Royal Pharmaceutical Society
of Great Britain

Helping pharmacists achieve excellence

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10 November 2006

Dear Sir/Madam

Response to *Good doctors, safer patients* and *The regulation of non-medical healthcare professionals*

Please find enclosed the response of the Royal Pharmaceutical Society of Great Britain (RPSGB) to the consultation on proposals for changes to healthcare professional regulation.

In preparing our response to the reports *Good doctors, safer patients* and *The regulation of non-medical healthcare professionals*, we have conducted a series of consultations with members of the pharmacy profession and pharmacy organisations throughout the United Kingdom. Members of the RPSGB special interest groups, individual members, Council members, Branch representatives, Society staff, and others have submitted views to inform the response. The RPSGB Council held special meetings on the 14th September, and 1st and 2nd November 2006, and had a session at its formal Council meeting on 11th October 2006 to consider the implications of these reports, and to frame the Society's response.

The pharmacy profession is currently undergoing significant changes, which are seeing the traditional roles of pharmacists and pharmacy technicians redefined and expanding. In light of these changes, the Royal Pharmaceutical Society of Great Britain has been proactive in reviewing and developing its role as the regulator of the profession in order for it to remain fit for purpose in serving the public interest. We see the current proposals for changes to healthcare professional regulation as an opportunity to further advance this work and welcome the opportunity to submit our own proposals for how best to achieve this. In terms of implementation, our main priority will be to secure a workable and sustainable outcome in relation to the specific proposals relating to regulation and professional leadership for pharmacy. In our response we also urge the joint implementation board for the Foster and Donaldson reviews to pursue a consistent approach between the medical and non-medical professions. We also recommend that the board prioritises changes for which there is good evidence regarding their ability to deliver the greatest benefits for patient safety and the quality of healthcare, while recognising the need to accommodate genuine differences between the professions.

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Ann M Lewis OBE FRPharmS Secretary and Registrar
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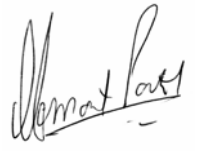
There is no evidence that the non-medical regulators have been slow to identify or deal with serious failings, nor evidence that they have slowed down the pace of change in respect of professional and service development. In fact, the RPSGB has a proven track record of adapting to continuing changes in society. We intend to communicate with you further on how we might make progress on the contents of our response, after the Council has had a chance to confirm a way forward in the first week of December. I am confident that by working together we can build on current strengths to the benefit of both the pharmacy profession, and patients and the public.

Yours sincerely,



Hemant Patel FRPharmS

President of the Royal Pharmaceutical Society of Great Britain

Public consultation on proposals for changes to *Healthcare professional regulation: good doctors, safer patients* and *The regulation of non-medical healthcare professionals*

Response of the Royal Pharmaceutical Society of Great Britain
10 November 2006

Introduction

The Royal Pharmaceutical Society of Great Britain ('RPSGB' or 'the Society'), the professional and regulatory body for pharmacists in Great Britain, welcomes the opportunity to respond to the proposals set out in these two reports.

Do stakeholders support the principles upon which 'Good doctors, safer patients' is based?

Good doctors, safer patients (the 'Donaldson report') is in many respects a well-researched and evidence-based report. We welcome the breadth of approach it takes in seeking to draw lessons for UK medical regulation from other countries and safety-critical industries outside healthcare, while also evaluating the effectiveness of the current arrangements for the safety and quality of medical care in the UK.

We do have some concerns about the lack of evidence for many of the conclusions of *The regulation of non-medical healthcare professionals* (the 'Foster report'), and the lack of costings for the proposals. There is a risk of increasing rather than reducing regulatory burden if changes to the regulatory bodies are not properly thought through and costed prior to implementation.

In our view both the reports are 'NHS-centric' despite their aim to cover independent contractors as well.

Do stakeholders support the approach advocated in the two reports?

Considered together, the two reports contain a number of common themes, but also certain inconsistencies. The most significant inconsistency is the perpetuation of 'medical exceptionalism', i.e. treating doctors differently to other health professionals, not for any objectively justifiable reason but simply because they are doctors. This was evident in the creation of separate reviews for medical and non-medical regulation, and persists in the conclusions of the two reports.

We see medical exceptionalism as highly undesirable in principle, and likely to hinder rather than promote improvements in the quality and safety of healthcare. It is also difficult to justify in terms of the public interest. We also believe that the approach contradicts the Foster report's expressed aim of achieving one integrated and consistent framework of regulation across the different professions.[1] We support that aim, though

[1] Foster report, page 6, paragraph 1

we emphasise that in supporting an integrated and consistent regulatory framework for all health professionals including doctors, we also recognise that there are genuine differences between the professions (e.g. in the types of services they deliver, ways of working and employment patterns) which must be reflected in the specifics of future systems of regulation.

There are also genuine differences between the professional regulators: in addition to its role in regulating individual practitioners, the RPSGB has statutory responsibilities under the Medicines Act 1968 and the Misuse of Drugs Act 1971.

What are the priorities for stakeholders in terms of implementation?

The RPSGB's main priority will be to secure a workable and sustainable outcome in relation to the Foster report's specific proposals relating to regulation and professional leadership for pharmacy. More broadly, we would urge the joint implementation board for the two reviews to pursue a consistent approach between the medical and non-medical professions, and to prioritise changes for which there is good evidence regarding their ability to deliver the greatest benefits for patient safety and the quality of healthcare.

It is essential that the implementation board encompasses expertise from those it seeks to reform if it is to command both public and professional confidence. The experience of other groups such as the legal profession, which have undergone similar government-initiated reforms, demonstrates the importance of securing the engagement of the professions.

Any changes to regulation stemming from the two reports will require identified resources for implementation at individual and organisational level.

1. Changes to the governance and accountability of regulators

Clarifying the separation of the RPSGB's regulatory and professional responsibilities

1.1. We recognise this as a key issue in the Foster report and we are seeking a constructive solution to it. We believe that some clarification of functions has already been achieved, and reforms in train will strengthen this distinction further. For example, the Society is in the process of establishing national Pharmacy Boards to provide leadership and support for pharmacy practice development in each of the three GB countries. However, in responding to this particular challenge in the Foster report, we would also argue that the Society's model is a complex one built up over 160 years of service to the profession and the public. As a Royal Chartered body, the Society has a range of statutory powers and duties, including those of regulating the profession, and a sweep of professional and leadership and development activities that themselves have been redefined over time, and on occasions by the courts. We therefore recognise clearly that, outside these discussions about the future shape of healthcare regulation, as part of any clarification of responsibilities, we need to articulate how we intend to take forward our Charter responsibilities to lead and develop the profession.

1.2. There needs to be a great deal more discussion of the issues between the RPSGB, governments and other stakeholders to explore and find an appropriate solution that meets the expressed concerns, while at the same time ensuring that the work across the Society's activities continues to support pharmacists in practice in meeting the challenges of new models of service delivery, including the opportunities for the profession and the public presented by independent prescribing, pharmacists with a special interest and the new community contracts in England and Wales and in Scotland. We recognise that we need to avoid protracted discussion, as this would be in neither the profession's nor the public interest since it could serve as a diversion, but we are confident of finding a solution that will achieve high standards in both sets of functions, in the public interest, and meet the expectations of governments and the public. We intend to communicate with you further (separately from this response) on how we might make progress on this point after the Council has had a chance to confirm a way forward in the first week of December.

Composition of Council and selection of Council members

1.3. The Foster report presents no evidence to suggest that the RPSGB's integrated regulatory and professional roles have had any detrimental effect on public safety, the standards achieved by the pharmacy profession, or the quality of pharmacy services. Nevertheless, we can see advantages in creating a clear distinction between a regulatory board and other structures, with the former overseeing and being directly accountable for the statutory regulatory functions. The RPSGB fully understands and accepts the argument for a lay majority on such a regulatory board.

1.4. However, the RPSGB's Council is not entirely persuaded by the arguments for at least some professional members of a structure which would oversee the professional functions being appointed rather than elected. We do not believe an entirely appointed body would command the confidence and commitment of the whole profession - which the Government has acknowledged remain necessary for professional regulation, in its broadest sense, to work. By that we mean individual practitioners regulating their own conduct and practice according to standards set by the regulator, not just disciplinary action taken against the minority whose registration is called into question.

Sharing functions and possible merger with PSNI

1.5. On the issue of sharing functions and a potential merger between RPSGB and the Pharmaceutical Society of Northern Ireland (PSNI), we consider that the Government's proposals require detailed investigation regarding the potential benefits, risks, costs and feasibility. We recognise the logic of consistency in regulating the pharmacy profession, like other health professions, at the UK level.

1.6. The Society believes that PSNI's views are paramount in any discussion of this issue, and we would not want to prejudge anything by making any comment at this stage on the merits or otherwise of this suggestion, save to state that if plans for shared functions and potentially a merger were to be taken forward, a joint approach between RPSGB and PSNI to the initial assessment work and any implementation plans emerging from it would be vital.

Proposed changes to the GMC's remit

1.7. While these proposals do not directly affect the Society, we oppose the recommendation to hand the GMC's role in setting the framework for education standards to PMETB because this would breach what is in our view a fundamental principle of professional regulation. Professional regulation depends crucially on the integrity of the register. All the regulator's core functions relate to determining entry to and exit from the register. Unless the regulator has confidence in all the inputs to the register, it is not operating a key instrument of public protection but simply holding a list of names whose bona fides are assumed to be guaranteed by other agencies. The regulator cannot have confidence in the register if it does not determine the high-level standards for education and practice, accredit education providers and courses, and decide whose licence to practise should be renewed (revalidation). These functions were included in Sir Ian Kennedy's definition of professional regulation, and in the absence of any evidence that it is no longer valid, that is the model of regulation that the RPSGB has continued to aspire to since the report of the public inquiry into Bristol Royal Infirmary was published.

2. The importance of defined operationalised standards against which to regulate

Common standards for all health professionals

2.1. We consider that there would be value in having common standards in some areas though not all. For instance, conduct issues, as Dame Janet Smith noted in the 5th report of the Shipman public inquiry, tend to be similar across the professions, involving dishonesty, abuse, sexual misconduct etc. Some areas of practice would have commonalities e.g. prescribing. Common education standards could be set for generic skills such as communication and consultation skills, but more difficulty could arise in relation to preparation for the specific knowledge and skills which make each profession distinctive – there would be some overlaps but also some substantial differences in educational content and methods of teaching and assessment.

2.2. However, there could be variation in the seriousness with which different regulators viewed certain forms of misconduct, negligence or poor performance, e.g. the RPSGB has viewed misconduct involving medicines or illicit drugs particularly seriously. The specialist expertise of professionals working in multiprofessional teams is taken into account in actions for negligence.[2]

2.3. This links to a second issue: there is a risk that in certain areas, a drive for consistency across professions could lead to a 'lowest common denominator' approach, resulting in the loss of specialist expertise. This would not be in the public interest.

2.4. The Council for Healthcare Regulatory Excellence (CHRE) should facilitate the development of common standards where appropriate but driving them should be the responsibility of the regulatory bodies themselves working together.

[2] Montgomery J (2003). *Health care law, 2nd ed.* OUP, p 179.

2.5. We support in principle the development of generic standards for healthcare professionals which can be operationalised in risk-based systems. In pharmacy we are developing our education policy to reflect changes in the roles and responsibilities of pharmacists and, in the future, pharmacy technicians. This review will inform development of new policy and the drafting of rules and standards under the Pharmacists and Pharmacy Technicians Order 2006.

Roles of regulatory and professional bodies in standard setting

2.6. We see the adoption, setting and enforcement of standards as the responsibility of the regulatory body (as part of its core role in determining entry to and exit from the register), but standards need to be dynamic and be capable of encompassing changes in health services. They must not hold back innovations that would improve patient care. The development of standards therefore requires the expert practical advice of the professional body. The creation of professional standards should be achieved through a close partnership between regulation and professional leadership, whether they are separate functions within one organisation or sit in separate organisations.

3. The appropriate standard of proof

3.1. The Statutory Committee of the RPSGB currently applies a civil standard of proof with a 'sliding scale', i.e. the more serious a case is, the more cogent the evidence required to prove it. The RPSGB's adjudication function has been independent of the Council for decades.[3] The forthcoming Pharmacists and Pharmacy Technicians Order 2006 will specifically preclude Council members from sitting on several committees, including those adjudicating on fitness to practise and considering registration appeals. We would encourage other regulators to adopt similar practices.

Adjudication panels – selection of panellists

3.2. We would in principle be supportive of the development of a shared pool of panellists, appointed through a common procedure, to serve on adjudication committees across the professions. There could be value in a sub-group of panellists building experience with several professions: this could help to bring consistency and a more independent perspective to the adjudication processes of different regulators (in practice this is already happening because some panellists now serve on the panels of several regulators).

3.3. Each regulator should also retain some panellists who are practising members of the profession(s) it covers and some lay panellists who have built up expertise in relation to the profession(s) covered by that regulator.

3.4. A further advantage of using some shared panellists would be a reduction in recruitment costs: as things stand with each regulator operating its own

[3] The 1954 Pharmacy Act does not in fact bar RPSGB Council members from sitting on the Statutory Committee, but this has not happened in recent decades at least. The Chair of the Statutory Committee is appointed by the Privy Council. The Human Rights Act 1998 and the common law set requirements for an impartial tribunal and a fair hearing, which preclude the involvement of Council members in the RPSGB's adjudication proceedings.

recruitment procedures, the regulators are often interviewing the same people for similar posts.

3.5. However, we would wish to caution against the use of full-time 'career' panellists: we consider that panellists, lay or professional, need to have a close and continuing connection with the wider world if they are to make sound judgements within regulatory processes.

3.6. The use of common appointment procedures and shared panellists should be piloted and evaluated prior to full roll-out.

4. Proposals for a 'spectrum of revalidation' across all healthcare professions

4.1. We agree with the Donaldson report's recommendation that the emphasis in the process of revalidation should be a positive affirmation of the practitioner's entitlement to practise, not just the absence of concerns being raised about their performance or conduct.

Risk-based revalidation

4.2. Individuals in similar job roles with comparable types and levels of risk should be subject to similar revalidation requirements, though the methods by which the information is produced and submitted might differ according to the practitioner's employment situation and other factors.

The contribution of information from appraisals

4.3. We also agree that if appraisal information is to be used for revalidation purposes, it would need to become both a summative and formative process. We have concerns about whether this could be achieved in practice, and whether there might be disadvantages e.g. an additional cost burden on employers. We do not think non-NHS employers should be forced to use appraisal in this way.

4.4. Ultimately it should be the responsibility of the practitioner to ensure that they can provide the necessary information for revalidation, with or without some input from an appraisal process.

4.5. The Donaldson report makes some important recommendations about how NHS appraisal processes would need to be strengthened if they were to become capable of producing valid and consistent information for revalidation, which we think should be explored further.

4.6. Appraisal information could be used for revalidation at two levels: at the level of information assembled by the practitioner to prepare for appraisal or revalidation, and at the organisational level, with the potential for direct transfer of appraisal results or perhaps more detailed appraisal information from the employer to the regulator: we explore this below.

4.7. We can see an advantage in the practitioner being able to use appraisal information for revalidation purposes because it avoids the problem of potentially having to prepare one set of information for appraisal and a different set for revalidation, thus reducing regulatory burden on the individual. The RPSGB

already has an established procedure for the recognition of employers' CPD recording-systems.

4.8. However, we think there needs to be further discussion about how information from appraisal might be communicated directly from the employer to the regulator. We recommended in our submission to the CMO's *Call for ideas*[4] that failure to submit corroborated evidence of a satisfactory appraisal to the regulator for revalidation purposes could trigger further investigation by the latter. However, if the results of an unsatisfactory appraisal were to be directly communicated by the employer to the regulator, there would need to be safeguards allowing for the practitioner to appeal or seek an independent review, otherwise there would be potential for unfairness: revalidation might be used by health service providers as a way of getting rid of unwanted employees.[5]

4.9. Privacy is also an issue: a safe and competent practitioner might justifiably not want all the information they disclose for appraisal purposes made available to the regulator (e.g. private information about family circumstances which the employee wants to discuss with the employer).

4.10. The above points are made subject to several important provisos:

- 4.10.1. appraisals would need to be made fit for revalidation purposes, where employers agree to this;
- 4.10.2. while the appraisal process would need to be compatible with revalidation, it should still be capable of fulfilling the original aims of appraisal;
- 4.10.3. information used for revalidation must be appropriate for that purpose;
- 4.10.4. the regulator, not the employer, must determine the standards required for revalidation, and make the judgement about whether an individual has met them (this stems from the regulator's need to have absolute confidence in all inputs to the register). This would also be essential to ensuring that employers work to a common standard;
- 4.10.5. information collected under the Knowledge and Skills Framework (KSF) could be used for revalidation purposes, provided it met the regulator's requirements;
- 4.10.6. however, the KSF does not cover attitudes and behaviour and the regulator will need to assess these in other ways. Unacceptable attitudes and behaviour are at the root of many fitness to practise cases;
- 4.10.7. patient feedback should be included as a source of information for the revalidation of individual practitioners. This should reflect the experience of satisfied as well as dissatisfied patients (dissatisfied ones might be more likely to volunteer comments);

[4] Our submissions to the Donaldson and Foster reviews' *Calls for ideas* are attached to this response as Appendices 1 and 2.

[5] An NHS employer would not normally employ a health professional without a valid registration. If the practitioner could not get their registration renewed, the employer could refuse to continue employing them.

4.10.8. alternative arrangements must be devised for staff who do not have NHS appraisals or performance evaluation by NHS commissioners; for situations where a service is directly commissioned from an individual contractor; and for those staff with several jobs which include at least one outside the NHS;

4.10.9. pharmacy locums and temporary workers comprise almost half of the community pharmacy workforce; no single employer can take responsibility for appraisal and oversight of their performance. The same concerns apply to single-handed independent pharmacists and the pharmacist proprietors of small pharmacy chains. There was a Department of Health proposal that pharmacists should be on a PCT performers' list, as GPs have to be. This has been deferred but it could in the future bring locums into a revalidation process that includes employers and commissioners;

4.10.10. locums could be at a disadvantage if revalidation evidence presented by large employers made their employees appear more professional;

4.10.11. a negative appraisal might reflect lack of suitability for a particular job or role. The practitioner might be a safe and competent performer in a different role, but how would they demonstrate this to the regulator if a negative report about them had already been submitted?

4.10.12. portfolio or combined job roles also present a challenge – where several employers/commissioners, or none, might be taking some interest in evaluating the person's performance;

4.10.13. we would envisage practitioners with several jobs going through a single revalidation process with the regulator, but they would need to present evidence relating to each job/role;

4.10.14. these situations must be recognised in devising systems for revalidation. These groups might have to be revalidated by the regulator;

4.10.15. another possibility is that the regulator could accredit other bodies to revalidate certain groups of practitioners according to standards set by it[6];

4.10.16. NHS appraisal systems should be inspected by the Healthcare Commission in England and Wales (equivalent arrangements would need to be made for Scotland). The Commission already inspects all NHS organisations and many private sector healthcare providers, and scrutiny of appraisal systems could be added to its inspection regime. The role of the Healthcare Commission in this respect could potentially be extended to the larger private-sector employers of community pharmacists (particularly as some of them will become subject to other aspects of the Commission's remit if they become alternative providers of non-pharmacy NHS primary and community health services). We do not propose that the Commission should

[6] This is the model used for revalidating New Zealand pharmacists. See Pharmaceutical Journal (28 October 2006), volume 277, p. 509.

inspect single-handed/independent pharmacies because there are too many of them;

4.10.17. however, the RPSGB Inspectorate visits all community pharmacies.[7] Consideration could be given to whether the Inspectorate should have a role in assessing the smaller community pharmacy employers' appraisal systems, to assess whether they could produce valid information that could contribute to revalidation. Expanding the Inspectorate's role and responsibilities in this way would have significant resource implications as its capacity and skills would need to be enhanced. As we have shown with our new responsibilities post-Shipman, we are willing to expand the Inspectorate providing the additional costs are covered.

4.11. The Foster report argues for a "risk-based approach, in which any new regulatory activity must be as simple and light touch as is consistent with their patient safety goals". But the Foster report presents no evidence on the risks which the non-medical professions present or even of the nature of those risks, which vary between and within professions. In section 7 of this response we set out the Society's approach to assessing risk in relation to the recording of higher-level/specialist practice.

4.12. The Society has developed a system of CPD for all pharmacists and registered pharmacy technicians. In the community setting, CPD, together with minimum competence requirements and standard operating-procedures to cover other pharmacy support workers, aims to deliver an integrated system of quality assurance for the whole pharmacy team.

4.13. While the Foster report envisages a significant regulatory role in the future for employers, the Donaldson report identifies a number of reasons why employers may not be the best people to regulate (e.g. some well-documented failures to act on very serious concerns raised about an employee by other staff and patients over many years).

4.14. Employers may have conflicts of interest vis-à-vis revalidation, and they could certainly experience conflicting demands between meeting government-set performance targets and the need to protect the public.[8]

4.15. Small employers, including many pharmacy providers, might not have the necessary capacity. In those cases the regulator (directly, or using other organisations it accredits for the purpose – see point 4.10.15) would have to remain the mainstay of quality assurance for pharmacists, particularly in the community sector where over half of all pharmacists work.

4.16. Although the community sector is largely working under contract to the NHS, the contractual relationship is between the commissioner and the community pharmacy contractor, or directly-contracted provider of an enhanced/additional service. Revalidation arrangements set up between the contractor, the

[7] And hospital pharmacies which are registered with the Society.

[8] As highlighted, for instance, in the Healthcare Commission's report on deaths caused by hospital-aquired *C. difficile* at Stoke Mandeville hospital. http://www.healthcarecommission.org.uk/nationalfindings/healthcareassociatedinfection/investigationintoclostridiumdifficile.cfm

commissioner and the regulator would not cover locums and other temporary staff working for the contractor.

4.17. Although the RPSGB is supportive of the principle of revalidation and is developing its own proposals for revalidation, the Foster report lacks clarity as to the precise costs of revalidation. We would suggest that no firm decisions are made with regard to choice of model for revalidation until the costs to all parties have been established. Of course, costs of necessity include opportunity costs: for example, community pharmacy contractors are stretched to deal with the opportunities presented by the new contract against a backdrop of an ever increasing prescription workload. They will need time for revalidation.

4.18. A report published recently by the Health Foundation presented evidence to show that:

> "… professionally-led, publicly reported regulation is more effective than employer-driven regulation."[9]

4.19. We urge the Government to consider the Health Foundation's findings before making any decisions about a significant transfer of functions from professional regulators to employers. We are firmly opposed to employer-driven regulation.

Dealing with persistent poor performance

4.20. Where an employer identifies persistent poor performance they should have a duty to report this to the relevant regulator.

Affiliates

4.21. Not withstanding the reservations outlined above, the Society believes that stronger links between employers and professional regulators would improve patient safety and the quality of care. The individual practitioner can face conflicting demands from employer and regulator, and may need support within the workplace to uphold professional standards. We already have experience, presented in evidence to the Foster review, of assigning responsibility for staff performance to named individuals – superintendent pharmacists – in all incorporated pharmacy businesses, large or small. But as our evidence pointed out, changes in the statutory framework are required before the role of the superintendent can be extended and relied upon as a means of assuring good practice. As things stand, loopholes exist – e.g. companies can avoid making superintendent appointments for substantial periods of time – which mean that the system cannot currently fulfil its potential contribution to patient safety. Any conflicts of interest in the superintendent role would also need to be addressed.

4.22. Two unique features of the pharmacy system – superintendent pharmacists and the Society's Inspectorate – may in some way provide the basis for a local affiliate model for pharmacy.

4.23. Pharmacy careers, particularly in the community, are very different from typical medical careers (for instance, a locum pharmacist might be working occasionally

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[9] Sutherland K & Leatherman S. (2006). *Regulation and quality improvement: a review of the evidence.* London: The Health Foundation , p.59.

in several pharmacies, rather than having a solid period of full-time temporary work with one organisation. Another common pattern is part-time community locum work combined with a part-time role in a primary care organisation or GP surgery[10]). If the affiliate model were to be applied to professions other than medicine, it would need to be flexible enough to work with the common career patterns and models of employment found in each of the professions.

5. Devolution of some regulatory activity to the local level

The single portal

5.1. We agree with the recommendation in the Foster report that there should be a single portal for complaints against healthcare professionals, with several provisos:

5.1.1. it should cover complaints against all healthcare practitioners including doctors;

5.1.2. direct access to the professional regulators should still be available to complainants who are already sure where to take their complaint[11];

5.1.3. clarification is needed on how the single portal would be funded, who would manage it and how information collected through it would be shared, transferred etc;

5.1.4. to make a substantial difference to complainants, a single portal would need to be effectively advertised to the public.

Single investigation

5.2. We also agree that there should be a single investigation process at the local level and, wherever possible, local resolution of complaints. The RPSGB has extensive experience, previously presented in evidence to the Foster review, of deploying a locally-based Inspectorate and we believe this might act as a model for developing a system for other regulators.

5.3. We support the Donaldson report's recommendation for direct referrals, where necessary, to be made from the Parliamentary and Health Service Ombudsman to the professional regulators, in parallel with a system of local affiliates. The RPSGB has a Memorandum of Understanding with the National Patient Safety Agency; it has agreements with the National Treatment Agency for Substance Misuse and the NHS Counter Fraud and Security Management Service; it also works in partnership with the Medicines and Healthcare Products Regulatory Agency. These agreements allow for joint investigations to be conducted where appropriate.

5.4. As mentioned previously (4.13), the Donaldson report identifies a number of reasons why employers may not be the best people to regulate.

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[10] *Competencies of the future pharmacy workforce, Phase 2 report* (2004). London: RPSGB

[11] We see the main benefits of the single portal as providing a clear and simple point of first contact for complainants, and the best point of entry for complaints about complex incidents and for patients/relatives who are not sure which body is the most appropriate or would have jurisdiction over the incident being complained of.

5.5. We think the links between employers and regulators need to be strengthened in these proposals if the public is to be sufficiently protected:

5.5.1. employers should have a duty to report the outcome of a local investigation to the relevant regulator(s);

5.5.2. employers should also have a duty to report the most serious cases to the appropriate regulator(s) at an early stage;

5.5.3. the Healthcare Commission (in England and Wales) should check that employers are performing these duties to an appropriate standard. Equivalent arrangements would be needed for Scotland. Employers' systems should be transparent and consistent;

5.5.4. a clear and workable definition of 'the most serious cases' will be needed.

5.6. Other aspects of local investigation that would need to be looked at include:

5.6.1. how would incidents occurring outside the NHS be handled, where there is no local NHS investigation to build on (e.g. where a patient or relative takes legal action against a self-employed private-sector practitioner)?

5.6.2. how would consistency between employers in their handling of cases be ensured?

5.6.3. how would learning from investigations be achieved at the whole-system level?

5.6.4. how would a comprehensive fitness to practise record for an individual practitioner emerge?

5.7. The role of CHRE should be to facilitate the agreement of protocols for local investigations, working with other relevant bodies including the professional regulatory bodies, the Healthcare Commission and its counterparts, the NHS Confederation etc.

5.8. We think there is a need for independent audit of the regulators' case-screening procedures and internal audit processes for the screening stage (particularly in respect of cases that are dismissed prior to detailed investigation), but we do not believe it would be cost-effective for an oversight body to scrutinise every case that has been dismissed. The audit process could include examination of a sample of cases from each of the regulators which were dismissed at an early stage.

Regulating clinical teams

5.9. Healthcare teams currently fall between individual and organisational regulation and neither report fully explores the implications of this gap. Given the growth of teams as the basic unit of service delivery, this appears to be an important area for development. The Society argued for the benefits of team-based regulation within a single profession (as for community pharmacy and dentistry where practitioners tend to work in single-profession teams), but we acknowledge that this approach would not be adequate for multiprofessional teams.

5.10. We suggest that further development of multiprofessional team regulation is needed. Facilitated by CHRE, this should be taken forward jointly by all the relevant stakeholders including:

5.10.1. the regulators of health and social care professionals (as community-based services increasingly bridge health and social care);

5.10.2. the regulators of health and social care provider organisations (as teams fall between the level of the individual and the organisation);

5.10.3. employers' organisations (e.g. the NHS Confederation); and

5.10.4. patient organisations.

6. The number of regulators for the non-medical professions

6.1. We welcome the recommendation that there should be no change in the number of regulators at least until 2011. We presented evidence to the Foster review about the likely costs and other disbenefits of forced mergers, and noted the lack of evidence to suggest that mergers would benefit public safety or the quality of healthcare, or reduce regulatory burden. Forced mergers could also be counterproductive if they resulted in reduced buy-in or engagement with the professions affected.

6.2. When the Government looks at this issue again, it should examine the regulators' achievements as well as any failures.

7. The requirement to record post-registration qualifications

7.1. The RPSGB is currently developing a risk-based approach to identifying which specialist and/or higher-level qualifications or roles should be recorded on the register. The guiding principle in our view should be to record post-registration qualifications or roles only where public protection would be served by this. Prescribing qualifications are already recorded on our register, but other practice developments need consideration e.g. consultant pharmacists and pharmacists specialising in particular areas of clinical practice. The recording of higher-level/specialist roles, particularly if they are not closely tied to specific post-registration qualifications, would present considerable challenges.

8. The role of regulation for student health professionals

8.1. We agree that the introduction of student/trainee registration would have certain advantages including early introduction to the regulatory system and identification of problems with performance and behaviour. Student/trainee registration could be considered for students of all healthcare disciplines. In pharmacy specifically the requirement for earlier registration is highlighted by the increasing clinical component of education and training, which is bringing students into contact with patients from an early stage in their courses.

8.2. The RPSGB has been discussing student fitness-to-practise, among other topics, with the Schools of Pharmacy in a series of informal visits over the last 18

months, as part of its *Fit for the future* programme – a comprehensive review of pharmacy undergraduate education and pre-registration training.

9. The need for standardised pre-employment English language testing

9.1. The Society requires non-British nationals and non-EEA nationals applying to join its register (other than exempt persons) to have passed the IELTS (International English Language Testing System) examination to a high standard.[12]

9.2. We support the CMO's view and believe that all potential registrants should undergo English language testing. We think EU policy on this should be challenged. Language competence has been an issue in some of our fitness to practise cases.

9.3. HEIs providing the conversion course for pharmacy can require all overseas applicants (including EEA ones) to have passed the IELTS as the EU regulations on free movement of professionals are not binding on education providers.

10. Extending the scope of regulation to include support workers and new roles in healthcare

10.1. The regulation of these groups should be appropriate and proportionate to the risk they pose to the public.

Support worker regulation

10.2. The Society has operated a voluntary register of pharmacy technicians since January 2005. Regulation of members of the pharmacy team by the RPSGB is becoming established. We urge the Government not to unravel these arrangements without properly evaluating their benefits (and those of a similar model used in dentistry) and comparing the outcomes with those achieved in the Scottish employer-led pilot.

Regulating new roles

10.3. We propose that any new occupational group in healthcare requiring statutory regulation should be regulated by the most appropriate existing regulatory body, which might or might not be the Health Professions Council. By 'most appropriate', we mean the regulator that has the most relevant expertise, experience and specialist knowledge to regulate that group. For instance, we have argued that 'physician assistant'-type roles (medical care practitioners etc.) should be regulated by the GMC because those practitioners work with doctors and their roles are more similar to doctors' than those of any other health profession.

[12] More information is available at http://www.rpsgb.org/registrationandsupport/registration/registrationfromothercountries.html

11. The importance, or otherwise, of a lay majority on the governing bodies of the various regulators

11.1. As discussed above (1.3), we would firmly endorse a lay majority on a regulatory board.

12. CHRE Council

12.1. We are not aware of any evidence that the current arrangements for appointing professional members of CHRE's Council are not fit for purpose. We do not think professional members appointed by some means other than nominations by the regulators would provide a sufficiently strong link with the regulators, nor would unelected representatives ensure the buy-in from the professions that we believe is crucial for CHRE to succeed.

12.2. The composition of CHRE's Council should be given further consideration by the regulators, governments and CHRE. If its professional members are to be appointed in future, the criteria for appointment should include close contact with or current/recent experience of healthcare practice, but the main consideration should be that the professional members have close links with the professional regulators.

13. Making registration information available to the public

13.1. Some useful research has already been carried out on what information the public wants and expects from the registers of healthcare professionals.[13] We suggest that further research is carried out before Recommendations 38 and 39 of the Donaldson report are taken further. That research should investigate not only what the public would expect from a register with several tiers of information, but what would be reasonable and fair to practitioners.

14. Overall conclusions

14.1. Despite the large amount of work which lies behind the Donaldson and Foster reports, the Society believes that there is a great deal more work to be done to produce a set of integrated, evidence based and workable proposals for the regulation of all health professionals that will deliver tangible improvements in public safety and the quality of healthcare at a reasonable cost, while reducing the burden of ineffective regulation.

14.2. The Society recognises that there must be some response to the challenges to the GMC identified in the Donaldson report. However, there is no evidence that the non-medical regulators have been slow to identify or deal with serious failings, nor evidence that they have slowed down the pace of change in respect

[13] Joint UK Health and Social Care Regulators PPI Group. *Making registers more usable.* Opinion Leader Research (August 2006)

of professional and service development. On the contrary, there are many examples of the regulators working singly and in partnership to anticipate changes in professional roles and healthcare delivery systems and to develop standards, guidance and advisory services to encompass those changes. Prescribing is an example where the regulators and professional bodies worked together in the late 1990s to lobby Government to extend prescribing powers to the non-medical professions, and having achieved that, they have ensured public protection by working with education providers to set standards for prescribing training.

14.3. The Society has presaged or supported a series of reforms which the Government has promoted in recent years through for example Pharmacy in a New Age (PIANA),[14] the development of pharmacy audit,[15] CPD (a professional requirement since 1994[16] and further developed by the Society through pilot work and the use of local facilitators), the *Fit for the future* programme which is reviewing initial preparation for pharmacy[17], clinical governance in community pharmacy[18], the future competencies project (which identified the knowledge, skills, attitudes and behaviour required for future pharmacist roles),[19] guidance to support several National Service Frameworks[20], and work on the contribution of pharmacists to the care of people with long-term conditions.[21] The Society is about to embark on the *Pharmacy 2020* project, which aims to identify the barriers to progress as well as the challenges and drivers affecting the challenges and drivers affecting the profession's ability to fulfil its potential in

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[14] RPSGB (1998). *Pharmacy in a New Age (PIANA)*

[15] http://www.rpsgb.org/registrationandsupport/audit/

[16] Participation in continuing education has been a professional obligation in the RPSGB's *Medicines, ethics and practice* guide since (1993). Guidance on CPD first appeared in the guide in 1994. The CPD obligation was formalised in 2005 when the register of pharmacists was split into practising and non-practising sections (CPD became a formal obligation for practising pharmacists at that time).

[17] http://www.rpsgb.org.uk/acareerinpharmacy/educationpolicy/

[18] http://www.rpsgb.org/registrationandsupport/clinicalgovernance/

[19] *Competencies of the future pharmacy workforce: Phase 1 report*, Royal Pharmaceutical Society of GB, April 2003 http://www.rpsgb.org.uk/pdfs/compfutphwfph1.pdf
Competencies of the future pharmacy workforce: results of the consultation on Phase 1
1. Summary report. Royal Pharmaceutical Society of GB, December 2003.
2. Full report. Royal Pharmaceutical Society of GB, December 2003
http://www.rpsgb.org.uk/pdfs/cfpwph1repfull.pdf
Competencies of the future pharmacy workforce, Phase 2 report (2004). London: RPSGB
http://www.rpsgb.org.uk/pdfs/compfutphwfph2repfull.pdf
Guidance on linking the NHS Knowledge and Skills Framework and competences for pharmacy (August 2006) RPSGB
http://www.rpsgb.org.uk/pdfs/compfutphwfksfguid.pdf

[20] *Practice Guidance on the Care of People with Diabetes* RPSGB November 2004
http://www.rpsgb.org.uk/pdfs/diabguid3.pdf
Practice Guidance on the Care of People With Asthma & Chronic Obstructive Pulmonary Disease RPSGB Revised July 2006
http://www.rpsgb.org.uk/pdfs/asthmaguid.pdf
Practice Guidance of the Care of People with Mental Health Problems RPSGB Mental Health Task Force September 2000
http://www.rpsgb.org.uk/pdfs/mhealthguid.pdf

[21] *Long-Term Conditions: Integrating Community Pharmacy – Executive Summary*, RPSGB & Webstar Health September 2006
http://www.rpsgb.org.uk/pdfs/ltcondintegcommphsumm.pdf

healthcare provision, identify good practice in pharmacy and prepare a forward strategy to take pharmacy to the year 2020.[22]

14.4. In drawing up this response, a number of recurring themes have emerged:

14.4.1. the need for any further reforms in professional regulation (e.g. any transfer of functions from regulators to employers) to be evidence-based and carefully planned and costed prior to implementation;

14.4.2. the need for evidence that any such reforms are capable of delivering substantial improvements in patient safety and the quality of healthcare, and will not result in the loss of benefits to patients currently delivered by the professional regulators;

14.4.3. if employers are to play a greater role in regulation, formal duties must be placed upon them to perform that role, and their performance in it will need to be monitored by the Healthcare Commission in England and Wales with similar arrangements put in place for Scotland;

14.4.4. the links between employers and the professional regulators will need to be strengthened.

14.5. The RPSGB already has a number of mechanisms in place (e.g. the pharmacy Inspectorate, the superintendent pharmacist role and the registration examination) which could help to facilitate implementation of some of the proposed reforms – e.g. the recommendations on local affiliates, local investigation and an examination for all students prior to entry to the register. We already have plans to strengthen the arrangements for superintendent pharmacists through the Pharmacy and Pharmacy Technicians Order 2006, and the registration examination is under review in the broader inquiry into pharmacy undergraduate and pre-registration preparation.

14.6. The Society has been proactive in making changes to improve its performance. It has already devoted significant time and resources to working with the Department of Health to achieve an up-to-date regulatory framework for pharmacists and pharmacy technicians, and is pleased to see this work coming to fruition. We look forward to working with the Department to implement the Pharmacists and Pharmacy Technicians Order 2006 in a phased and manageable way.

[22] *Council agrees to develop a vision for pharmacy in 2020*
http://www.pjonline.com/editorial/20060304/society/p277vision.html
The Pharmaceutical Journal Vol 276 No 7390 p277, 4 March 2006.
Council agrees vision for pharmacy in 2020
RPSGB Press Release 27 February 2006
http://www.rpsgb.org/pdfs/pr060227a.pdf

Appendix 1

Call for ideas – clinical performance and medical regulation: Chief Medical Officer's review following the Shipman Inquiry reports

Response of the Royal Pharmaceutical Society of Great Britain

16 May 2005

INTRODUCTION

The Royal Pharmaceutical Society of GB (RPSGB) is the regulatory and professional body for pharmacists in GB. The Society welcomes the CMO's Review and is pleased to have the opportunity to comment on the initial scope of the review.

We do not feel qualified to comment in detail on the arrangements for regulation of another profession. We have instead considered the overall principles for how future arrangements for the regulation of the medical profession might work, given our knowledge of the regulation of pharmacy (on the assumption that the government may seek similar arrangements for all the professions overseen by CHRE).

The structure of the review

We would suggest that the review should take as its starting point the overall fitness for purpose of the current regulatory framework for the medical profession, then move on to more detailed issues such as revalidation. Regulation of the medical profession should not be considered in isolation but in the broader context of healthcare regulation as a whole, and what that must achieve.

The context for the review

We are aware of the very strong push now to reduce the burden of regulation in both the private and public sectors (the Hampton report[23], *Less is more*[24], the Arms Length Bodies review[25] etc). The Shipman Inquiry, conversely, has recommended a number of measures that would create substantial increases in regulatory activity. This Review, therefore, is being undertaken in the context of directly conflicting pressures – to reduce, and increase, regulation.

[23] Hampton P (2005). *Reducing administrative burdens: effective inspection and enforcement.* HM Treasury. http://www.hm-treasury.gov.uk./media/AAF/00/bud05hampton_641.pdf
[24] Better Regulation Task Force (2005). *Regulation – less is more. Reducing burdens, improving outcomes.* Cabinet Office. http://www.brtf.gov.uk/docs/pdf/lessismore.pdf
[25] Department of Health (2004). *Reconfiguring the department of health's arms length bodies.* http://www.dh.gov.uk/assetRoot/04/09/81/36/04098136.pdf

It is obviously right that ineffective or unnecessary regulatory activity should be eliminated, but we do have a concern about making the reduction of regulation a goal in its own right (*Less is more* p 1*)*. We support the principles of regulation adopted by the Better Regulation Taskforce – that regulation should be proportionate, accountable, consistent, transparent and targeted. That might mean reducing it or increasing it, depending on the types of harm and levels of risk which regulation is intended to protect against. In other words, regulation should be fit for purpose: it should deliver public protection.

Another important aspect of the wider context is the transformation of the NHS from sole/majority provider of care to commissioner of care from multiple providers – public, private and voluntary sector, UK-based and international. The blurring of demarcations between professions, the emergence of new health occupations, 'hybrid' practitioners and multiple support grades for many professions are further complicating factors. Boundaries are also blurring between provider organisations: care is increasingly organised around care pathways involving multiple providers; practitioners may be part of 'virtual' organisations such as clinical networks, hold joint appointments, or be working in shared services or other partnership arrangements. An increasing number of pharmacists have two or more jobs at the same time.[26] All these changes are creating additional regulatory challenges, some of which we have experience of in regulating pharmacy.

The specific context for the Society's response includes the forthcoming Foster Review and the long-awaited Section 60 Order under the Health Act 1999, which will strengthen the Society's regulatory powers in several important areas, bringing us into line with other healthcare regulators and enabling the Society to better protect the public. The new community pharmacy contracts across the constituent parts of the UK will increase the volume and range of clinical services provided and hence change the risk profile of community practice. Future regulatory mechanisms will need to be able to respond to this.

The overall regulatory framework

In considering the issues raised in the *Call for Ideas,* we have also drawn on various reviews of regulation outside the healthcare sector and our detailed analyses of the relevant inquiry reports such as Kennedy and Shipman. Several of these reviews have identified the need to consider two fundamental dimensions of regulation:

- The single regulator approach versus several frontline regulators plus an oversight regulator.
- The unit (or level) to be regulated e.g. individual practitioner, small firm/practice, or large organisation.[27]

These dimensions (among others) determine how regulation of a sector is organised and delivered. We suggest that in considering the future design of medical regulation, the review considers these fundamental issues before moving on to more detailed points.

[26] Hassell K and Shann P (2003). *Pharmacist work patterns: summary of the 2002 pharmacy workforce census.* RPSGB/University of Manchester, p 19.

[27] In the healthcare context it would be relevant to add the multidisciplinary team to this list.

- **Single regulator, or frontline regulators plus an oversight regulator?**

A regulatory body must have appropriate competence and expertise.[28] A specialist regulator with detailed knowledge and experience of the profession or industry it regulates will function differently to a regulator with a wide scope of activity across several professions or industries. This is true not just of pharmacy or medicine but of almost any field of endeavour: every profession or industry is special and different in its own way. For example, the Royal Pharmaceutical Society regulates self-employed and employed pharmacists, working in primary care, hospitals and industrial settings, in both the public and private sectors. "Inspectors need the expert knowledge possible only with specialisation."[29]

Several recent reviews of regulation in sectors other than healthcare have concluded that a single regulator is not the best model: they have recommended the retention of specialist frontline regulators which would be monitored by a single oversight regulator operating across a sector (e.g. Carsberg[30], Clementi[31], Morris[32]). This type of arrangement is of course very similar to CHRE's oversight role in relation to the specialist regulators for particular health professions.

- **The unit to be regulated**

Other reviews of regulation (outside healthcare) have addressed the issue of whether the main focus of regulatory activity should be on the individual practitioner or a larger unit. We suggest that this issue is long overdue for review in healthcare and could be tackled in the CMO's Review. We have identified two major reasons for this:

1. Registers of healthcare professionals generally arose in an era when healthcare as an industry was much smaller, and was organised in a very different way. Most practitioners now work in teams, not alone.[33] In most health professions the majority are likely to be employees (though not necessarily of the NHS) rather than self-employed (pharmacy is an exception: 54 per cent of community pharmacists are self-employed proprietors or locums[34]). Only a minority offer their services directly to the public/patients without some oversight by an intermediary (e.g. a primary care organisation, hospital, pharmacy chain etc). Scrutiny of healthcare provider organisations has been greatly strengthened in recent years (notably by the

[28] Cullen report: *The Public Inquiry into the Piper Alpha Disaster* (1990) p. 380 (quoting a submission by the UK Offshore Operators Association)
[29] *Consumer counsel: streamlining regulation must not weaken competition policy*. Financial Times editorial, 23 March 2005.
[30] *Carsberg report on the regulatory role of RICS* (2005). The Royal Institution of Chartered Surveyors. http://www.rics.org/NR/rdonlyres/D55BD6CA-4591-4D9E-B9CA-A552CB2691B5/0/carsberg_report0405.pdf
[31] Sir David Clementi (2004). *Review of the regulatory framework for legal services in England and Wales: final report.* http://www.legal-services-review.org.uk/content/report/report-chap.pdf
[32] *Morris review of the actuarial profession: final report* (2005). HM Treasury.
[33] 'Working with other professions' and 'Effective team working' were the most commonly required competencies for all three main sectors – community pharmacy, hospital and primary care - in the RPSGB's *Competencies of the future pharmacy workforce Phase 2 report*, November 2004.
[34] Hassell K and Shann P (2003). *Pharmacist work patterns: summary of the 2002 pharmacy workforce census.* RPSGB/University of Manchester. Table 20, p 23.

Healthcare Commission). NHS organisations have clinical governance systems. There is still an important role for regulation of the individual, but the way this is carried out should be modernised to match the organisation of modern healthcare and to take account of the roles played by employers and other bodies in the overall regulatory framework. This would reduce duplication in regulatory activity, but some areas may need to be strengthened, for instance the role of the professional regulatory bodies in setting standards for education to ensure that the necessary values and ethical codes are inculcated from the beginning.[35]

2. The tension between professional self-regulation and learning from errors/the no-blame culture.

The aviation industry has demonstrated clearly that a culture of learning from errors can be successfully assimilated across a sector. It is also an industry that has achieved dramatic improvements in safety over several decades. The oil and gas sector has also achieved a major culture change regarding safety, and demonstrable improvements in its safety record. What is striking about both these examples is that major improvements in safety were achieved through measures taken at the strategic level, for a whole sector and for organisations. The current mechanisms of professional self-regulation, by contrast, might be characterised as placing a greater emphasis on identifying individuals who can be blamed, punished and ultimately excluded. (This may reflect the 'blame culture' which seems to permeate society as a whole.) Professional self-regulation is still largely based on the notion of the autonomous practitioner (in community pharmacy practice this is still the predominant model). It does not see the person in the context they work in – as part of a team or organisation. It fails to recognise that those in junior frontline roles have the least power to influence practice, care and outcomes[36]. There is a choice to be made about what kind of regulation the public wants – a form that encourages learning from mistakes, or one that punishes every slip. That choice should be based on evidence about what works best in improving healthcare safety and effectiveness.

Professional registration of individual practitioners plays no part in the regulatory arrangements for the offshore oil and gas industry. All offshore personnel undergo regular medical checks and survival training for the mandatory offshore certificate. Their qualifications, professional competence, criminal record etc would be assessed by employers as part of recruitment, appraisal etc. However, we tend to the view that registration of individuals is necessary in healthcare because healthcare has particular features e.g. the imbalance of knowledge between patients and practitioners, the fear and vulnerability of patients and carers when illness strikes, and the need to be able to trust the individual practitioner absolutely at that time of crisis.

APPRAISAL

Adequacy of appraisal as a measure of current competence or performance

There may be some tension in trying to combine the objectives of supporting individual development and assessing fitness for practice/purpose in a single tool. This could reduce the effectiveness of appraisal for either purpose. Appraisal will only be useful in

[35] *Ethics test 'a must' for student doctors.* The Guardian 10 May 2005, p 9.
[36] Review of impact of CESDI reports by OPM (1999?)

the regulatory context if it goes beyond individual development: it must assess whether performance has been satisfactory and identify areas where skills or knowledge need to be enhanced, or where the person's attitudes, values or behaviour are problematic. Complaints, adverse incidents and concerns raised about an individual should trigger a more formal performance assessment.

A more significant problem is that staff providing NHS services but who are not directly employed by the NHS may not have NHS-style appraisals. An NHS commissioner could in theory make appraisals a contractual requirement, and require problems highlighted at appraisal to trigger further assessment or referral to another body. However, a separate mechanism would be needed for sole contractors and self-employed locums. It would be difficult for agencies to comply with.

We would suggest that practitioners who work for a well-regulated healthcare provider (public or private), with effective clinical governance systems, regular independent inspections, and regular appraisal of individual staff members, could be subject to 'lighter touch' regulation by their professional regulator. This could be based on the employer's appraisal system with some mechanism for triggering formal performance assessment if all is not well at appraisal. For example, registrants could be asked to make an annual return to their regulatory body, countersigned by the employer, indicating that their most recent appraisal was satisfactory. A failure to make such a return could trigger the next stage of the process.

Because of the way that healthcare provision is changing in the UK, regulators will increasingly need to engage with private-sector providers. The Cullen report (on the offshore oil and gas industry) recommended self-regulation by the industry, but said the regulator should review the operator's own audits and have the power to carry out further audits if it thought fit (para 1.20, p 4). This could be a useful - and in high-risk areas possibly essential – power. Extended powers for health regulators to deal with corporate bodies and statutory corporate responsibility should be considered.

The RPSGB has considerable experience in this area because it registers community pharmacy premises as well as individual pharmacists. In addition, under the Medicines Act 1968 a body corporate must appoint a superintendent pharmacist who is responsible for good professional practice across the organisation. The Society is seeking to strengthen its powers both in relation to premises and the accountability of the superintendent. The oversight and accountability framework together with the ability to impose appropriate sanctions is a powerful tool in protecting the public. In fact, there is an urgent need to review the regulation of corporate bodies involved in the provision of healthcare. This is an increasingly important aspect of regulation which applies to pharmacy, optometry and dentistry and seems likely to be a growing factor in other sectors. We would welcome an opportunity to discuss this with the review team.

More scrutiny may be needed of practitioners who work in small businesses or on their own, including locums, but this should be proportionate to the work they do and the level of risk to the public it carries. A freelance journalist, for instance, who wants to retain their professional registration, requires a different level of scrutiny to a Harley Street plastic surgeon. Local commissioning organisations (e.g. PCTs) could play an important role in monitoring self-employed contractors and locums. It will be important not to discourage single-practitioner businesses by creating unreasonable regulatory hurdles:

we know from our own research with patients that they value small local pharmacies and their long-term relationships with individual pharmacists.[37]

The RPSGB has a dedicated inspectorate which carries out regular visits to community pharmacies, visiting more frequently where they find problems. The inspectors give advice on compliance with legal requirements and best practice; they also have enforcement powers.

Practical measures - 360º appraisal, confidential reporting, log books

360° appraisal could be more useful. Within and across healthcare teams, and multiprofessional care pathway approaches to patient management, individual professionals could be subject to assessment by a number of people, providing a true 360° view. This could include a variety of superiors and subordinates, colleagues from inside and outside the professional speciality as well as other professionals in the care pathway who are in a position to form a view of the competence of an individual practitioner. We feel it is important to recognise that technical competence is one component of good professional practice, but so is the ability to communicate with patients. 360° appraisal should, therefore, include patients and carers where possible. We can also see an additional advantage for this kind of approach, as it could be used to identify areas of good practice, which could then be investigated as a contribution to the wider quality agenda. However, 360° appraisals would be more difficult to implement with independent contractors who directly employ their own staff than in large organisations.

Finally, we would also suggest that, while 360° appraisal might require a major cultural change, it could be achieved much more quickly than the time it is likely to take for a system organised around whistleblowing ever to become effective.

Confidential reporting has proved useful in the aviation and healthcare industries. The oil and gas industry also uses it. All the indications are that confidential reporting would be far more successful, and be much fairer to those who want to raise genuine concerns, than 'whistleblowing' – which leaves the complainant exposed to victimisation and facing an invidious choice between their conscience and their livelihood. Anonymous reporting is needed to enable staff to raise concerns. It would be especially useful for the junior staff of private sector contractors who would otherwise probably be much too fearful of losing their jobs. Locums and agency staff are deterred from reporting concerns by the fear of not working again. The RPSGB has recently published guidance on raising concerns.[38] 360° appraisal could be triggered early in the revalidation process by adverse confidential reports from staff plus a number of complaints from the public.

Log books could be very useful to document clinical experience, learning and continuing education. The RPSGB's CPD system requires pharmacists to document their learning and provides tools to help them do it. Some GPs with a Special Interest are using log books as part of an accreditation process overseen by supervising medical consultants in the same specialty. Log books could potentially be used in the revalidation process for non-medical prescribers: they would demonstrate the extent to which the practitioner has

[37] Results from patient workshop conducted for the RPSGB's *Competencies of the future pharmacy workforce* project, 1 March 2005.
[38] http://www.rpsgb.org.uk/pdfs/raisingconcernsguid.pdf

prescribed, the range of conditions treated etc. A validation process is necessary e.g. periodic endorsement by a supervisor or mentor.

Patient and public views

Service providers should be seeking feedback from patients as part of good business practice. Patient feedback parties have been used with great success by GPs.[39] If seeking feedback from patients became more routine, it could help identify problems at an earlier stage.

Commissioners and regulators should also sample patients' views. Local Patient and Public Involvement bodies should be involved in these exercises. A guarantee would be needed that critical comments would not be attributed/attributable to individuals and would not affect their future treatment. Patients, carers and the public should also be able give feedback to a third party (commissioner or regulator) if they want to. Direct public access to the regulator provides an important safeguard and should not be lost.

Learning lessons from patient complaints

A review of patient complaints should be a routine part of appraisal systems for individual practitioners.

At the organisational level, an independent third party would be needed to compile the comments and feed them back constructively (e.g. PCO, PPI body, Dr Foster, Healthcare Commission?).

Purpose of revalidation

The most important function of revalidation is to ensure that practitioners seeking to renew their registration are fit to practise. But what does that mean? Does it mean that the person meets a common set of minimum standards applied to all, or does it mean they are competent to do their particular job, which might be at a much higher level (i.e. fitness for purpose)?

What would the public expect revalidation to guarantee? This should be investigated. The regulators' primary purpose is to protect the public, but what do the public expect to be protected from, and what measures do they think provide sufficient protection? Securing and maintaining public trust and confidence are the key aims: all the other aims mentioned contribute to this.

If revalidation is to be the responsibility of the professional regulatory bodies, it has to be based on (a) validated information provided by trusted third parties (e.g. the results of NHS appraisals), (b) assessments carried out by the regulators themselves, or (c) both. It should not rely solely on information supplied by the registrant, as for CPD – by itself that is too weak to protect the public.

It is important to recognise that, while in an ideal world the revalidation of individual professionals might require an active process, it should be practical too. If the purpose

[39] Lynn Faulds Wood (2004). *Are we missing out on expert patients?* In *Perspectives on the expert patient,* RPSGB.

is to provide the public with assurance that health professionals are competent, then some mechanism is needed to focus in on poor practice. The logistics to deliver a revalidation system to cover all professionals, including the time commitment that might take professionals away from direct patient care, could be prohibitive.

Process for revalidation

The process could be made simpler for low-risk areas of practice and practitioners employed by well-regulated organisations. The Healthcare Commission (and its equivalents in the other GB/UK countries), as the inspector of healthcare organisations, would be well placed to accredit employers and workplaces for this purpose. Memoranda of agreement between the Commission and the professional regulatory bodies could be used to allow the Commission to act on their behalf.

We support the three-stage model proposed and suggest a fourth component for areas of practice with the highest risk:

1. Screening, with feedback to the individual on areas for development. Screening would identify (or draw on existing information relating to) the level of risk and the employment status. There could be other triggers for further investigation e.g. failure to submit the required information, complaints raised with the disciplinary body.
2. Additional gathering of information for those in high-risk areas of practice, locums, independent contractors, agency staff etc, or where specific concerns have been noted. The regulatory body could require submission of additional information from practitioners.
3. An assessment/testing procedure where fitness-to-practise is in doubt.
4. A fourth level or component could be considered for people who work in particularly high-risk areas: periodic mandatory updating (as for midwifery), comprising an educational element and an assessment. Those who did not participate or who failed would not be allowed to renew their registration.

The requirement for local registration has now been extended under the new community pharmacy contract in England. Feedback from PCOs to the regulator will be an important part of this. The ‘proper officer’ within PCOs may be an appropriate person to assume responsibilities for monitoring revalidation arrangements.

Strengthening revalidation requires a culture change in the professions. Some people will not make the grade and will need additional training and supervision or a managed exit from the profession.

Attributes required for renewal of registration – knowledge, skills, behaviour and attitudes

Knowledge and skills should be related to the person’s speciality/area of practice and seniority. Behaviour and attitudes should be common to all healthcare professionals and set out in a common ethical code drawn up by CHRE and patient groups and widely consulted on. ‘Professionalism’ is also important.

Sufficient recent experience in the person’s chosen field is also important. The NMC’s revalidation scheme requires a minimum number of hours in practice along with other registration and validation requirements. Validated log books could be a useful tool in

documenting practice (and electronic recording would enable the information to be shared with employers, service commissioners and regulators). For non-medical prescribers, for instance, should revalidation as a prescriber signify more than having a qualification in prescribing? We believe the public would expect it to mean that the person continues to be competent to prescribe.

Standards and criteria for revalidation

The GMC's *Good Medical Practice* and NMC's *Code of Professional Conduct* are examples of core standards expressed in a very generic way which have wide application across many different sectors, settings and levels of seniority. But such codes become more difficult to interpret and apply the further the registrant moves away from direct patient care. We face this issue in relation to registered pharmacists working in the pharmaceutical industry, higher education, journalism, in government, in our own organisation and in other pharmacy bodies.

While core standards can be expressed generically, it is much more difficult to come up with broadly-applicable criteria and evidence sets.

Failure to revalidate

If a practitioner passed the minimum requirements to stay on the register but did not reach the level of competence required for their current post, an employer could deal with the shortcomings through additional training or supervision on an interim basis. In higher-risk situations, especially where there is no employer, the regulator could record this on the register (e.g. by not renewing a higher-level or specialist annotation until the practitioner met the requirements for it).

Fitness to practise and public protection

Where there are serious concerns it is essential that the regulator can take immediate action e.g. an interim suspension order or placing restrictions on the person's practice. This relies on robust arrangements for rapid referral to the regulator and speedy complaints-handling and investigation procedures.

Regarding compliance with conditions imposed on a practitioner, there are particular issues with independent contractors and locums. In community pharmacy, the RPSGB's inspectorate can speedily identify issues and ensure that appropriate steps are taken.

Students training for the healthcare professions need to understand that it does not guarantee a job for life: it requires a licence to practise which has initial and continuing requirements, like being an airline pilot. But this will require a major change in culture. It conflicts with the traditional idea of having a vocation to become a doctor (or other health professional).

The responsibilities of HEIs in selecting students who are suitable to become healthcare practitioners, and in ensuring that students identified during training as unsuitable are not allowed to complete their qualification, are extremely important. Exit strategies are needed for these students, to allow them to pursue other qualification routes that will not expose the public to harm.

Retraining is not an option in all cases: serious professional misconduct is usually about conduct, not deficient knowledge or performance – the latter can potentially be remedied (though some practitioners will be intractably incompetent which must then be addressed through removal from the register). The recurrent themes of misconduct in all the health professions, as Dame Janet Smith noted, are about dishonesty, abuse etc. In some cases it would be appropriate to remove the person from the register permanently, to protect the public.

Other measures

The public needs clarity regarding the responsibility of different bodies for dealing with complaints (e.g. the NHS Complaints System, the professional regulators, the Healthcare Commission etc etc): the current situation is confusing. The public want to be assured that complaints are appropriately investigated and action taken where necessary: ready access to information on the registration status of practitioners and progress with complaints is imperative.

Sound decisions in fitness-to-practise cases will also build public confidence. The actual or perceived leniency of some past decisions did much to undermine public confidence in professional self-regulation and feed suspicions that the professions 'look after their own'. CHRE's role in challenging unduly-lenient decisions is important here, both as a deterrent and a remedy. CHRE should also undertake ongoing audit of standards of decision making, committee training and legal challenges and outcomes.

Information on practitioners

The GMC and other professional regulators cover both the public and private sectors so they are in a better position to hold this information than an organisation within the NHS. Independent sector organisations and Foundation Trusts might be less happy to cooperate with an NHS body than a neutral one like the GMC.

It is not necessary to set up a national database outside the GMC – especially as there is a strong push now to consolidate regulators, not set up new ones. The GMC already holds a lot of the relevant information so there would be duplication and inefficiency in another body holding it as well.

While in theory it is possible to combine information from several databases, this could be technically formidable and produce conflicting information. However, from the viewpoints of the public and employers as users of this information, it would be much more straightforward to provide access to a single consolidated database on practitioners. The Society supports the latter approach.

Should complaints go directly to the GMC or be filtered first?

There are arguments on both sides: delay could be introduced by forcing complainants to go through another body first, but only if the system is badly designed and operated. There should be a fast-track procedure for forwarding complaints involving serious misconduct to the professional regulators.

Conversely, inefficiency can arise when the professional regulators have to sift complaints that should not have come to them.

The single portal

The single portal has a role, especially where more than one organisation might potentially have some jurisdiction over a complaint. Direct access by the public to the regulators should be retained.

Another issue is the threshold applied by different regulators – e.g. rudeness would be insufficient to take forward a fitness-to-practise complaint, but would be a matter of concern for the employer or local service commissioners. Members of the public will not necessarily know this.

Better guidance and advice to the public about how to complain and how to choose the right body to complain to would be helpful.

Future regulation of the medical profession

The organisations and their functions should align with the expertise required (e.g. education design and delivery; disciplinary procedures against individuals). Pulling all these functions into one body to regulate the medical profession (given that they are currently separate: the situation is very different for pharmacy where the RPSGB currently combines a number of functions successfully) would not necessarily increase effectiveness and efficiency: the specific focus of the current bodies could be lost, submerged by more generic objectives, and the necessary expertise dissipated. But any duplication of activity by the current bodies should be eliminated. Several aspects of the regulators' current operations could potentially be shared.

The future role and structure of the GMC

The Council should act like the board of a company: it should set strategic direction, make policy, agree the professional standards that practitioners must meet, and ensure proper governance of the organisation. Council members should not be involved in the delivery of the GMC's functions, especially fitness to practise procedures (the RPSGB provides a good model for this: its Statutory Committee – Disciplinary Committee in future - has a legally-qualified chair and is a Committee of the Society, not the Council i.e. it is independent of the Council and no Council members are involved). The delivery side, however, needs to feed information back into policy making: this would be more difficult if delivery were carried out by a separate organisation.

The balance between regulation and freedom to practise including innovation

There is a trade-off between them, but risk assessment and management are essential in service development and innovation.

If practice and specialisation are tied down in legislation and regulations, there are huge barriers to change. This may prevent improvements to patient care and workforce deployment, and that acts against the public interest. Protocols and guidelines can be updated more easily and allow for more flexibility.

Evidence from other industries on this issue is somewhat contradictory: the literature on aviation safety points to the acceptance of the pre-flight checklist as a major step

forward (and, as is often pointed out, pilots do not complain about 'cookbook flying'). However, the 'big idea' in the Cullen report which is credited with leading to major safety improvements in the offshore oil and gas industry was about goal-setting - replacing safety 'solutions' with 'objectives':

"Many regulations are unduly restrictive in that they are of the type which impose 'solutions' rather than 'objectives' and are out-of-date in relation to technological advances. Guidance notes are expressed … in such a way as to discourage alternatives. There is a danger that compliance takes precedence over wider safety considerations; and that sound innovations are discouraged. The principal regulations should take the form of requiring stated objectives to be met… On the other hand I accept that in regard to certain matters it will continue to be essential that detailed measures are prescribed." (Para 1.21, p 4)

Accountability to the public

As indicated in our introduction, we support the retention of specialist frontline regulators for the health professions with effective oversight by the CHRE. Each of the frontline regulators should also be directly accountable to Parliament (e.g. their chief officers can be summoned to appear before a Select Committee). But we cannot see how Parliament could carry out ongoing monitoring of the frontline regulators in the way the CHRE does, so both mechanisms are needed.

The contribution CHRE makes to regulation should be independently assessed e.g. by the NAO.

Other issues

The review should also examine overseas models of regulation and any evidence regarding which ones best protect the public.

Eileen Neilson
Head of Policy Development
RPSGB

Appendix 2

REVIEW OF NON-MEDICAL PROFESSIONAL REGULATION: CALL FOR IDEAS

Response of the Royal Pharmaceutical Society of Great Britain
19 August 2005

INTRODUCTION

The Royal Pharmaceutical Society of GB (RPSGB) is the regulatory and professional body for pharmacists in GB. It has also set up a voluntary register for pharmacy technicians. The Society is pleased to have the opportunity to comment on the Foster Review's six key themes and on some broader issues which we raised in our response to the CMO's review of the GMC and would also like the Foster Review to consider.

The structure of the review

We would suggest that the Review should, in addition to the six key themes, consider the overall fitness for purpose of the current regulatory framework for the non-medical professions. Regulation of the professions should not be considered in isolation but in the broader context of healthcare regulation as a whole, and what that must achieve.

The context for the review

We are aware of the very strong push now to reduce the burden of regulation in both the private and public sectors (the Hampton report40, Less is more41, the Arms Length Bodies review42 etc). The Shipman Inquiry, conversely, has recommended a number of measures that would create substantial increases in regulatory activity, and not just in relation to the medical profession. This Review, like the CMO's Review of the GMC, is therefore being undertaken in the context of directly conflicting pressures – to reduce, and increase, regulation.

It is obviously right that ineffective or unnecessary regulatory activity should be eliminated, but we do have a concern about making the reduction of regulation a goal in its own right (Less is more p 1). We support the principles of regulation adopted by the Better Regulation Taskforce – that regulation should be proportionate, accountable, consistent, transparent and targeted. That might mean reducing it or increasing it, depending on the types of harm and levels of risk which regulation is intended to protect against. In other words, regulation should be fit for purpose: it should deliver public protection.

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[40] Hampton P (2005). *Reducing administrative burdens: effective inspection and enforcement.* HM Treasury. http://www.hm-treasury.gov.uk./media/AAF/00/bud05hampton_641.pdf
[41] Better Regulation Task Force (2005). *Regulation – less is more. Reducing burdens, improving outcomes.* Cabinet Office. http://www.brtf.gov.uk/docs/pdf/lessismore.pdf
[42] Department of Health (2004). *Reconfiguring the department of health's arms length bodies.* http://www.dh.gov.uk/assetRoot/04/09/81/36/04098136.pdf

There is something of a gap between government's aspirations to reduce unnecessary regulation and the experience of those at the frontline. Our independent contractor Council members have told us that for community pharmacists there is an increasing burden of regulation (in a broad sense, not just professional regulation), particularly in relation to the clinical governance requirements of the new community pharmacy contract. Independent contractor pharmacists can feel especially burdened by this because they are not part of large organisations, which provide support in such areas. They would like implementation of the contract requirements to take account of this. It is important not to discourage single-practitioner businesses by creating unreasonable regulatory hurdles: we know from our own research with patients that they value small local pharmacies and their long-term relationships with individual pharmacists.[43]

Having to provide the same information more than once is another important aspect of regulatory burden. Any changes to the current regulatory system should not create further duplication of the information that practitioners have to provide for various bodies – regulators, commissioners (PCOs) etc – and any current duplication that could be eliminated should be. Appropriate, secure systems for sharing information should be put in place.

Another important aspect of the wider context is the transformation of the NHS from sole/majority provider of care to commissioner of care from multiple providers – public, private and voluntary sector, UK-based and international. The blurring of demarcations between professions, the emergence of new health occupations, 'hybrid' practitioners and multiple support grades for many professions are further complicating factors. Some practitioners will be registered with more than one regulator (e.g. as a doctor and a pharmacist). Boundaries are also blurring between provider organisations: care is increasingly organised around care pathways involving multiple providers; practitioners may be part of 'virtual' organisations such as clinical networks, hold joint appointments, or be working in shared services or other partnership arrangements. An increasing number of pharmacists have two or more jobs at the same time.44 All these changes are creating additional regulatory challenges, some of which we have experience of in regulating pharmacy. Regulation needs to be applicable in all sectors and contexts in which healthcare practitioners work.

The specific context for the Society's response includes the long-awaited Section 60 Order under the Health Act 1999, which will strengthen the Society's regulatory powers in several important areas, bringing us into line with other healthcare regulators and enabling the Society to better protect the public. The new community pharmacy contracts across the constituent parts of the UK will increase the volume and range of clinical services provided and hence change the risk profile of community practice. Future regulatory mechanisms will need to be able to respond to this.

[43] Results from patient workshop conducted for the RPSGB's *Competencies of the future pharmacy workforce* project, 1 March 2005.
[44] Hassell K and Shann P (2003). *Pharmacist work patterns: summary of the 2002 pharmacy workforce census.* RPSGB/University of Manchester, p 19.

The overall regulatory framework

In considering the issues raised in the *Call for Ideas*, we have also drawn on various reviews of regulation outside the healthcare sector and our detailed analyses of the relevant inquiry reports such as Kennedy and Shipman. Several of these reviews have identified the need to consider two fundamental dimensions of regulation:

- The single regulator approach versus several frontline regulators plus an oversight regulator.
- The unit (or level) to be regulated e.g. individual practitioner, small firm/practice, or large organisation.[45]

These dimensions (among others) determine how regulation of a sector is organised and delivered. We suggest that in considering the future design of non-medical regulation, the review considers these fundamental issues before moving on to more detailed points.

- **Single regulator, or frontline regulators plus an oversight regulator?**

A regulatory body must have appropriate competence and expertise.[46] A specialist regulator with detailed knowledge and experience of the profession or industry it regulates will function differently to a regulator with a wide scope of activity across several professions or industries. This is true not just of pharmacy or medicine but of almost any field of endeavour: every profession or industry is special and different in its own way. For example, the Royal Pharmaceutical Society regulates self-employed and employed pharmacists, working in primary care, hospitals and industrial settings, in both the public and private sectors. "Inspectors need the expert knowledge possible only with specialisation."[47]

Several recent reviews of regulation in sectors other than healthcare have concluded that a single regulator is not the best model: they have recommended the retention of specialist frontline regulators which would be monitored by a single oversight regulator operating across a sector (e.g. Carsberg[48], Clementi[49], Morris[50]). This type of arrangement is of course very similar to CHRE's oversight role in relation to the specialist regulators for particular health professions.

[45] In the healthcare context it would be relevant to add the multidisciplinary team to this list.
[46] Cullen report: *The Public Inquiry into the Piper Alpha Disaster* (1990) p. 380 (quoting a submission by the UK Offshore Operators Association)
[47] *Consumer counsel: streamlining regulation must not weaken competition policy.* Financial Times editorial, 23 March 2005.
[48] *Carsberg report on the regulatory role of RICS* (2005). The Royal Institution of Chartered Surveyors. http://www.rics.org/NR/rdonlyres/D55BD6CA-4591-4D9E-B9CA-A552CB2691B5/0/carsberg_report0405.pdf
[49] Sir David Clementi (2004). *Review of the regulatory framework for legal services in England and Wales: final report.* http://www.legal-services-review.org.uk/content/report/report-chap.pdf
[50] *Morris review of the actuarial profession: final report* (2005). HM Treasury.

- **The unit to be regulated**

Other reviews of regulation (outside healthcare) have addressed the issue of whether the main focus of regulatory activity should be on the individual practitioner or a larger unit. We suggest that this issue is long overdue for review in healthcare and could be tackled in the current reviews of medical and non-medical professional regulation.

Registers of healthcare professionals generally arose in an era when healthcare as an industry was much smaller, and was organised in a very different way. Most practitioners now work in teams, not alone.[51] In most health professions the majority are likely to be employees (though not necessarily of the NHS) rather than self-employed (pharmacy is an exception: 54 per cent of community pharmacists are self-employed proprietors or locums[52]). Only a minority offer their services directly to the public/patients without some oversight by an intermediary (e.g. a primary care organisation, hospital, pharmacy chain etc). Scrutiny of healthcare provider organisations has been greatly strengthened in recent years, notably by the Healthcare Commission. NHS organisations have clinical governance systems. There is still an important role for regulation of the individual, but the way this is carried out should be modernised to match the organisation of modern healthcare and to take account of the roles played by employers and other bodies in the overall regulatory framework. This would reduce duplication in regulatory activity, but some areas may need to be strengthened, for instance the role of the professional regulatory bodies in setting standards for education to ensure that the necessary values and ethical codes are inculcated from the beginning.[53]

The involvement of corporate bodies in healthcare provision is increasingly important. There is a need, therefore, for corporate regulation to be reviewed. Standards for employers could set out their responsibilities for supporting employees' competence and safe and effective practice. The RPSGB has considerable experience in this area because it registers community pharmacy premises as well as individual pharmacists. In addition, under the Medicines Act 1968 a body corporate must appoint a superintendent pharmacist who is responsible for good professional practice across the organisation. The Society is seeking to strengthen its powers both in relation to premises and the accountability of the superintendent. The oversight and accountability framework together with the ability to impose appropriate sanctions is a powerful tool in protecting the public.

The regulators' accountability to the public

As indicated above, we support the retention of specialist frontline regulators for the health professions with effective oversight by the CHRE. Each of the frontline regulators should also be directly accountable to Parliament (e.g. their chief officers can be

[51] 'Working with other professions' and 'Effective team working' were the most commonly required competencies for all three main sectors – community pharmacy, hospital and primary care - in the RPSGB's *Competencies of the future pharmacy workforce Phase 2 report*, November 2004.
[52] Hassell K and Shann P (2003). *Pharmacist work patterns: summary of the 2002 pharmacy workforce census.* RPSGB/University of Manchester. Table 20, p 23.
[53] *Ethics test 'a must' for student doctors.* The Guardian 10 May 2005, p 9.

summoned to appear before a Select Committee). But we cannot see how Parliament could carry out ongoing monitoring of the frontline regulators in the way the CHRE does, so both mechanisms are needed.

The contribution CHRE makes to regulation should be independently assessed e.g. by the National Audit Office. This should include consideration of its Section 29 powers, given their potential to push the smaller regulators into insolvency.

The current regulators have experienced delays to the reforms they were already seeking, due to lack of resources within government to support the S60 Order process. CHRE should not take a lead in determining the content of future S60 Orders: CHRE oversees the regulatory framework, and therefore it can and should suggest potential improvements to government, but it should not determine the framework it is overseeing.

Other issues

The Review should also examine overseas models of regulation, their potential applicability to the UK, and any evidence regarding which ones best protect the public.

THE KEY THEMES

A. What measures are needed to demonstrate practitioners initial and continuing fitness to practise?

This question covers the processes of

- *entry to the professional register, which for most practitioners takes place when they achieve the appropriate qualifications, and*
- *continuing to be included on the register, which for most practitioners currently requires them to satisfy just three criteria –*

  i. payment of appropriate fee
  ii. avoiding removal or suspension from the register because of conduct or poor performance that has endangered patients
  iii. (for many but not all) providing some evidence of continuing personal development (CPD).

Entry to the profession

The ability to set and monitor education standards that appropriately reflect current practice but which also take account of changing public expectations and employer requirements forms a key plank in regulation of the pharmacy profession. The Society's current education standards and quality assurance processes offer a measure of consistency of outcome across, currently, 19 Schools of Pharmacy. Teaching in pharmacy is funded directly by the higher education funding councils, as is the case with medicine and dentistry. The Society's re-accreditation process sits alongside and is complementary to the Quality Assurance Agency (QAA)'s audits. However, the QAA has

recently announced that it is withdrawing its subject audits, so in the future the Society's accreditations will be the only 'coalface' check on Schools of Pharmacy.

In pharmacy the Society has set standards for undergraduate programmes (currently in the format of an indicative syllabus) since the profession became graduate entry in 1970. The indicative syllabus enables the Society to ensure consistency in the core areas of the syllabus while allowing the Schools some flexibility in curriculum development. Linked with the pre-registration performance framework and the Society's examination, the indicative syllabus and accreditation framework allow core areas of knowledge, skills, attitudes and values to be assessed in different ways at the point of entry to pre-registration training (equivalent to entry to the Foundation 1 year in medical training) and at the point of registration.

The Society monitors the quality of provision of education and learning in the established Schools through its five-yearly re-accreditation cycle (using the accreditation framework plus the indicative syllabus as the standards) and accredits any potential new Schools as and when higher education institutions (HEIs) make applications to offer accredited pharmacy courses. The standard monitoring processes (of degree accreditation and re-accreditation) provide an ongoing dialogue with the Schools and have allowed the Society to manage the ongoing expansion in the Schools (both in terms of student numbers and school numbers) and maintain the quality of the courses and the outputs. This expansion in pharmacy places and Schools, unlike the expansion in medical schools, has not been centrally planned, resourced and driven through Department of Health workforce planning policy.

The Society, through the regular reviews of the indicative syllabus, has the ability to reflect changes in the profession's Code of Ethics and practice standards and to feed back issues emerging from the fitness-to-practise (FtP) procedures. The current integrated structure of pharmacy regulation supports this feedback efficiently and allows the Society to integrate its standards across the various functions including education, practice and FtP.

Pre-registration training

In addition to setting and monitoring education standards at undergraduate level, the Society, like the GMC, is responsible for the pre-registration programme. The Society sets and runs a national examination which is one of the requirements for membership of the RPSGB[54] – membership being the registerable qualification in relation to the relevant EU legislation. This combination provides opportunities to build on the knowledge, attitudes and values, and basic skills developed at undergraduate level and to ensure a smooth transition from academic study to autonomous practice.

The Society is currently reviewing its education policy and standards to further develop integration of the curricula at each level and is also reviewing the assessment methods applied in the core areas of the indicative syllabus, the pre-registration performance standards and exam syllabus. This review is linked with the development of a performance framework being drafted to underpin the anticipated broader range of FtP

[54] Other requirements for entry to the register include satisfactory evidence relating to health and character. In future, evidence of appropriate indemnity arrangements will be needed to join the practising register.

powers, which may (depending on the forthcoming S60 order) include performance and health as well as conduct.

The Society is awaiting the outcome of the review of the MPET (Multi-Professional Education and Training) levy to see the extent to which the pre-registration training workforce can be developed, and to better integrate training and assessment at key points of advanced practice – in line with the recent introduction of the Knowledge and Skills Framework (KSF) and consultant posts in pharmacy.

Post-registration

The Society's approach to development and regulation of professional practice in pharmacy can be viewed from national and international perspectives.

The Society has introduced a CPD framework for all pharmacists registered as practising. Participation in CPD is a professional obligation and is expected to become a legal requirement when the S60 Order takes effect in 2006. When CPD becomes a legal requirement, the Society will monitor pharmacists' CPD records for evidence of participation and to ensure that learning through CPD is linked to practice improvement.

Within the NHS, the Competency Development and Evaluation Group (CoDEG) is pursuing a DH-funded programme to develop competency frameworks for pharmacists working at General, Advanced and Consultant levels of practice[55]. These frameworks have been generated in response to Agenda for Change and the Knowledge and Skills Framework. The frameworks and associated assessment tools provide detailed information to support practitioners with CPD and to support managers with recruitment, training and development and performance review of staff; they thus support the employment structures and policies of the NHS.

The competency structure developed by CoDEG is one of a range of competency and other frameworks available to pharmacists to support the analysis of learning needs for CPD. The Society is aware that a number of specialist interest groups within the profession have produced similar frameworks to guide career development and to regulate admission to specialist group membership. Information generated to facilitate education and training and career development does not necessarily support the regulation of the profession where clear statements of the scope of professional practice[56] are necessary for the identification and regulation of advanced practice such as prescribing. The role of the Society is to set the learning outcomes that are the minimum required for entry to the register at initial registration and for the recognition of advanced or specialist practice. Currently, the Society has no power to regulate advanced practice apart from prescribing but the Section 60 Order will make regulation possible. The Society will need to decide if the regulation of advanced practice will be implemented on a case-by-case basis or according to a set of principle-based criteria.

[55] Competency Development and Evaluation Group; London, Eastern and South East Specialist Pharmacy Services (2005). http://www.londonpharmacy.nhs.uk/Clinical/Competency/default.asp

[56] Walshe K & Benson L (2005). BMJ **330:** 1504 – 1506

While participation in CPD should ensure the maintenance of professional competence, confirmation of fitness to practise requires some form of summative assessment. Outside the UK, Canada and New Zealand have made the most progress with CPD and approaches to revalidation in Pharmacy. Mechanisms for the revalidation of pharmacists have been developed and implemented in two provinces in Canada and in New Zealand. All three regulators used a competence-based approach for the revalidation process. The pharmacy regulators in New Zealand and British Columbia have substantially revised their requirements after unfavourable responses from the profession. New Zealand has retained a simplified competence-based approach in which pharmacists self-assess the patient benefits arising from their CPD. British Columbia has devised a short *Framework of Professional Practice* for pharmacists to use for learning needs analysis. The revalidation of pharmacists in British Columbia is based on a choice of knowledge assessment or review of a professional development portfolio.

Advanced and specialist practice

The need to be able to link initial education standards to standards for extended/advanced practice and perhaps specialist practice is crucial to support modernisation in the NHS and, in the future, revalidation. The Society's recent experience in regulating the supplementary prescribing curriculum at various stages is worthy of consideration in thinking about how education and training aspects of holistic regulation help the regulators to deliver patient safety and public confidence whilst supporting and indeed driving innovative practice and service redesign. The Society currently has limited powers in relation to post-registration education and training but is anticipating that this will be broadened beyond supplementary prescribing in line with other regulatory bodies.

The Society thus delivers education functions currently covered by the Royal Colleges, the Postgraduate Medical Education Training Board (PMETB) and GMC for the medical profession.

Attributes required for renewal of registration – knowledge, skills, behaviour and attitudes

Knowledge and skills should be related to the person's speciality/area of practice and seniority. Behaviour and attitudes should be common to all healthcare professionals and set out in a common ethical code drawn up by CHRE and patient groups and widely consulted on. 'Professionalism' is also important.

Sufficient recent experience in the person's chosen field is also important. The NMC's revalidation scheme requires a minimum number of hours in practice along with other registration and validation requirements. Validated log books could be a useful tool in documenting practice (and electronic recording would enable the information to be shared with employers, service commissioners and regulators). For non-medical prescribers, for instance, should revalidation as a prescriber signify more than having a qualification in prescribing? We believe the public would expect it to mean that the person continues to be competent to prescribe.

Laying the foundations for fitness-to-practise during initial education and training

Students training for the healthcare professions need to understand that it does not guarantee a job for life: it requires a licence to practise which has initial and continuing requirements, like being an airline pilot. But this will require a major change in culture. It conflicts with the traditional idea of having a vocation to become a healthcare professional.

The responsibilities of HEIs in selecting students who are suitable to become healthcare practitioners, and in ensuring that students identified during training as unsuitable are not allowed to complete their qualification, are extremely important. This may involve assessing applicants' attitudes, values and certain personality traits. Exit strategies are needed for students who are identified as having fitness-to-practise problems during the undergraduate programme, to allow them to pursue other qualification routes that will not expose the public to harm. The role of HEIs in this area will become increasingly important if clinical training during the pharmacy undergraduate programme is strengthened and expanded: at the moment, contact with patients is largely concentrated in the pre-registration year. Training for prescribing is to be built into the M.Pharm programme: this will also require students to have contact with patients. HEIs should have a proactive role in ensuring that high ethical standards are promoted and supported in a consistent way in all aspects of the undergraduate programme.

B. What changes are needed to the process of carrying out fitness to practise investigations in order to maximise public safety, the quality of health care, fairness to registrants and satisfaction of complainants?

This question covers the full range of current fitness to practise procedures, designed to identify, investigate and determine cases where participants' actions or attitudes may pose a risk to patient safety. At present –

- *most cases are identified on the basis of complaints from members of the public or reports from fellow professionals or employers*

- *most cases are investigated by a special panel established by the regulator*

- *most cases are then determined on the evidence by a hearing involving professional and lay people*

- *a judgement is made about the truth of the allegation(s) and about whether patients could be at risk*

- *if fitness to practise is impaired, the panel has a range of sanctions available, from removal from the register ("striking off") via suspension, imposition of conditions on practice, issuing a caution to simple admonishment.*

Fitness to practise and public protection

Where there are serious concerns it is essential that the regulator can take immediate action e.g. an interim suspension order or placing restrictions on the person's practice. This relies on robust arrangements for rapid referral to the regulator and speedy complaints-handling and investigation procedures.

Regarding compliance with conditions imposed on a practitioner, there are particular issues with independent contractors and locums. In community pharmacy, the RPSGB's inspectorate can speedily identify issues and ensure that appropriate steps are taken. It plays a crucial role in protecting the public and helping pharmacists to improve their practice, providing a direct link between the regulator and community pharmacists.

Retraining is not an option in all cases: serious professional misconduct is usually about conduct, not deficient knowledge or performance – the latter can potentially be remedied (though some practitioners will be intractably incompetent which must then be addressed through removal from the register). Some health cases also raise issues re. the potential for retraining. The recurrent themes of misconduct in all the health professions, as Dame Janet Smith noted, are about dishonesty, abuse etc. In some cases it would be appropriate to remove the person from the register permanently, to protect the public.

Other measures

The public needs clarity regarding the responsibility of different bodies for dealing with complaints (e.g. the NHS Complaints System, the professional regulators, the Healthcare Commission etc etc): the current situation is confusing. The public want to be assured that complaints are appropriately investigated and action taken where necessary: ready access to information on the registration status of practitioners and progress with complaints is imperative. There should be a public-protection justification for the information on practitioners which is made accessible to the public.

Sound decisions in fitness-to-practise cases will also build public confidence. The actual or perceived leniency of some past decisions did much to undermine public confidence in professional self-regulation and feed suspicions that the professions 'look after their own'. CHRE's role in challenging unduly-lenient decisions is important here, both as a deterrent and a remedy. CHRE should also undertake ongoing audit of standards of decision making, committee training and legal challenges and outcomes.

Should complaints go directly to the professional regulators or be filtered first?

There are arguments on both sides: delay could be introduced by forcing complainants to go through another body first, but only if the system is badly designed and operated. There should be a fast-track procedure for forwarding complaints involving serious misconduct to the professional regulators.

Conversely, inefficiency can arise when the professional regulators have to sift complaints that should not have come to them.

The single portal

The single portal has a role, especially where more than one organisation might potentially have some jurisdiction over a complaint. But direct access by the public to the regulators should also be retained.

Another issue is the threshold applied by different regulators – e.g. some issues will be insufficient to take forward a fitness-to-practise complaint, but would be a matter of concern for the employer or local service commissioners. Members of the public will not necessarily know this.

Better guidance and advice to the public about how to complain and how to choose the right body to complain to would be helpful. The single portal has the advantage of simplicity for the complainant who is unsure which organisation to take their complaint to. Time and energy for pursuing a complaint are also an issue: the complainant may waste time complaining to the wrong body initially and give up.

C. How can we best ensure that support workers provide safe and reliable services to patients? Should they be subject to a formal and fully developed system of professional regulation?

Currently support workers – including health care assistants, and other support staff in laboratories, diagnostic departments and the full range of clinical facilities in hospitals and primary care – are not subject to regulation of any kind. Even if their behaviour or lack of competence in a specific job leads to disciplinary action, they may then be able to take up a similar post with a different healthcare employer with little difficulty.

A widespread consultation was carried out in 2004 about possible ways of regulating this group of staff. There was a general agreement that some form of regulation was needed but no consensus about how this might be brought about.

The extent to which support workers should be regulated depends on the work they do and the risks they pose to the public. Staff who are doing similar work may need regulating differently because their working context is different and they are differently supervised. For example, health care assistants in hospitals work under the supervision of registered nurses; home care workers in domiciliary care do not – they normally work alone with the client and will meet with a manager occasionally.

There are also concerns about the accountability of NHS managers who are not registered healthcare professionals.

Hospital pharmacy has developed in recent years to free the pharmacist from the dispensary to work on the wards, and technicians are now also taking up medicines management roles outside the dispensary. If parallel developments were to be considered for community pharmacy, safe and effective models for periodic or remote supervision would need to be developed, perhaps building on the models successfully developed for trainee surgeons, GPs and other groups of staff.[57] If community

[57] Meadows S, Harrison A, Williams S and Genekar L (2002). *Supervision: a review of current practice in a range of health and social care professions*. RPSGB (unpublished).

pharmacy developed in this way (there is considerable opposition to the idea within the sector), a greater degree of regulation of individual support workers would be appropriate as they would be assuming more autonomy, responsibility and risk than they take on now.

Clearly the issue of employment mobility means that disciplinary action by individual employers cannot provide the whole solution: it does not prevent the person from moving elsewhere and continuing to cause harm. Employers may be reluctant to raise concerns about an employee in a reference because of the risk of being sued for defamation. Action by employers does not provide for the effective management of situations where remediation is important (e.g. health or performance). It does not always provide for thorough investigation of the professional aspects of a practitioner's problem.

Another aspect of this issue is that struck-off practitioners sometimes enter support worker roles to continue working. There are examples of pharmacists continuing to work in the same pharmacy as dispensers following removal from the register, and it is common for struck-off nurses to seek employment as health care assistants in nursing homes. They may choose not to mention that they have ever been qualified or registered, thus avoiding a check on them by the new employer which would have revealed their offence. This practice suggests there may be a need in future for more of those providing direct patient care to be registered than is the case now, and in the interim for employers to check the history of those they employ. A system for sharing or pooling registration data between the regulators – some form of one-stop shop - would make it simpler for employers to make these checks. The costs of registering particular groups of support workers should be balanced against the extent to which they are supervised, their geographical mobility and the risks they pose[58].

At a minimum, national standards for education/training and practice, criminal record checks, some form of national registration, and the means to remove people from the register would seem to be indicated for support staff providing direct patient care, except where the risk to the public is low and/or direct supervision by a registered professional can provide sufficient public protection. The Society does not consider registration to be necessary for pharmacy support staff other than technicians because regulation can be achieved within the pharmacy environment through professional requirements for standard operating procedures and minimum requirements for support workers' training and competence.

Registration data on registered support staff must be readily accessible to employers. Additional components such as CPD and full revalidation would be indicated for groups who work with a high degree of autonomy and who present substantial risks to patients.

It would make sense for support staff to be regulated by the body which regulates the profession(s) they work most closely with. The new practitioner grades (for anaesthesia, medical care and surgical care), should be regulated by the GMC because they are

[58] All the potential risks should be considered, not just those of the treatment/intervention: home care workers, for instance, have the opportunity to abuse, steal from and exploit their clients in numerous ways. The care setting (the client's home) is easily accessed and is usually unsupervised, while the clients are usually very vulnerable – physically and/or mentally.

supervised by doctors and their work more closely resembles medical practice than that of any other currently regulated group. Part of the rationale for this is that the GMC will have the necessary expertise to regulate them; another regulator e.g. HPC will not. The GDC and RPSGB have already gained experience in regulating the support workers for dentistry and pharmacy respectively, and there may be useful lessons from this experience for regulating other groups of support workers.

D. How should new and extended professional roles be regulated?

This question involves two distinct groups of practitioners:

(i) those who, like psychologists, healthcare scientists, or psychotherapists, are currently not covered by statutory regulation but have been subject to varying forms of voluntary regulation for some time and are well established as distinct professional groups; and

(ii) a relatively small number of staff, most often already subject to statutory regulation in other professions, who have extended their scope of practice so far as to have effectively established a new professional grouping requiring separate regulation.

In order to safeguard patients and public and also to enable other healthcare professionals to be able to delegate or refer confidently to other members of the clinical team, both these groups need to be brought within the ambit of professionally led regulation. The present route for doing so is via the addition of new groups to the range of professions already regulated by the HPC.

Devising regulatory solutions to these issues requires going back to first principles e.g.

1. Which groups are currently not regulated at all but should be regulated to protect the public? And who should regulate them?

2. Which groups <u>are</u> currently regulated, but have moved so far away in their practice from their original professional training that their current regulator does not have the necessary expertise to regulate them effectively (particularly re. education and training requirements, competence requirements, standards for practice, CPD, revalidation and professional advice).

One way of judging whether a role is a new or extended is to look at how essential the practitioner's original training is to the new role. Prescribing training for non-doctors, for instance, typically involves adding enhanced patient assessment and consultation skills for pharmacists, and adding new pharmaceutical expertise for nurses. But each group makes extensive use of their original training when prescribing (for pharmacists, this will be their existing expertise in the properties, actions and uses of medicines; for nurses, it will be their patient assessment and consultation skills).[59] However, if we consider the example of midwifery, midwifery is not an extended nursing role: it is a direct-entry profession in its own right: there is no need to have trained as a nurse first (though some practitioners take this route).

[59] Beth Taylor, personal communication, 12 July 2005.

The question then arises, how should role extensions such as prescribing be regulated? Do the existing non-medical regulators have the necessary expertise, or should it fall to the GMC, since prescribing is part of the core role of a doctor? There may be scope for co-operation between the regulators here: e.g. pharmacist and nurse prescribers would continue to register with their existing regulators, but all the bodies regulating prescribers could develop common standards for their education and registration, and could co-operate on developing professional advice and revalidation for prescribing, and re. fitness to practise cases involving prescribing.

The balance between regulation and freedom to practise including innovation

There is a trade-off between them, but risk assessment and management are essential in service development and innovation.

If practice and specialisation are tied down in legislation and regulations, there are huge barriers to change. This may prevent improvements to patient care and workforce deployment, and that acts against the public interest. Protocols and guidelines can be updated more easily and allow for more flexibility.

Codes of conduct and practice should be based on principles which encourage the exercise of professional judgement, but be supplemented by more detailed guidance on matters of particular concern, new issues in professional ethics, etc. Key concepts are flexibility, the maintenance of trust, and the ability to justify decisions and actions taken in good faith. The supposed problem of stifling innovation is more one of theory than of practice: are there really many examples of this happening in practice? Medical and healthcare knowledge and practice continue to develop at a startling rate, despite ever-increasing regulation.

Evidence from other industries on this issue is somewhat contradictory: the literature on aviation safety points to the acceptance of the pre-flight checklist as a major step forward (and, as is often pointed out, pilots do not complain about 'cookbook flying'). However, the 'big idea' in the Cullen report which is credited with leading to major safety improvements in the offshore oil and gas industry was about goal-setting - replacing safety 'solutions' with 'objectives':

"Many regulations are unduly restrictive in that they are of the type which impose 'solutions' rather than 'objectives' and are out-of-date in relation to technological advances. Guidance notes are expressed … in such a way as to discourage alternatives. There is a danger that compliance takes precedence over wider safety considerations; and that sound innovations are discouraged. The principal regulations should take the form of requiring stated objectives to be met… On the other hand I accept that in regard to certain matters it will continue to be essential that detailed measures are prescribed." (Para 1.21, p 4)

E. How does regulation fit into its wider context? How does it relates to the new NHS workforce systems (Agenda for Change, the Skills Escalator, etc) and to the wider network of strategic healthcare priorities and modernised systems, including the extension of IT?

This question probes the relationship between professionally led regulation and the new systems and processes progressively being adopted in and by the modernised NHS. In particular it seeks to identify areas where current regulatory practice may be obstructing innovation and development or where restrictions on practice may have negative effects on the services provided to patients, in terms of the quality or accessibility.

It also raises the issue that regulatory systems are currently UK – wide (except for pharmacists) and extend beyond the NHS.

The tension between professional self-regulation and learning from errors/the no-blame culture

The aviation industry has demonstrated clearly that a culture of learning from errors can be successfully assimilated across a sector. It is also an industry that has achieved dramatic improvements in safety over several decades. The oil and gas sector has also achieved a major culture change regarding safety, and demonstrable improvements in its safety record. What is striking about both these examples is that major improvements in safety were achieved through measures taken at the strategic level, for a whole sector and for organisations. The current mechanisms of professional self-regulation, by contrast, might be characterised as placing a greater emphasis on identifying individuals who can be blamed, punished and ultimately excluded. (This may reflect the 'blame culture' which seems to permeate society as a whole.) Professional self-regulation is still largely based on the notion of the autonomous practitioner (in community pharmacy practice this is still the predominant model). It does not see the person in the context they work in – as part of a team or organisation. It fails to recognise that those in junior frontline roles have the least power to influence practice, care and outcomes[60]. There is a choice to be made about what kind of regulation the public wants – a form that encourages learning from mistakes, or one that punishes every slip. That choice should be based on evidence about what works best in improving healthcare safety and effectiveness.

Professional registration of individual practitioners plays no part in the regulatory arrangements for the offshore oil and gas industry. All offshore personnel undergo regular medical checks and survival training for the mandatory offshore certificate. Their qualifications, professional competence, criminal record etc would be assessed by employers as part of recruitment, appraisal etc. However, we tend to the view that registration of individuals is necessary in healthcare because healthcare has particular features e.g. the imbalance of knowledge between patients and practitioners, the fear and vulnerability of patients and carers when illness strikes, and the need to be able to trust the individual practitioner absolutely at that time of crisis.

[60] Review of impact of CESDI reports by OPM (1999?)

Does professional regulation restrict innovation and service quality/accessibility?

The view that current regulatory practice may be obstructing innovation and improvements in patient services is often stated but how much evidence is there for it? Regulation of extended practice by nurses shifted from local certification by employers to the 'scope of practice' approach (i.e. where the practitioner is responsible for identifying their own sphere of competence and ensuring that they do not step outside it) precisely because the local approach was inflexible: it was not transferable between employers. The disadvantage of the 'scope of practice' approach is that the practitioner may fail to recognise that they do not have the necessary competence for a role/activity ("you don't know what you don't know"). There is also some evidence (from nursing) that most role extensions are driven by employers, not the individual, and that individuals may come under inappropriate pressure to take on a new/extended role when they do not feel adequately prepared for it.[61] The current systems of professional regulation rely on individual practitioners taking responsibility for working within their own sphere of competence. Any changes to the system of regulation must:

- recognise the extent to which 'scope of practice' underpins the whole system
- acknowledge the potential weaknesses of the 'scope of practice' approach
- avoid magnifying those weaknesses (ideally any revisions to the system should remedy current weaknesses) and thereby reducing public protection (e.g. a move to employer-led regulation could weaken the practitioner's ability to resist inappropriate employer pressure to work outside their competence. A practitioner is protected in law from an employer's demands to do anything unlawful or unreasonable; 'unreasonable' acts would include those which contravene the professional standards set by the practitioner's regulatory body).

What does seem to be a genuine barrier to innovation and flexible service provision is the 'tribalism' of the health professions. This tribalism has positive and negative aspects. Genuine differences between the professions exist and should be acknowledged – in culture, ways of working, the scope of practice etc (pharmacy is distinctive in its focus on medicines as an intervention, rather than on any specific group of patients or medical conditions).

Certain conditions have to be satisfied for new roles and ways of working to be widely adopted. The professions tend to pursue role developments such as prescribing that are likely to enhance their occupational status and job satisfaction. They resist developments that could threaten their current position. Similarly, the devolution of traditional professional roles to support workers has been welcomed when the registered professionals can see a clear route to taking up new/extended roles. This has been the case in hospital pharmacy, but less so in community pharmacy, where a sustainable path to new medicines management roles is only now beginning to be established through the new community pharmacy contract.

The existing tribes can feel very threatened both by role extensions in other established tribes and by the emergence of new occupational groups, unless these groups are under

[61] Magennis C et al (1999). *Nurses' attitudes to the extension and expansion of their clinical roles.* Nursing Standard **13** (51): 32-36.

their control. For instance, there is resistance among GPs to the proposals for community matrons, particularly if the matrons do not report to them and are allowed to hold their own budgets. But GPs would like to see more district nurses.[62] In pharmacy, technician and other support worker roles have developed rapidly in the hospital sector, but those groups remain under the managerial control of registered pharmacists, who have thereby been freed from the dispensary to take up extended clinical roles on the wards.

There is no reason to think that the current regulators are the prime cause or repository of tribalism, nor that it would disappear if the current regulators were swept away.

F. What changes are needed in the structure, functions, governance and number of healthcare regulators?

This question asks what changes may be needed to enable professional regulation to meet current and future demands and changes, and in particular to respond to those recommendations made by the Shipman Inquiry which extend beyond the need for change in the GMC. There are currently nine independent regulators of healthcare professions, with the possibility of a tenth being established to bring acupuncture, herbal medicine and traditional Chinese medicine into statutory, professionally led regulation. The Annex lists all nine current regulators and provides some background information derived from published accounts.

When considering any change to the number of regulators, it should be borne in mind that many private sector company mergers fail, often because of incompatible organisational cultures.

Reorganisation of the professional regulatory bodies is not akin to reorganising government-funded regulatory agencies: the former are funded by their registrants/members, not by government. Government is entitled to be satisfied, on behalf of Parliament and the public, that the professional regulators discharge their statutory responsibilities effectively, so the governance of these bodies should be open to scrutiny. But beyond that, is it legitimate for government to intervene in the structure, number and functions of the regulators? Their members/registrants might prefer to pay a slightly higher fee to a body such as the RPSGB in return for the ownership and control they have over it. They would pay less to a 'super-regulator' registering hundreds of thousands of practitioners, but what connection would they have to it and how confident could they be that such an organisation would provide the guidance and support the Society provides now? A narrow interpretation of 'regulatory burden' in terms of cost per registrant should not be applied.

It is very important for the professions to retain a sense of ownership of their regulatory bodies and processes. Each profession must collectively create and defend its own standards of practice. Organisations for homogeneous and discrete professional groups work better than merged ones because they capitalise on professional identity and the professionals' ownership of the mechanisms and standards they define and promote. Cooperation is always likely to achieve higher standards than coercion: the latter will

[62] GPC, personal communication, 30 March 2005.

tend to result not just in resentment but in negotiating downwards to the lowest common denominator.

At the same time, each of the regulators recognises the importance of involving patients and the public in its decision-making and processes. The RPSGB now has 10 lay members on a Council of 30 in total. The Council recently agreed a major piece of work to develop a patient and public involvement (PPI) strategy for the Society. This will draw on the experience of other health organisations which have been implementing PPI for some time, and aims to knit PPI into all the Society's main functions and activities.

Organisational change in the professional regulators would be extremely disruptive and difficult to implement. What evidence is there that merging some/all of the existing bodies would result in more effective regulation? What are the probability, risks and likely outcomes of such a move failing? Failure would involve political risks for government and a loss of public confidence in professional regulation, as well as risks to public protection.

Creating new or merged organisations would require primary legislation, itself a complex, resource-intensive and politically sensitive exercise. The timing of legislative change would be vulnerable to shifts in political priorities. In the meantime, the organisations earmarked for merger/closure would suffer a lengthy period of 'planning blight' and demoralisation, unable to make progress or to attract and retain high quality Council members and staff. Once the necessary legislation was in place, It would take at least two years for new/merged organisations to get up and running.

Major organisational change at this point would halt the positive evolution, co-operation and mutual learning which is currently taking place between the existing regulators, some of it at the instigation of CHRE but some of it predating CHRE. This can be seen at four levels (NB the table below gives examples, not an exhaustive list):

Examples of co-operation and mutual learning between the professional regulators and with CHRE

Level	Mechanisms	Outcomes
1. Overarching - CHRE	• S29 referrals • CHRE works with regulators to identify and spread adoption of good practice • CHRE fitness-to-practise forum	• Establishing benchmarks for the deliberative processes and decisions of regulatory tribunals • Harmonisation • Indicative sanctions guidance
2. Joint – between all/most of the current regulators	• Lobbying to modify EU Directive on professional services • Collaboration on FoI policies	• Avoided duplication of work

	• Patient & public involvement (PPI) group • Policy leads group • Working group on *Crown II* proposals on non-medical prescribing (1998-9)	• Joint public information leaflet on the professional regulators (in development) • Good practice toolkit for PPI in professional regulation (in development) • Identify common policy issues, share information and ideas • Joint letter to lobby government to implement *Crown II* proposals • Influenced government decision to introduce supplementary prescribing
3. Ad hoc learning/co-operation between 2+ regulators	• Reviews by one regulator of practice/procedures in the others; identifying transferable lessons • Working group on *Covert administration of medicines*	• RPSGB's *Future competencies* work (2001-2003) built on similar exercises by the other regulators (e.g. GMC's *Tomorrow's Doctors)* • RPSGB review of supervision in other professions (2002) • NMC guidance on covert administration
4. Individual staff members	• Secondments e.g. from RPSGB to CHRE	• Secondee brings experience to the second organisation, broadens their own experience, and takes back transferable lessons to their employer • Enhanced co-operation and information- sharing between the two organisations

Potential consequences of moving the RPSGB's regulatory functions elsewhere

Although the current regulators have co-operated willingly and fruitfully, they all have slightly different spans of responsibility, so it would be no easy matter to merge them. The pharmacy profession would be particularly badly affected because of the RPSGB's professional body role, for which there would be no secure source of funding if its regulatory responsibilities were transferred elsewhere. If the HPC took on the regulation of pharmacists, there is a real possibility that (in the interim at least) there would not be an organisation dealing with education and professional standards for pharmacists (HPC works in partnership with the professional bodies for the professions it regulates, the latter developing educational and practice standards and accreditation), so it is unclear how pharmacists would be regulated if the Society were dismantled. It is by no means a given that the Society would or could transform itself into a 'Royal College'. The Society's inspectorate (which has been commended by CHRE) and enforcement functions would not be easy to transfer to another body.

There are also several positive reasons for keeping the RPSGB's regulatory and professional body functions together:

1. The unified body provides a mechanism for mediating between the regulatory and professional perspectives where there is a difference of view, and arriving at a single position (whereas there is no mechanism for mediating between the GMC and BMA, or NMC and RCN, when they disagree)[63]
2. The professional body function can be made legitimate, explicit and transparent within a unified organisation. In a professionally-led regulator (without a professional body role), there is a risk that professional interests may be pursued without the appropriate transparency.
3. The Society's separate adjudication process has demonstrated that it is possible to operate a robust, independent fitness-to-practise system within an organisation holding professional as well as regulatory responsibilities. Comparing the Society's record on fitness-to-practise to that of other regulators suggests that separation of the regulatory and professional roles does not necessarily produce a more effective professional disciplinary system than can be achieved within a unified body.
4. Communication and mutual learning between the regulatory and professional functions are easier in a unified body. For instance, recurrent fitness-to-practise problems can be tackled by commissioning research into their causes[64], and through targeted professional standards, guidance and advice.
5. The profession is more likely to 'buy into' professional standards developed by its own professional association than by a regulatory body with which it has no such close connection.
6. The Society does not have a trade union role: its 'representative' role does not encompass employment issues (such as pay and working conditions) which could produce conflicts of interest with public protection. (However, it is not

[63] "… One of the political weaknesses of medicine is the absence of any coordinating body capable of producing a unified response.." Salter B (2004). *The new politics of medicine.* Palgrave Macmillan, p 120.
[64] Ashcroft D et al (2005). *Patient safety in community pharmacy: understanding errors and managing risk.* RPSGB/University of Manchester

uncommon for professional regulators abroad to combine trade union functions with responsibility for registration and professional standards.[65]). The Society currently has the first four of the following five functions[66]:

i Learned society (preservation and enhancement of the knowledge base)
ii Certifying association (transmission and accreditation of knowledge)
iii Licensing association (fitness to practise)
iv Representative association (lobbying)
v Trade union association (economic negotiation).

All successful regulation depends on the quality of the partnerships that are developed. For any regulatory system to work, three essential components are required: a means of representing the professional group concerned and promoting its interests (professional associations, trade unions); a means of driving forward standards and setting aspirations for the group (educational institutions, colleges); and a means of protecting the public interest (regulation, maintenance of a definitive register). These roles can be combined provided that the body exercising them gives due weight to each and does not allow a single one to predominate.[67]

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[65] Salter 2004 p 10
[66] These functions are identified in relation to medicine in Salter 2004 p 9
[67] A comprehensive review of fitness-to-practise regulatory systems is contained in Gomez D & Glynn J (2005). *Fitness to practise: health care regulatory law, principle and process.* Sweet and Maxwell.