Re-validation and re-certification appear to be the way forward for prescribing pharmacists

In the final article of this set focussing on how pharmacists are educated and evaluated, Barry Strickland-Hodge describes re-validation and re-certification, explaining what are they and what this means to the prescribing pharmacist.

Introduction

In the first article of this series[1] I discussed the way pharmacists are educated and assessed to enable them to gain a practise certificate in independent and supplementary prescribing. The second article[2] considered continuing professional development (CPD) and the mandatory requirement to carry out CPD for practising pharmacists. This final article considers re-validation of the pharmacist's initial registration and the possible re-certification of specialist pharmacists in particular prescribing pharmacists.

In 2001, Fawz Farhan[3] reviewed CPD in the light of the Society's focus on mandatory CPD. In this far-ranging article, the author discussed the need for feedback following evaluation and assessment of the material collected by pharmacists. The link between mandatory CPD and re-validation was also highlighted.

What is re-validation?

Generally, re-validation is said to be the renewal of the pharmacist's original registration by showing that he or she remains competent, up-to-date and works within their own scope and the regulator's (currently the Society's) *Code of ethics*.[4]

Benson[5] suggests there are four major goals of a model re-validation process. By requiring all health care professionals to meet specified standards of practise throughout their careers (rather than just at the beginning of them) re-validation would:

- improve the quality of patient care
- define measurable standards of practise
- foster a spirit of lifelong learning
- reassure the public that incompetent practitioners will be identified and dealt with appropriately.

The Nursing and Midwifery Council (NMC) expect their practitioners to declare that they have met a set of post-registration education and practice (Prep) standards in the three years before the renewal becomes due. Declaration forms are self-completed but the NMC undertake random testing of compliance by requiring practitioners to submit a 'prep audit' of evidence that these requirements have been met.

Why the current interest in re-validation?

It might be thought that consideration of a need to in some way re-accredit health care professionals at intervals throughout their careers to ensure continued fitness to practise has come about because of recent high-profile inquiries. The reports of the Shipman inquiry, the Bristol Royal Infirmary and the case against the consultant gynaecologist Rodney Ledward and others certainly provided the catalyst to formalise and make mandatory medical postgraduate education and training.[6] However, discussion about re-validating the initial professional qualification of medics had been going on since the early 1970s and resulted in the Medical Act of 1983 being amended[7] to enable the General Medical Council (GMC) to introduce re-licensing and re-validation of its members. Interestingly, the GMC did not begin to develop its proposals for revalidation until 1998. Just before this, in April 1995, all nurses and midwives were required to comply with the prep standard for CPD.

In 2005 Gillian Hawksworth discussed a need to strengthen the fitness to practise procedures to ensure appropriate re-validation of new roles where there is patient contact.[8] This point is important when we consider the two types of registration — for practising and non-practising pharmacists. The council of the Royal Pharmaceutical Society of Great Britain (RPSGB) was enabled to introduce mandatory CPD for practising pharmacists after publication of the *Pharmacists and Pharmacy Technicians Order* (P&PTO).[9] In the P&PTO the two parts of the register — practising pharmacists part 1 and non-practising

pharmacists part 2 — were outlined with the emphasis being on part 1, the practising pharmacist's need for CPD.

The arrangement for national regulation of the pharmaceutical workforce in the UK has remained unaltered for generations even though the profession has changed significantly, particularly since publication of the Noel Hall and the Nuffield reports.[10]

Once qualified and registered, assuming there was no cause for disciplinary action, a pharmacist could expect to remain on the register until retirement with no necessary further involvement in educational activities even though this would be encouraged. Changes outlined in the P&PTO will be phased in[11] but there is no doubt that change will happen.

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Foster review

In March 2005 the then Secretary of State for Health established a review of non-medical health care professions. This became known as the Foster review[12] and was published in July 2006. The review was in response to the reports of the Shipman inquiry after which a MORI poll suggested that the public expected periodic checks to show a person remained fit to practise.

The objective of the review was to create a system that would provide objective and robust assurance that individual professionals remained fit to practise and to standardise the content and enhance the value of workplace appraisal. The review stated that re-validation was necessary for all professionals. The review defined re-validation as: 'The process by which a regulated professional periodically has to demonstrate that he or she remains fit to practise.' Appraisal was also mentioned in the report. It was defined as: 'the process by which others (whether peers, superiors or others) assist a person to review their performance and draw lessons from it'.

Appraisal

In the fifth report of the Shipman inquiry[6] it was stated that: 'If appraisal is intended to be a clinical governance tool', it must be 'toughened up'. If that is to be done, the following steps will be necessary. Appraisers should be more thoroughly trained and should be accredited following some form of test or assessment. Appraisers should be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by GPs from another PCT. Standards should be specified, by which a GP 'successfully completes' or 'fails' the appraisal. All appraisals should be based on a nationally agreed core of verifiable information supplied by the PCT to both the appraiser and the appraisee'. If this appraisal forms the basis of the annual re-validation of the pharmacist's fitness to practise lessons from the existing and revised appraisal systems need to be learnt.

Trust, assurance and safety

The White Paper[13] that followed the Foster review restated the view that re-validation was necessary, but changed the emphasis in the definition slightly to encourage engagement and to suggest the benefits to the professionals. Re-validation, it said, allows health professionals to demonstrate that they remain up-to-date and fit to practise. Clear standards are required to ensure validity of the process and acceptability to the professionals. Two new terms were introduced in the White Paper. The first was re-licensure. This assumes that the health care professional will become licensed to practise when they first qualify and that this will require re-licensing or re-licensure regularly. The second term is re-certification, which means an additional requirement for professionals on a specialist register or who are practising in a high risk certified area of practice such as, in the case of pharmacists, prescribing. These terms may become common practise in future so that the pharmacist does not merely register but gains a license to practise.

> Generally, re-validation is said to be the renewal of the pharmacist's original registration by showing that he or she remains competent, up-to-date and works within their own scope and the regulator's (currently the Society's) code of ethics.

The words fitness to practise occur in various forms in various professional articles. To date pharmacists have been expected to work within a code of ethics,[4] which required them to make the care of patients their first concern. In order to ensure this is carried out appropriately the pharmacist must ensure he or she is up-to-date and understands the legal aspects of the activities being undertaken. The White paper[13] moves from the pharmacist ensuring they are safe and up-to-date to the patients' expectation of the pharmacist providing objective assurance to underpin their trust in him or her.

The need to have two parts to the register of pharmacists.

The P&PTO[9] divided the register into two parts — practising and non-practising. A practising pharmacist is defined in the Statutory Instrument as a pharmacist who undertakes any work or gives advice in or in relation to the science of medicine or the practise of health care, and includes pharmacists working in industry, academia and administration (see http://www.uptodate.org.uk/PlanandRecord/Pharm_Guidance.pdf). The definitions as given in the Statutory Instrument differ from, say, those in Canada where practising pharmacists means those who are dealing directly with the public — and non-practising pharmacists are those who do not deal directly with the public. In the UK definition as given in the

P&PTO all pharmacists who are entitled to register in the register of pharmacists are to be registered in part 1, the practising part, unless there is an undertaking given to the registrar that that pharmacist will not practise. This seems something of a missed opportunity.

The order also introduced mandatory CPD for all practising pharmacists. One further point in the Statutory Instrument is that there is a provision for annotating the register to denote specialisation or advanced practise. This allows the Society to decide what training is necessary and who has undertaken it satisfactorily, and to annotate the register accordingly. Currently, practising pharmacist prescribers have the letters SP or IP after their entry in the pharmacists' register.

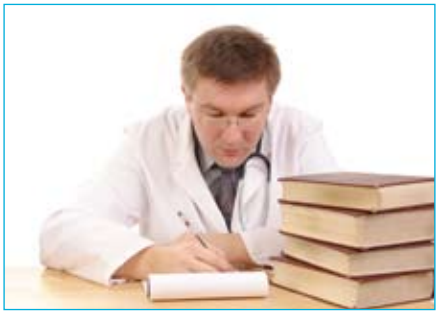
The timetable given in the order has perhaps been put on hold as the whole structure of the Society and the creation of the General Pharmaceutical Council (GPhC) takes precedence. Re-certification of specialists was expected to be introduced in 2008/09 but no new timetable has yet been established. Specific obligations of the Society were outlined (to be the responsibility of the new professional body) with regard to these specialist groups. For example, the requirement to determine the nature, extent and content of the education, training, experience and CPD required for the purpose of obtaining annotations in respect of specialisations.

Transitional committee

Since the publication of the Statutory Instrument, a Transitional Committee (TransCom) has been established to oversee the development of the new professional body (NPB) for pharmacy. The working group on improved, advanced and specialist practice (IASPWG) is one of seven working groups set up by TransCom to carry out various aspects of its work. The terms of reference of the IASPWG are to advise on arrangements within the NPB to: -

- enable and encourage generalists in all branches of the profession to improve and advance their practice
- welcome and support advanced and specialist practice across the whole of pharmacy
- provide support for existing professional groups and organisations seeking to join the NPB
- provide for appropriate accreditation processes to establish independent verification of particular advanced and specialist qualifications.

Although the White Paper[13] considered that re-certification might only apply to medicine and not to other health professionals this is unlikely. The RPSGB reiterated the definition of re-validation as a process of ensuring that pharmacists and pharmacy technicians on the practising register were up-to-date and fit to practise.[14] However, in appendix 3 of that update it is stated that advanced practitioners, for example prescribers, may require additional assessment. All registrants would go through the same process in principle with additional requirements justified by risk to the public. This update goes a long way to explain the thinking of the Society with regard to re-validation and re-certification. In its document the Society says that the standard for re-validation should be the same as the standard required for initial registration as a pharmacist and therefore does not require professional development. In Appendix 2 — the draft high level principles for non-medical re-validation — principle 5 states that CPD should be seen as being integrated into the process of re-validation, which again may provide outcome evidence that will contribute to the regulatory body's decision on whether or not to re-validate a pharmacist.



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It further explains that registrants must periodically (probably every 5 years) demonstrate that they are as fit to practise as those who are coming onto the register for the first time.[14] So this takes what may be a self-completed re-registration form plus, say, annual appraisal even further.

This is a clear view that re-validation will be required in the near future to remain on the practising register of pharmacists in accordance with the statutory instruments' powers and the requirements of the White Paper.

Is medical re-validation a model for pharmacists?

Again in July 2008, the Chief Medical Officer reported on medical re-validation.[15] The main principles outlined were for medical practitioners, but they are valid for pharmacists and give an insight into the process as it could appear in the near future. Rewording the main principles outlined in this document for pharmacists gives us:

- Must support pharmacists in meeting their personal and professional commitment to continually sustaining and developing skills.
- Should include within it a strong element of patient and carer participation and evaluation.
- Should be seen primarily as supportive, focussed on raising standards not a disciplinary mechanism to deal with the small proportion of pharmacists who may cause concern.
- Must include remediation and rehabilitation as essential elements of the process for the very few who struggle to re-validate giving them help wherever possible.
- Should be a continuing process not an event every five years so that problems can be identified and resolved quickly and effectively.
- Should avoid bureaucracy, add value and provide a reasonable level of reassurance to colleagues, employers, patients and the public.
- Should be introduced incrementally through piloting to ensure that it works well.

- Should provide reasonably consistent assurance of standards across the UK whatever the practice model.
- Should be based on evidence drawn from local practices with robust systems of clinical governance to support it.
- Will depend on the quality consistency and nature of appraisal to ensure the confidence of patients and pharmacists.

Re-validation for medical doctors has two strands:

- Re-licensing (confirming that doctors practise in accordance with the GMC (GPhC) generic standards) which was defined above.
- Re-certification confirming that doctors on the specialist and GP registers conform, with standards appropriate for their specialty of medicine.

Problems

There are problems associated with any scheme for re-validation and re-certifying any large group of professionals — some of which are again outlined in the working party report and reworded again for pharmacists.[15] Briefly these are:

- That there is a diversity of roles and of settings for pharmacists — private and public sectors, industry, academia and so on — yet we anticipate a generic standard to accommodate all.
- Whatever system and process we develop it must be valid, reliable, proportionate and fair. It must also be acceptable to the membership and largely owned by them (see the comments on the Ontario system).
- Any form of re-validation should have the ability to use other information gathered previously, such as from appraisal or the mandatory CPD record.
- Re-validation (the overarching process of ensuring fitness to practise) must be seen as a mechanism for quality improvement and not merely identifying problems.
- Re-licensing (the annual requirement to remain on the register) will rely on annual locally-based appraisal informed by periodic multi-source feedback.
- Re-certification (for specialists such as pharmacist prescribers) will involve the specification of a clear set of standards — formulated by whom? (See the Ontario system later.)
- There should be overlaps between re-licensing and re-certification such that the appraisal proposed as an annual requirement for re-licensing can be used to inform the decision to re-certificate an individual.
- The re-certification component will involve the specification of a clear set of standards formulated by each specialist group (equivalent to the Medical Royal Colleges — perhaps College of Pharmacy Practice, National Prescribing Centre or UK Clinical Pharmacy Association).
- Methods for evaluating specialist practice will vary but will need to be rooted in actual practice.
- It should avoid a single high stakes test and ensure that it is part of a wider assessment of practice over the five-year period of re-validation.

Re-validation for the individual pharmacist will be a process rather than an event

The process of re-validation — the Ontario experience

In 2003, Austin and colleagues reviewed the process of re-validation of pharmacists in Ontario.[16] The system showed how re-validation could be achieved involving the pharmacists who were also to be assessed. As in the UK, candidates for registration (called licensure in Ontario) must graduate from an accredited School of Pharmacy and have undertaken in-house service training completing various national and local examinations. This leads to a license to practise — or in our case registration. Most jurisdictions require demonstration of CPD usually measured by attendance at continuing education (CE) events[1,16] or self-guided lessons. Again in Ontario, as in the UK currently, the individual is then free to practise in a relatively unhindered way for the rest of their careers. As a consequence of various surveys and studies the Ontario College of Pharmacists (OCP)

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(equivalent to the RPSGB) decided that continuing education did not relate to quality of patient care. Nevertheless, this is still mandatory for pharmacists — even though it rarely demonstrates the impact this has had on pharmacists' practise.

The Ontario process is an interesting one and may be followed at least in part in the UK. The practise of pharmacy is governed by the OCP, whose mandate is self-regulation and public protection. The University of Ontario-based Faculty of Pharmacy, however, is primarily responsible for the education of entry level practitioners.

In an effort to balance the advantages of self-regulation with the need for greater public control and scrutiny the Regulated Health Professions Act introduced new concepts into professional regulation. Mainly it mandated the OCP to regularly directly assess its members for competency to practise pharmacy. This was enacted in 1993. The quality assurance process is a mandatory provision of the legislation governing the practise of 23 health care professions. The whole paper is well worth reading, but briefly the process for re-validation is as follows. The OCP have a four part quality assurance model:

- First there is a two-part register where practising pharmacists declare that they provide direct patient care and where non-practising pharmacists who cannot provide direct patient care register but must maintain personal records of their CE. All remain as pharmacists and use this title. This seems to me to be a sensible approach — compare this with the UK definitions.
- Second there is a learning portfolio to demonstrate lifelong learning. This could at least be in part the online CPD log currently kept with the RPSGB.

- Third is a practice review process with remediation.
- Finally, the fourth part is a process of remediation of inappropriate behaviour towards patients or clients.

All pharmacists whether practising or non-practising must maintain a record of continuous learning and submit this to the College on request. Like the RPSGB system this is not simply a record of CE undertaken but a method of identifying gaps in knowledge and action plans to overcome these gaps. It gives the pharmacists the opportunity for self-reflection. Support is given by providing documentation tools and information, but it does not stipulate what type or quantity is required.

Practising pharmacists' review

The practice review is for pharmacists in part A (practising) of the register only. Those who are pharmacists but not practising i.e. not providing direct patient care, do not have to undergo this review and remediation. This seems reasonable as the objective is to maintain patient safety and those in industry and academia, for example, may not require further review over and above the appraisal and the portfolio of CE and CPD. However, if these individuals are involved with educating future practitioners, perhaps they should be measured by the same standard as those actually practising. Additionally, many lecturers may go into the practise environment at least part-time during their academic careers.

Phase 1

Of all those pharmacists who declare themselves to be practising 20% are selected each year for phase 1 of the practice review. This equates to 1,600 in Ontario. Every practising pharmacist will be selected, therefore, once every five years. Phase 1 involves self-assessment and a summary of their continuing education activities.

The phase 1 survey includes pharmacist self-assessment of knowledge and skills in various therapeutic areas, identification of personal learning needs and methods by which these needs are being met. Other key areas included are ethical/legal/professional responsibilities, drug distribution, practice management and access, retrieval, evaluation and dissemination of drug information.

Phase 2

Phase 2 of the practise review is more in-depth. Once selected for phase 1 the pharmacists remain in a larger pool from which 200 are selected for phase 2. (Phase 1 is not a screening tool).

Phase 2 includes measurement of competencies in particular direct patient care competencies — the reason why the pharmacist elected to be on the practising part of the register. This will include clinical knowledge, information gathering, patient management and education and communication skills.

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Phase 2 consists of three activities. The first is a two-hour open-book written test of clinical knowledge consisting of 15 cases each followed by four multiple choice questions (60 questions in all). The second activity involves five 12-minute standardised patient interview scenarios (these could equate to OSCEs used in various assessment settings in the UK). The third activity is a 60-minute education sharing session on CPD and the learning portfolio.

The development of the competencies and the assessors is beyond the scope of this article, but the article by Austin and colleagues[16] gives some detail on this stressing the need to use pharmacists in various settings to create the questions and the cases. Like the RPSGB website and the NPCi website, the OCP has developed several resources to help prepare pharmacists for phase 2. After the sessions each pharmacist is provided with individual and cohort feedback. Pharmacists who have difficulties meeting the standards are required to submit an educational plan.

Re-certification

In the Chief medical Officer's review,[15] re-certification confirming that doctors on the specialist and GP registers conform with standards appropriate for their specialty of medicine was suggested as the second part of a two-part re-validation process.

The introduction of prescribing rights for pharmacists brought with it the first example of restricted practice for pharmacists in England. To secure the right to prescribe the pharmacist has to demonstrate competence after attending an accredited course. The pharmacist must also undertake a period of clinical supervision before gaining a practice certificate in independent (and or supplementary) prescribing.[1] The pharmacist is then restricted only by his own expertise and limitations governed by the *Code of Ethics*.[4] Pharmacist prescribers have their names annotated on the Register of Pharmacists.[10]

There has been a general acceptance that pharmacists will undergo some form of re-validation or re-licensing to continue to practise in the near future. However, there is a growing belief that specialist pharmacists in various areas particularly those who have been specifically certified to carry out work such as prescribers and who have had their specialty annotated on the register of pharmacists may require re-certification periodically. How this is done and how frequently is to be discussed first by TransCom and then hopefully by the membership as a whole.

Brief survey of non-medical prescribing leads

In a recent very small non-generalisable but potentially transferable survey there were 19 responses from non-medical prescribing leads, (seven from PCTs, 11 from hospital and one from a community mental health trust), the suggestion that re-certification would be needed for prescribing pharmacists was discussed.

Most (14) agreed that re-certification was important to maintain the pharmacist's fitness to practice. One felt it was unnecessary and that fitness to practise would be

maintained by regular CPD adding that re-certification would be a tick-box exercise. Twelve responders thought that appraisal with a set of nationally agreed standards was the most appropriate way forward. When asked who should carry out the appraisal before re-certification 11 thought it should be done in-house and, where appropriate, through the non-medical prescribing lead. This was a multi-answer question and other suggestions were an outside health care professional, inspectors employed by the GPhC, senior doctors and higher education institutes. As non-medical prescribing leads are not necessarily prescribers, this would only be appropriate if the re-certification was of a general nature looking at the number of prescriptions written, for example, or considering a set of national generic standards. If the quality or appropriateness of prescribing was to be measured then it would be important for credibility and appropriateness that the appraiser was a prescriber — not necessarily a pharmacist. In the White Paper[13] and the Chief Medical Officer's working party report,[15] feedback was considered very important to ensure continued improvements to practise. The difficulty would be working out who would provide the feedback to large numbers of pharmacist prescribers.

Many of the responders (11) to this small survey considered that they would require further training if they were to be asked to carry out assessments. One area of practise that might be difficult to assess would be the self-employed community pharmacist prescribers. Seven of the 19 responders considered that a health care professional from the PCT should carry out their assessment. Finally, the non-medical prescribers were asked how frequently the re-certification should take place for prescribing pharmacists. Although most published papers on the topic seem to suggest every five years for re-certification after annual re-validation, the survey suggested every three years was more appropriate. A comment from one non-medical prescribing lead was: 'Once pharmacists have reached a level of specialist practice (such as prescribing) they are professional, accountable and responsible for their actions and CPD. At that level there are very few individuals who can assess your practice and you have to ensure that you critically appraise your own actions and decisions through supervision and a robust CPD framework. It is my opinion that this is the route that should be taken as I see the option in question very much a tick-box exercise'.

If pharmacy alone was undergoing these changes we might argue this case, but all health care professionals are having to seriously consider re-validation at least. However, would any of these actions have prevented Shipman, Ayling, Haslam, Allott or Ledward or any of the other disasters in medicine and health care? Probably not. Will they improve patient trust in the health care professions? Possibly. The genie is, however, out of the bottle and we must proceed with what will be a difficult time at first but, as can be seen from the Ontario experience, a rewarding one, and one way of allaying some of the fears of the public.

Summary

The terminology can be confusing. Currently we pay our annual registration fee to the Society. We declare we are practising or non-practising. In the near future we will pay a statutory fee to the General Pharmaceutical Council (GPhC) and can elect to join the new professional body. If the GPhC decides that we become licensed to practise we will be looking at re-licensure if we remain as we are, and then there will be re-validation. This might take the form, as in medicine, of a structured assessed appraisal annually. It may be that, as in the Ontario situation, a sample of these will be further assessed. If we decide to impose a re-certification for all of those specialists who have become certified in their own specialty such as prescribing or who have their names annotated on the register of pharmacists, this re-certification would take place periodically every three to five years and would need a structured method of assessment, preferably in the workplace and undertaken by trained professionals. Whether re-validation and re-certification should be general assessments rather than subject specific remains to be decided.

Conclusion

Whatever is eventually decided with regard to the national regulation and assessment of the fitness to practise, re-validation and re-certification of pharmacist prescribers, change is inevitable. ✣

Declarations of interest

The author has no interests to declare.

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