine what the key risks were in the optical professions. They considered a classification of risks based on ‘adverse events’, which are clinical actions that could result in harm to a patient, such as misdiagnosis of glaucoma; and ‘contextual factors’, which are the factors independent of the clinical specifics of a patient-practitioner encounter that could influence the level of risk in that encounter, such as the length of time in practice.

4.4 In Table 1, we offer a classification that follows a broadly similar model to this one. It identifies a range of factors that could determine whether a practitioner poses a risk to service users. We have used the research carried out by the different regulators to inform the classification, as well as the table provided in Trust, Assurance and Safety and the research carried out by NCAS on its casework. The factors in the table relate to the practitioner and their continuing fitness to practise, and fall into two categories:

- **Context**: this covers variables relating to the context of the professional’s employment, and to their education and training.
- **Activity**: this covers factors associated with different health and social care tasks, that determine how risky they may be.

4.5 The table was developed with reference to materials in which causal risk factors were identified as applying, or potentially applying to certain professions or groups within a profession, and we have noted the source of the information in the table for reference. We recommend that the source material is referred to for more detailed information about how these risk factors are thought to apply to specific professions.

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23 For the purposes of this paper, we have not considered the specifics of these risks, which of course vary from one profession to another, however, we have considered a broad classification.

24 We recommend that the source material is referred to for more detailed information about how these risk factors are thought to apply to specific professions.
4.6 The table also includes our own interpretations of what each risk factor might entail.

4.7 We have excluded from the table:
- Factors where the risk to the patient is unaffected by the individual’s competence and/or conduct
- Spurious indicators\(^{25}\) of risk that may indicate the presence of but are not in a causal relationship with an increase in risk.

4.8 With regard to the latter point, examples of indicators are age, gender and ethnicity, or the ‘locum status’ of a practitioner. Taking the locum status as an example, the research carried out by Europe Economics for the GOC concluded that ‘there is no compelling reason why a locum practitioner should be inherently less competent than one who is permanently employed. [...] It is likely that any increased risk is a combination of individual characteristics [...] and systemic failures [...]\(^{26}\). The important term here is ‘inherent’. If locum practitioners are found to present a greater risk than non-locums, this can most likely be explained by factors relating to employment arrangements, rather than something inherent in locum practitioners.

4.9 In considering whether these causal factors apply to the groups they regulate, we would urge regulators to look for the impact they might have both on the competence and the conduct of their registrants.

4.10 This table exemplifies the broad range of factors that regulators might wish to consider when determining how much resource to put into continuing fitness to practise, and how to design the continuing fitness to practise mechanisms. Some of them are likely to apply to all professions, such as the length of time in practice. Others may not apply to all professions, or indeed to all groups within a profession.

\(^{25}\) We acknowledge that the distinction between spurious and causal is not always clear-cut or indeed easily identifiable – determining which is which is a notorious challenge for researchers. But it is important to note that while spurious indicators may provide a useful indication of where further research is needed, identifying them will not in and of itself enable a regulator to understand the nature of the risk that is posed by its registrants.

Table 1: Risk factors associated with continuing fitness to practise

<table>
<thead>
<tr>
<th>Risk factor (source)</th>
<th>CHRE description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Context</strong></td>
<td></td>
</tr>
<tr>
<td>Effectiveness of clinical governance (or equivalent) mechanisms (GOC)</td>
<td>What measures are in place to manage risk and learn from mistakes</td>
</tr>
<tr>
<td>Effectiveness of qualifying training (HPC)</td>
<td>How well the course has taught skills, knowledge, and professionalism</td>
</tr>
<tr>
<td>Frequency of practice (PSNI, TAS)</td>
<td>If practitioner is well-versed in his/her field, e.g. returners to practice, practitioners in predominantly management roles</td>
</tr>
<tr>
<td>Level of autonomy (TAS)</td>
<td>Extent to which practice is monitored and practitioners able to practice independently</td>
</tr>
<tr>
<td>Level of isolation (GOC)</td>
<td>Level of interaction with other practitioners (linked to practice context)</td>
</tr>
<tr>
<td>Level of support (PSNI)</td>
<td>Quantity and quality of appraisals, learning opportunities, etc. to which registrant has access</td>
</tr>
<tr>
<td>Practice context (GOC, GOsC, TAS)</td>
<td>Whether practising in private practice, NHS or non-NHS managed environments, or domiciliary</td>
</tr>
<tr>
<td>Time since qualification (GOC, NCAS, TAS)</td>
<td>Length of time since practitioner qualified (linked to age)</td>
</tr>
<tr>
<td>Workload (PSNI)</td>
<td>Pressure on practitioners to be more efficient; increased stress</td>
</tr>
<tr>
<td><strong>Risk factor (source)</strong></td>
<td>Description</td>
</tr>
<tr>
<td>Activity</td>
<td>Complexity of task (GOC, TAS)</td>
</tr>
<tr>
<td>Emotional and psychological engagement (CHRE)</td>
<td>Extent to which intervention poses an emotional and/or psychological risk to the service user</td>
</tr>
<tr>
<td>-----------------------------------------------</td>
<td>-------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Level of responsibility for service user safety (TAS)</td>
<td>Whether responsible for service user safety, how many responsible for; vulnerability and/or severity of condition</td>
</tr>
<tr>
<td>Likelihood and severity of treatment side effects (GCC)</td>
<td>Extent to which practitioner manages negative side-effects</td>
</tr>
<tr>
<td>Medical invasiveness (TAS)</td>
<td>Whether the intervention requires invasive medical treatment</td>
</tr>
<tr>
<td>Rate of evolution of techniques (GOC)</td>
<td>Level of need for ongoing training and learning</td>
</tr>
<tr>
<td>Sexual invasiveness (GOsC)</td>
<td>Whether the intervention requires undressing and/or contact with intimate areas</td>
</tr>
</tbody>
</table>

**CHRE:** although it did not feature in any of the literature reviewed, this risk factor has been added by the authors, on the basis that if medical and sexual invasiveness can be said to result in heightened risks for service users, so too can psychological or emotional ‘invasiveness’.


**HPC:** Health Professions Council, October 2008. *Continuing Fitness to Practise, Towards an evidence-based approach to revalidation.* Health Professions Council.


**PSNI:** University of Manchester, June 2011. *Assessing Risk Associated with Contemporary Pharmacy Practice in Northern Ireland, Executive Summary of the Final Report.* Pharmaceutical Society of Northern Ireland


**Towards a proportionate and targeted approach**

4.11 The principles of right-touch regulation suggest that regulatory responses should be proportionate to risk.

4.12 The severity and prevalence of any risks relating to continuing fitness to practise should guide decision-making about the regulatory force that is needed to address them. This approach can also guide decisions about the resources it should be dedicating to continuing fitness to practise.
4.13 Judgements will need to be made about how serious and prevalent a risk factor needs to be in order to trigger a regulatory response; which particular factors or combinations of factors are cause for greatest concern; and when the low-level presence of multiple factors becomes problematic.

4.14 We find it helpful to think of the range of possible continuing fitness to practise frameworks on a risk-based continuum, with those providing the highest levels of assurance (for the highest-risk professions) at the top of the scale, and decreasing levels of assurance as the risk decreases.

4.15 This can be usefully illustrated with a graph: the level of risk is on the x axis (the independent variable), and the level of assurance/ reliability of measurement on the y axis (the dependent variable).

**Figure 1: How levels of risk drive levels of assurance**

4.16 The information derived from quantifying risks could also allow continuing fitness to practise measures to focus on the practice areas or groups that present the greatest risks.

4.17 The regulator can tailor the tools it uses to collect evidence of continuing fitness to practise processes to gather information about specific areas of performance or conduct. For example, if there were serious concerns about one-to-one consultations involving intimate examinations, information on that topic could be gathered through continuing fitness to practise mechanisms to try to identify and root out sub-standard practice.

4.18 Some methods of collecting evidence of continuing fitness to practise can by their very nature help to mitigate certain risks. If, for instance, isolated practice is identified as a major risk factor, practitioners could be required to provide feedback from peers on their performance. This provides the regulator with valuable third party feedback, but is also a way of getting practitioners to engage with each other and reflect on their own and others’ practice and behaviour.

4.19 Continuing fitness to practise requirements can be adapted to improve performance in specific areas in order to help registrants meet standards – continuing
professional development requirements in particular. For example, the regulator may wish to mandate training on record-keeping if this has been highlighted, perhaps from analysis of fitness to practise data, as an area of particularly poor performance and one which is putting patients and service users at risk.

4.20 Regulators can also use continuing fitness to practise mechanisms to better assure themselves of the fitness to practise of specific groups, if they have good reason to believe that they pose a higher risk to patients and the public. Practitioners with responsibility for a greater number of patients, or who practise with particularly vulnerable groups could be targeted for non-random sampling, for instance. Care must always be taken to ensure that such targeted methods do not discriminate against any groups who share the protected characteristics as defined in the Equality Act 2010.

Making use of existing mechanisms

4.21 Right-touch regulation suggests that regulators may want to make use of any existing local or national mechanisms that can help with the delivery their regulatory aims. This can help reduce costs to the regulator, as well as keeping a check on the overall regulatory burden by avoiding duplication of effort. With continuing fitness to practise, the regulator may be several steps removed from the practitioner – peers, employers, and patients and service users are no doubt closer than the regulator to assess fitness to practise. In the NHS, quality and clinical governance systems, including existing appraisal and patient feedback mechanisms, could be a valuable source of information. For professions who sit outside the NHS, professional bodies may also be able to provide some support.

4.22 The challenge will be to ensure that any mechanisms which are chosen are fit for their purposes, as we believe regulators should retain responsibility for assuring their registrant’s continuing fitness to practise. This means they must make sure any such delegated mechanisms are providing them with the type and quality of information necessary for them to make timely and accurate decisions about an individual’s continuing fitness to practise.

In summary

4.23 In this section we have illustrated the breadth of factors that can determine whether or not there are risks associated with the continuing fitness to practise of a profession, explained how evaluations of risk can be used to ensure that continuing fitness to practise mechanisms are proportionate and targeted, as well as how regulators can reduce the regulatory burden by making use of existing national and local mechanisms.
5. Developing effective and proportionate continuing fitness to practise measures

5.1 We feel that measures of continuing fitness to practise should provide assurances of the competence and conduct of professionals. This means that they must allow regulators to make informed decisions about a registrant’s fitness to practise. In this section we consider how this could be achieved in a way that is in line with principles of right-touch regulation.

Developing reliable and consistent measures of continuing fitness to practise – the theory

5.2 The techniques used to periodically reaffirm fitness to practice should, in theory, consistently and accurately identify as a ‘pass’ those registrants who continue to meet standards, and as a ‘fail’ those who do not – in other words their measurement techniques should yield reliable results.

5.3 It may be useful here to look to quantitative research, which often relies on measurement techniques that measure indirectly something that is very difficult if not impossible to measure directly. In order for such research methods to be valid, it must be shown that these indirect measurements consistently track the variations in the phenomena they purport to measure – in other words, proxy measures need to be shown to be reliable.

5.4 Opinion polls attempt to predict election outcomes, but what they actually measure is what people are willing to say are their voting intentions in response to an interview or questionnaire. Similarly, a self-assessment questionnaire can only directly measure a registrant’s ability to successfully complete the questionnaire, so what regulators using this technique may want to demonstrate is that their questionnaire can be used as a reliable indirect measure of continuing fitness to practise. Its ability to do so can be improved by making improvements either to the questionnaire or to the interpretation of the results.

5.5 Another technique used by researchers is ‘triangulation’, which is the use of a minimum of two instruments to measure the same phenomenon. This works on the basis that overall reliability of measurement can be improved by using several measurement techniques. We consider the basic principle of evidence corroboration can be of huge value, by improving the accuracy of measurement mechanisms. For example, combining a self-assessment questionnaire with patient feedback is likely to result in a more reliable overall assessment than the use of one of them alone.

5.6 A researcher presented with the problem of how to measure fitness to practise would seek to reduce the margins of error as much as possible. Two types of error will arise from these assessments. The first are ‘false alarms’, also known as false negatives, where assessments incorrectly identify a person as unfit. These errors have cost implications and present difficulties for registrants and sometimes employers, but they are not risky as such. The second are false positives, when the
system fails to identify someone who is not fit to practise – these errors present a greater risk than false negatives. Improving reliability is important because it should help to reduce both types of error.

5.7 This concept is usefully illustrated by the multi-stage funneling processes proposed by some regulators. These processes involve an initial high-level screening of a large number of registrants with triggers for further investigation, examination of more detailed evidence, referral for assessment, and finally regulatory action if the registrant is identified as unfit to practise. Built into this model is the tacit acknowledgement that the initial screening process will inevitably pick out for further investigation a number of registrants who are fit to practise, but the model is designed to screen out these registrants in subsequent stages of the process.

5.8 Typically, reducing the number of false alarms results in an increase of false negatives – ‘lowering the bar’ to avoid missing any genuine concerns will undoubtedly lead to more false alarms – and vice versa. We should expect some trade-off between reducing (or not increasing) the burden of regulation, and reducing the number of incorrect ‘fit to practise’ outcomes. For this, we suggest regulators consider the levels of risk that they are prepared to tolerate when it comes to the false positives.

5.9 That said, generally improvements can be made to reduce both types of error, for example by changing the nature of the test, or by improving the regulator’s assessments of continuing fitness to practise submissions. For this to happen, however, regulators would need to develop a sound understanding of the results their continuing fitness to practise tests are yielding, in terms of false negatives and as well as false positives. This will involve scrutinising and learning from their own data as well as from external research resources.

5.10 Reliability refers here to the extent to which a regulator’s test of continuing fitness to practise accurately identifies as ‘passes’ the individuals who continue to meet their standards and as ‘fails’ those who do not. We put forward this concept as a useful way of thinking about the levels of assurance that different continuing fitness to practise measures can provide. Some measures will be more reliable than others, and we suggest this variation should influence the design of each regulator’s continuing fitness to practise mechanisms.

5.11 Developing an understanding of reliability and consistency can take place in testing and piloting, but we recommend it also forms part of the regulator’s ongoing performance monitoring of continuing fitness to practise. An intelligent and agile continuing fitness to practise function should be capable of improving and adapting over time, without necessarily becoming more costly or burdensome.

Developing proportionate and effective measures of continuing fitness to practise – the practice

5.12 Following the principle of proportionality, if reliability is the key defining variable of different continuing fitness to practise frameworks, then it is the level of risk that should determine how reliable a response needs to be. The extent to which regulators are willing to compromise on reliability of measurement should be
determined by their assessment of what **level of risk they are prepared to tolerate**.

5.13 As we saw above, the risks presented by different professions are likely to differ in type, severity and prevalence, so the challenge faced by each regulator is different.

5.14 For a very high risk profession, it would be appropriate for a regulator to seek highly reliable ways of measuring registrants’ continuing fitness to practise. Regulators of lower risk professions on the other hand may not need to have such high levels of confidence in their continuing fitness to practise decisions.

5.15 Effectiveness can be defined as the ability of a measure to achieve the desired result. On that basis, the question of whether a continuing fitness to practise framework is **effective** should be decided by **whether it is as reliable as it needs to be to mitigate the risks presented by the profession**.

5.16 Finally, in line with the Better Regulation Principles\(^{27}\) of **transparency and accountability**, we feel it is important that the **public can understand the levels of assurance** these mechanisms can provide; there should also be transparency about **what lies behind these decisions** that determine how much regulatory force is needed to mitigate identified risks.

**In summary**

5.17 In the final section of this paper, we considered the theory of effective continuing fitness to practise measurement, and suggested that reliability of measurement might be a useful way to think about how effective a continuing fitness to practise model is. We went on to apply the all-important principle of proportionality to this, by recommending that regulators ensure that the levels of assurance of continuing fitness to practise they seek are appropriate to the level of risk presented by the profession.

6. Conclusion

6.1 At the time of writing, there was significant variation in the continuing fitness to practise proposals being developed by the regulators we oversee (see Annex 1). This reflects the range of professions they regulate as well as the different circumstances in which these professionals practise. We feel this is in keeping with everything we have put forward in this paper – there are many possible responses to the challenge of continuing fitness to practise, revalidation is just one of them.

6.2 The focus of this paper is the role that the regulation can, and we feel should play in supporting registrants to continue to meet the regulator’s standards of professional conduct and competence. We hope that it may provide some useful guidance to regulators for the development and review of their continuing fitness to practise mechanisms.

6.3 We recognise the crucial role that professionalism can play in maintaining and improving standards of care and practice. However, regulators nevertheless have a duty to maintain the integrity of their register, and continuing fitness to practise seems likely to become the regulatory function that fulfills this role.

6.4 We have suggested in this paper that regulators may want to think about the effectiveness of their continuing fitness to practise measures in terms of how reliably they identify registrants who fail to meet their standards.

6.5 How reliable they need their continuing fitness to practise mechanisms to be should be determined by the seriousness and prevalence of the risks presented by each profession. When considering such risks, we should take a broad view, to encompass factors relating both to context and practise, and conduct as well as competence.

6.6 We also put forward the concept of a risk-based continuum on which potential continuing fitness to practise responses could sit, with revalidation at the top end, and other responses further down the scale. In our view, different professions sit at different points on this scale, and regulators may want to think about how their position(s) on this scale might influence their response(s). We hope that the approaches taken will be both intelligent and agile, making use of existing mechanisms where possible, and adapting in response to intelligence about their effectiveness and impact.
7. Annex 1: health and care regulators’ plans for continuing fitness to practise

CHRE oversees nine health and social care professional regulators in the UK. This annex describes their plans for continuing fitness to practise. These descriptions were confirmed as accurate by each of the regulators in November 2012.

General Chiropractic Council

In 2010, the GCC consulted on a revalidation scheme based on improving ‘sub-optimal outcomes’. These proposals were developed from the research they commissioned into the risks of chiropractic, which focused on clinical risks. The responses to the consultation were not overly supportive and in March 2011 its Council decided not to proceed with these revalidation proposals on the grounds that they would not deliver sufficient demonstrable benefits.

In September 2011, the GCC set up a new Revalidation Working Group to take forward the revalidation work, reporting to Council on a regular basis. The Council formally recognised the need for it, as a regulator to assure the continuing fitness to practise of its registrants.

In June 2012, the GCC’s Council stated that patient expectations and the views of key stakeholders should inform the proposals to be put to Council later in the year, and that a full consultation on a proposed revalidation scheme would be conducted during late 2012 – early 2013.

The GCC is in the process of developing proposals for consultation based on a broad definition of risk covering both conduct and competence, and informed by the work on patient expectations and the outcomes of its initial communication with key stakeholders.

The Council’s long-term aim is to introduce an effective and proportionate system for assuring chiropractors’ continuing fitness to practise that will achieve the public’s confidence and enhance the quality of patients’ care.

Useful links


General Dental Council

The GDC regulates seven dental professionals (dentists, dental nurses, dental hygienists, dental therapists, orthodontic therapists, dental technicians, clinical dental technicians). It is committed to developing a revalidation model for dentists that is ‘workable,
proportionate and cost effective. It consulted on a set of revalidation proposals for dentists in late 2010 based on a three-stage process.

In April 2012 it held a national conference on ‘Maintaining Quality and Impact of CPD in Dentistry’ in the context of continuing assurance of fitness to practise, and published an associated discussion document. There has been further extensive engagement with the dental sector on revalidation and CPD through regular presentations, an online survey and a call for views.

In response to the publication of Enabling Excellence, it is now consolidating its evidence base for revalidation in parallel with a thorough review of mandatory CPD requirements.

Some research has recently been undertaken into CPD, looking at the literature available in dentistry about effectiveness of CPD, and employer and registrant perspectives on CPD. The former report found some evidence of benefits of long-term, self-directed and planned CPD activity. The latter research report focused on perspectives on the GDC’s specific CPD framework, looking at how CPD is undertaken and what factors influence it. It found support for the main elements of the CPD framework, but recommended moving towards the recording of outcomes rather than just inputs. A proposed outcomes-based model of CPD linked to Standards for Dental Professionals and registration retention was opened for public consultation in late 2012.

In November 2012 a study commissioned by the GDC and delivered by the Picker Institute Europe considered the effectiveness of existing performance management and quality assurance tools in dentistry for indicating continuing fitness to practise. The GDC is also in the process of commissioning research into risks in dentistry.

It is currently intended that the introduction of new enhanced scheme of mandatory CPD, based on planning, reflection and learning outcomes, and linked to on-going registration, is a key step in providing further assurance of continuing practice of dental professionals. A fuller scheme of revalidation will continue to be developed and be introduced for dentists as appropriate once a new CPD scheme is embedded.

Useful links

General Optical Council

In 2009, the GOC commissioned extensive research into the risks of the optical profession. The research highlighted two categories of risk areas: adverse events, which are competency issues that can present a risk to patients, and the contextual factors that can have an effect on the likelihood or severity of the risk.

The researchers recommended that revalidation should focus on improving decision-making in the higher risk areas through focused training requirements, that areas of lower risk could be addressed through an enhanced CET scheme, and that revalidation could include an interactive element.

http://www.gdc-uk.org/Dentalprofessionals/Revalidation/Pages/default.aspx, accessed 20/03/12

Europe Economics, March 2010, Risks in the optical profession: A report for the General Optical Council
The GOC also carried out a number of consultation events\(^{30}\) and incorporated the feedback obtained from patients, public and other stakeholders at these events into their proposals. In 2010 and 2011 the GOC conducted further research into the use of appraisal, patient feedback, the effectiveness of its existing CET Scheme and the impact of undertaking CPD on changing behaviour.

The GOC used the research findings to formulate a business case to enhance its CPD scheme to respond to the risks identified. The enhanced CPD scheme stipulates a minimum number of CPD points and compulsory learning topics based on the GOC standards of competence and conduct for each of its registrant group. Registrants are required to undertake 50% of their activity in interactive learning methods and it is compulsory to participate in peer review.

All CPD activities are accredited by the GOC in advance with greater weight given to activities involving discussion with peers and reflection on own and others practise than self study and distance learning. It also will show less leniency towards non-compliance than at present with registrants progress being tracked annually and failure at end of the 3 years cycle resulting in the registrant failing to be able to demonstrate their continued fitness to practise and therefore at risk of being removed from the Register.

The GOC will introduce its enhanced Continuous Education and Training (CET) scheme on 1 January 2013.

**Useful link:**

**General Osteopathic Council**

Following the publication of *Trust, Assurance and Safety* in 2007, the GOsC consulted on a revalidation scheme in 2009\(^{31}\) from which emerged a model\(^ {32}\) consisting of a four-stage process, the first of which is a self-assessment. The other three stages constitute an escalation of measures for submissions that are deemed not to have met the required standards.

Since then, the GOsC has developed its thinking to focus on enhancing quality as well as meeting minimum standards and is undertaking a year-long pilot to produce a scheme which supports osteopaths to demonstrate continually that they are up to date and fit to practise (as opposed to a one point-in-time fixed assessment).

Osteopaths typically work in independent practice – without teams or employers – and usually operate as a point of first contact for patients. Research has shown that complaints to the regulator and to insurers comprise both conduct and competence issues (see adverse events below). The GOsC has therefore explored a scheme which enhances both the regulatory role and the individual role to make up for the absence of teams or employers, and which looks across all the standards for registration.

Being aware of the limits of competence and being able to refer are key components of practice and using evidence to inform a self-assessment is important in this context. The


GOsC has commissioned a series of projects about risk in osteopathy which were coming to fruition at the time of writing. These findings will be incorporated into an independent evaluation and impact assessment of our revalidation pilot to support an understanding of proportionality and patient safety in the context of osteopathy.

The GOsC is developing its thinking in two ways:

- It is piloting a self-assessment scheme with approximately 10% of its registrants. The standards for the revalidation pilot are the Osteopathic Practice Standards – the core standards for registration. Assessment criteria have been developed. The participants in the pilot are required to produce a variety of objective and subjective evidence to demonstrate they meet all the standards. An independent evaluation and impact assessment, due for publication in the spring of 2013, of the scheme will explore the costs and benefits and proportionality of the approach in osteopathy.

- It is also exploring how the existing CPD scheme might be enhanced to better support osteopaths to demonstrate that they are up to date and fit to practice through its CPD Discussion Document. The Document looks at what makes CPD effective in osteopathy and how it might be enhanced. The responses will be analysed and published in the spring of 2013.

Detailed proposals for regulating continuing fitness to practise in osteopathy should be published in the spring of 2013 for further consultation.

Useful links

- Evaluating the revalidation scheme including costs, benefits and proportionality - http://www.osteopathy.org.uk/practice/Revalidation/Research/

Revalidation Pilot Manual (September 2011) – the Revalidation Pilot Participation Manual consists of the following:

General Medical Council

The GMC is on track to introduce revalidation at the end of 2012. At this point, responsible officers and other medical leaders will be required to revalidate in order to maintain their licence to practise. By 2018, all licensed doctors will have undergone revalidation to maintain their licence.

Revalidation is the process by which licensed doctors will periodically demonstrate that they remain up to date and fit to practice. Licensed doctors must participate in revalidation in order to maintain their licence. The licence was introduced in November 2009, and revalidation will enable the GMC to control access to the practice of medicine based on the outcomes of individual revalidation decisions.

The revalidation framework relies on local appraisals, to which doctors must contribute a portfolio consisting of six different pieces of evidence: continuing professional development, quality improvement activity, significant events, feedback from colleagues, feedback from patients, and a review of complaints and compliments.

It is the role of the responsible officer to make a recommendation to the GMC, based on the appraisal outcomes and any other information available to them, about whether or not the doctor is up to date and fit to practise.

The GMC will carry out its own checks to ensure no other concerns have been raised about that doctor. If this is the case, the doctor is revalidated and they continue to hold their licence to practise.

Useful links:
- The Good Medical Practice Framework for appraisal and revalidation, which translates the key guidance into a set of domains for doctors and appraisers to use in appraisal – [www.gmc-uk.org/doctors/revalidation/revalidation_gmp_framework.asp](http://www.gmc-uk.org/doctors/revalidation/revalidation_gmp_framework.asp)
- Guidance on the supporting information doctors have to bring – [www.gmc-uk.org/doctors/revalidation/revalidation_information.asp](http://www.gmc-uk.org/doctors/revalidation/revalidation_information.asp)

General Pharmaceutical Council

The GPhC is committed to introducing revalidation to require pharmacists and pharmacy technicians to demonstrate their continuing fitness to practise. They have decided to proceed with this work on the grounds that it may act as a catalyst for improving practice.

They set up a Task and Finish Group in February 2011 to advise their Council on how best to take forward the revalidation agenda. They were tasked with considering the outputs from the Royal Pharmaceutical Society of Great Britain (the previous pharmacy regulator) on revalidation, the terminology to describe what the GPhC was trying to achieve, revalidation in the context of the risks in pharmacy practice, and approaches taken by other regulators.

This led the GPhC Council to agree a definition of revalidation 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.”
A number of high level principles for revalidation have also been agreed, and the GPhC is committed to building on these principles as a basis for taking forward revalidation development. To inform the development of its proposals, it held an event in July 2012 for stakeholders, including pharmacists, pharmacy technicians, and patients and public representatives. The event enabled discussion of the principles of revalidation, and focused on sources of information and evidence, and the types of assessment and standards that would be relevant for revalidation, including existing systems that potentially could contribute.

How the GPhC’s revalidation mechanisms would relate to its existing CPD requirements has yet to be decided. Its CPD scheme is based on a reflective cycle, as set out in the requirements made by the CPD standards and CPD framework.

**Useful documents**

**Health and Care Professions Council**

When considering the question of continuing fitness to practise in 2008, the HCPC (formerly HPC) found that the majority of its cases concerned conduct and lack of professionalism rather than competence, and that revalidation might not be the most appropriate response to the risks posed by their registrants.

They suggested that ‘further regulation [in the area of continuing fitness to practise] was not necessary for the professions regulated by the HPC’, but identified a number of areas for further investigation.

They subsequently embarked on an extensive programme of work to understand the risks posed by their registrants, and how they can address them. A key focus of this work so far has been professionalism as a means of preventing the risks. The HCPC is also in the process of analysing its FtP and CPD data to determine the common characteristics of the registrants who fail to meet their Standards.

The HCPC’s CPD framework does not specify the amount of learning that must be undertaken. Registrants who are audited must report on the CPD they have undertaken and how they feel it has benefited their practice and service users.

**Useful links:**

**Nursing and Midwifery Council**

The NMC’s initial proposals for revalidation were signed off by Council in 2011 and have been refined following a UK-wide engagement exercise with around 2,000 stakeholders.
The NMC remains committed to introducing revalidation, but other priorities mean that this will happen no earlier than 2015.

The NMC model relies on its existing legislation at the outset but aims to provide greater assurance that registrants are upholding standards of proficiency and the code, and remain fit to practise, by introducing new post registration standards and enhancing the renewal of registration process. All nurses and midwives must complete this process every three years to stay on the register.

Nurses and midwives will be required to comply with new ‘revalidation standards’. These will emphasise that it is their responsibility to maintain their continuing fitness to practise. The standards will compel registrants at the point of renewal to demonstrate that they have:

- Complied with the Code (NMC’s standards of conduct, performance and ethics)
- Met the standards of proficiency relevant to their part(s) of the register and ensured that their skills and knowledge remain up to date and relevant to their practice
- Engaged in CPD that has a positive impact on patient safety and well being
- Obtained third party confirmation that they have met these standards, which may include evidence of employer appraisals, supervision meetings for midwives (and for nurses where these exist, for instance in Northern Ireland), peer review and patient or user feedback.

A sample of nurses and midwives will be selected for audit from the group that is due to renew its registration. If the evidence they submit is not deemed sufficient to demonstrate compliance, they will be offered the opportunity for remediation. If remediation is unsuccessful or not taken up, their application to renew will not be granted and their registration will lapse. There will be a right of appeal. The revalidation sample is likely to include a random stratified element and a targeted element, the latter based on risk hypotheses that will be tested through comparison with the generality of registrants. This approach will enable the NMC to develop a sounder picture of risk and its mitigation over time.

Useful links

**Pharmaceutical Society of Northern Ireland**

The PSNI has considered the question of revalidation, and commissioned research into the risks of the pharmacy profession. The research found that patient-facing roles and returners to practice presented the greatest risks, and recommended that any revalidation scheme should be based on a set of practice standards, and make use of CPD in a risk-based model.

The current Council of the PSNI remains committed to ensuring the continuing fitness to practise of its registrants, although it has not formulated explicit plans, as a completely new Council will be appointed on 1st October 2012 following amendment to the legislative framework. The current Council is in the process of putting its CPD framework on a statutory footing as a consequence of legislative reform.
The new Council, currently in shadow form, has committed to entering dialogue with the Department of Health, Social Services and Public Safety in relation to the Department’s policy on continuing fitness to practise for pharmacists in Northern Ireland, recognising that their approval would be required before introducing the necessary legislation to support any new model.

**Useful links**