

## The Foster and Donaldson reports – briefing 2: other issues for RPSGB

### Introduction

This paper follows Briefing 1 which covered the three key recommendations in the Foster report for the RPSGB (clarifying/separating the Society’s regulatory and professional leadership functions, the composition of Council, and sharing functions/merging with PSNI).

The remaining recommendations of the Foster Report have been dealt with under the following headings:

1. The overall system of regulating the health professions
2. Revalidation
3. Investigation
4. Adjudication
5. Regulating support staff
6. Residual issues re. the role, structure, functions, governance and numbers of regulatory bodies (not covered in Briefing 1)
7. Ongoing review of the regulators.

### **1. The overall system of regulating the health professions – integrated with health services and employers’ systems, and risk-based**

*What does the Foster report say on this topic?*

#### **“Regulation of the professions should be**

- **co-ordinated with the regulation of health services;**
- **build on systems used by employers (and NHS commissioners) where possible;**
- **form one integrated and consistent framework of regulation across the different professions, in which departures from the standard approach need objective justification in terms of public protection;**
- **and adopt 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.” [Recommendation 1.]**

#### *Notes*

1. The Society supported risk-based regulation in its responses to the Foster and Donaldson *Calls for ideas*, contrasting the situation of NHS-employed pharmacists whose organisations are regulated by the Healthcare Commission (or its equivalents), with that of locums and other temporary staff.

2. The Society supported the idea of making annual NHS appraisals part of the regulation of health professionals. The Donaldson report supports this proposal and suggests how the appraisal system would need to change to fulfil this purpose.

**“Regulators should be more consistent with each other about the standards they require of a person entering the register for the first time, and**

- **employers and regulators should agree on common standards as far as possible.**
- **All regulators should adopt a single definition of “good character”, one of the legal requirements for getting registration. This should be based on objective tests.” [Recommendation 2.]**

**”When a professional start their first job they have to get onto a regulator’s register and satisfy the requirements of their employer. Employers and regulators should co-ordinate their information requirements so that the person provides each piece of information only once”. [Recommendation 3.]**

#### *Key questions*

1. The Society’s position to date has been to support, within the context of risk-based regulation, a role for employers, but to express concerns about its limitations in respect of locum and other mobile staff. Should this still be our position?
2. Given our interest in strengthening the role of superintendents, what other points might we wish to explore in connection with the corporate nature of pharmacy (a factor largely outside the experience in healthcare of Andrew Foster)?
3. CHRE is clearly in a position to support and develop greater uniformity in standards and procedures between the regulators – there are various strands of this type of work in place at the moment. Do we think this could extend as far as definitions of “good character” or even pooling panelists?
4. Is it still the Society’s position that the design of revalidation processes should reflect the risks attached to different roles i.e. so that the regulation of support workers should depend on the risks they pose to the public.

## **2. Revalidation:**

*What does the Foster report say on this topic?*

**“Revalidation is necessary for all professionals.**

- **The regulatory body needs to be in charge of setting the standard which a person must meet to stay on the register.**

- **Information already collected by the employer/commissioner should be used to meet both their and the regulator’s needs. [Recommendation 4. See also Recommendations 5-8.]**

Chapter 3 goes on to say:

- “The revalidation system should be both formative (an aid to development) and summative (a check that a required standard is met)
- Within the NHS, information gathered under the KSF should be the basis of revalidation. Any additional requirements should be justified by risk analysis.
- Professionals will fall into one of three groups for revalidation:
  - i. employees of an approved body – revalidation carried out as part of the routine staff management or clinical governance system
  - ii. self-employed staff providing services commissioned by NHS primary care organisations – revalidation processes built into the relevant NHS arrangements and carried out under the supervision of the commissioning organisation
  - iii. all others – regulatory bodies develop direct revalidation arrangements.
- The Healthcare Commission in England (or its equivalent in each of the other UK countries) should approve employers who can deliver reliable revalidation processes.
- Post-registration qualifications should be recorded in the register where the specialisation is relevant to patient care and patient safety, can be defined in terms of extra skills required, and is at a level substantially beyond basic registration.”

### *Key questions*

1. Do we continue to support the view that any process of revalidation should be both formative and summative?
2. During Foster, the Society argued for any employer role to be subject to the overall control of the regulator, but clearly there may be a role for health commissioners in this. How do we view this, and specifically what might seem to be the difficult areas of locums, and achieving consistent standards across the multiplicity of pharmacy employers?

### *Notes*

1. The involvement of employers in revalidation could potentially be extended to employers of community pharmacists.
2. The Donaldson report sets out how the NHS appraisal system would need to be strengthened to make it suitable for revalidation purposes.
3. Category ii above most probably refers to self-employed professionals *directly commissioned* by primary care organisations to deliver enhanced services. It is unlikely to cover most community pharmacy locums, so the RPSGB would still need to be directly involved in their revalidation.

### 3. Investigation: the single portal and single investigation process

*What does the Foster report say on this topic?*

- **“There should be a single source of advice to those who want to express concerns about registrants**
- **and a single investigation process at local level that would provide a report and evidence that would, where possible, meet the various needs such as resolving a complaint and deciding whether to refer to a regulator. Any investigation needs to determine what actually happened.” [Recommendation 9 and chapter 4. See also the Donaldson Report’s recommendations on local GMC affiliates.]**
- **CHRE should organise the agreement of protocols for local investigations which would ensure that their findings of fact could be relied on by regulators if a case had to go to them for resolution. [Recommendation 10.]**
- **[CHRE’s] audit role should be extended to include a duty to sample decision taken by regulators not to proceed to formal investigation of cases referred to them.” [Recommendation 10.]**
- **“Employers should remain ready to refer the most serious cases to the national regulator, that is, every case where investigation might lead to removal from the register.” [Recommendation 11.]**

See Chapter 4.

#### *Key questions*

1. The Society has in the past acknowledged the case for a single portal, but has argued that direct access to the regulator should be maintained. Is this still our view? (If so would it mean rejecting the proposals for a single investigation process at local level?)
2. How should the Society play the role of the inspectorate into its response? Is the Society’s unique inspectorate part of the case for adopting a different approach? Or could it be integrated with a single local investigation process?
3. Linked to this, what would we like to say about the proposals for local investigations?

#### *Notes*

1. The RPSGB, in its submissions to the Foster Review, supported the idea of a single portal for signposting complaints but in addition to direct access to the regulators, not in place of it. The proposal above goes further, in saying there should be both a single portal to advise complainants and a single investigation process. It seems to imply that direct complaints to the regulators would not be permitted.

2. The Council took the view in discussion about the single portal that preventing direct access to the regulator could waste valuable time in dealing with a practitioner who might present a serious risk to the public. However, direct access also permits many complaints to go to the regulator which it will end up dismissing or referring to another body because a) they do not call the practitioner's registration into question or b) they should have gone elsewhere. These complaints can clog up the system, add considerably to costs and hamper the regulator in dealing with complaints that fall within its remit.
3. Local investigation, if carried out to a sufficiently high standard and backed by a national system to ensure quality standards and consistency, could benefit both the public and the regulators – by leading to speedier resolution for complainants (at present time can be wasted in complaining initially to a body whose remit does not cover the issue or which cannot offer the outcome sought by the complainant, e.g. financial compensation), and by avoiding duplication of investigation by more than one body. Investigation costs could thereby be reduced, benefiting the taxpayer and registrants of professional regulatory bodies.
4. Recommendation 11 is important: any changes to the current investigation system must allow for practitioners who seem to present a serious risk to patients or the public to be referred rapidly to the regulator so that interim suspension procedures can be instigated where necessary.
5. If the public is to be prevented from referring cases directly to the regulator, the burden of responsibility on employers will be increased. A national system of support for and audit of employers' actions will be needed.
6. Chapter 4 discusses support for complainants in bringing complaints. The Health & Social Care Regulators' Patient & Public Involvement Group is likely to be holding a seminar on this topic in the next few months, as part of a seminar series on sharing experience and good practice in PPI.<sup>1</sup>

#### 4. Adjudication

*What does the Foster report say on this topic?*

- **“The task of adjudicating on concerns about impaired fitness to practise should be carried out either (a) by a single separate adjudicator for all the professions, (b) as now for the non-medical professions or (c) under the control of regulators as now, but by shared panellists working to common standards. [Recommendation 12.]**
- **Each panel hearing a case about fitness to practise would include lay and professional members; the latter selected with regard to the area in which the person appearing was working. [Recommendation 13.]**

See Chapter 4.

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<sup>1</sup> Eileen Neilson represents the RPSGB on this group and has led a sub-group to develop this series of seminars.

### *Key questions*

1. Three options for adjudication:
  - a) single separate adjudicator for all the professions
  - b) no change
  - c) separate adjudication by the regulatory bodies but with shared panellists working to common standards.

### *Notes*

1. The separation of the Statutory Committee from the Council, and the arms-length nature of the new fitness to practise committees means the Society has always viewed this particular issue with varying degrees of acceptance.

### **5. Regulating support staff (“staff with lower levels of qualification”)**

- **The Scottish pilot of employer-led regulation of support workers, which should provide important evidence about whether this is the best way to proceed, will continue until the end of 2006. A successful outcome for the pilot could lead to the adoption of a UK-wide employer-led approach to the regulation of this group of workers. [Recommendation 14.]**
- **The new roles using the working titles of Anaesthesia, Emergency Care, Endoscopy, Medical Care and Surgical Care Practitioners need statutory regulation... Work remains to be done [on] whether they should be regulated as one group with specialisms or as up to five groups. [Recommendation 15 and Chapter 6.]**
- **One or more existing regulators will become the ‘lead regulator’ for new groups. The lead regulator will set the standards applying to everyone registering as a member of the new group. Where someone joins the new group from an existing profession, they can remain registered with their existing regulator and avoid costly dual registration. [Recommendation 16 and Chapter 6.]**

### *Key questions*

1. Does the RPSGB support employer-led regulation for support staff (subject to the Scottish pilot demonstrating that this would be the best option)? What would this mean for the RPSGB, GDC and any other regulator wishing to implement team-based regulation?

### *Notes*

1. The Society argued for team-based regulation for support workers, on the model already being successfully rolled out for pharmacy and dentistry. The Foster report has not responded to the Society’s case for team regulation.

2. The Scottish pilot (as far as we know) is not comparing the effectiveness of employer-led regulation of support workers with the team regulation model, so it will not be able to demonstrate that the employer model is superior. (cheaper, more effective etc.). We do not know if the Scottish pilot allows for evaluation of the potential weaknesses of the employer-led model (e.g. in cases where the employer themselves is at least partly to blame).
3. The new practitioner grades are not of direct relevance to pharmacy, but the Society proposed in its response to the CMO's *Call for ideas* that they should be regulated by the GMC because those staff work with doctors (in similar roles to US physicians' assistants).

## **6. Residual issues re. the role, structure, functions, governance and numbers of regulatory bodies (not covered in Briefing 1)**

*What does the Foster report say on this topic?*

- **Common standards:**

**“There are substantial areas in which common standards would be desirable – in particular most aspects of conduct. The more difficult task of identifying common educational standards in areas such as the knowledge needed to underpin safe prescribing should not be ducked either. The regulators and CHRE should work to introduce common standards in all those areas where this would benefit patient safety.” [Recommendation 18 and Chapter 7.]**

*This item is for discussion, though on the face of it, it appears entirely consistent with current Society activity.*

- **CHRE Council:**

**“Changes are needed to the membership of CHRE’s Council which will preserve its lay majority (and UK-wide makeup) while securing a professional voice through appointments against objective criteria, in place of the existing *ex officio* membership of Regulatory Bodies’ Presidents.” [Recommendation 19 and Chapter 7.]**

*This item is for discussion.*

- **Multi-professional regulation**

**“A regulator like the Health Professions Council, dealing with a range of disparate professional groups, can deliver the functions which public protection requires.” [Recommendation 22 and Chapter 7.]**

**“Any new profession coming into statutory regulation should be regulated by one of the existing regulatory bodies, most likely the HPC.” [Recommendation 23 and Chapter 7.]**

*These items are for discussion.*

*Notes:*

1. The Society challenged the repeated assertions throughout the course of the Foster Review about the HPC's effectiveness and fitness for purpose, on the grounds that no independent evaluation of HPC's performance has been carried out since it was set up. The Society recommended in its formal submissions to the Foster Review that before the HPC model was applied any more widely, it should be subject to formal evaluation by an independent body such as the National Audit Office. That evaluation should include the views of the professional associations for practitioners registered with HPC.
2. The Society cited evidence in its response to the CMO's *Call for ideas* on the importance of the regulator having specialist expertise in the profession or activity regulated. The Donaldson report acknowledges this point. If a multi-professional regulator such as HPC has to employ specialists from the professions it regulates to carry out specialist functions (such as accrediting HEI courses and providers for specific health professions), then it is simply replicating the processes carried out by single-profession regulators but bringing them under one roof.
3. The Department of Health has not applied a consistent standard in making judgements about the fitness for purpose of the RPSGB and HPC. The RPSGB has a long track record as a regulator, the HPC does not. There is no evidence that patients or the public are dissatisfied with RPSGB's remit or performance; conversely, there is no evidence that the public has particular confidence in the HPC. The evidence on public awareness of the regulators of the health professions (from MORI surveys commissioned by the DH) shows that the public know of the existence of the GMC, but not of the other regulators, though they make assumptions about *how* health professionals are regulated and "checked up on".

- **Role of professional bodies**

**"Professional bodies dedicated to providing leadership and setting standards are also needed: the two work together." [ Recommendation 22 and Chapter 7.]**

*This item is for discussion. The Council will have noted the views of the Chief Pharmacists at BPC in support of the thinking behind this recommendation.*

*Notes:*

1. This point sounds like a truism but it is much more complex to achieve in practice than it sounds. What if the professional body comes up with standards that the regulator thinks inadequate for public protection? What if the professional body believes it is acting in the public interest, but the regulator chooses to ignore it? At the end of the day, the regulator holds the power because it has the statutory responsibilities; the professional body's role is in effect advisory.
2. There is no UK evidence of separate regulatory and professional bodies working together successfully in the way described - although the proposals

within Donaldson for new ways of working between GMC and the Royal Colleges, as mediated by PMETB, may provide a new opportunity for effective working (GMC/BMA and NMC/RCN – in both cases there are many examples of clashes – notably the way that the BMA forced the GMC to water down its revalidation plans, which were condemned by Dame Janet Smith and then withdrawn after government intervention).

3. The combined pharmacy regulatory and professional body in New Zealand has apparently split with a successful outcome, and the regulatory College of Pharmacists in Ontario has a cordial relationship with the federal professional body in Canada. However, we understand a similar split in Western Australia has come to grief and the CPD proposals from the regulatory College in British Columbia were withdrawn under pressure from the profession. (We are gathering more evidence on these overseas bodies which should be available for the October Council meeting.) This point is of course crucial to Key Issue 1 (see Briefing 1) on clarification/separation of the Society's regulatory and professional leadership functions.

- **Number of regulators**

**[Apart from proposals on sharing functions between/merging RPSGB and PSNI] there should be no other changes to the number of regulators at present.” [Recommendation 24 and Chapter 7.]**

## **7. Ongoing review of the regulators up to 2011**

*What does the Foster report say on this topic?*

- **“In the longer run, the question of whether there should be further progress towards fewer regulatory bodies will be kept under review – with the intention being to hold a formal review of the position after five years, in 2011. It may be that in practice the need for further structural change can be avoided by closer collaboration and harmonisation between all the remaining regulatory bodies.” [Recommendation 24 and Chapter 7.]**

Chapter 9 goes on to say:

- **“This substantial programme of legislation [the S60 Orders for pharmacy, doctors, psychology and healthcare sciences, which “will be honoured”] will need to be matched by redoubled efforts from the world of professional regulation, and from employers, to secure a more integrated and effective approach to regulation.” [para. 5, p. 46]**

*Notes:*

1. The second quotation above is a warning to the current regulators that they must be able to demonstrate improvements by 2011 – in working more closely with each other and working more effectively.
2. The RPSGB argued in its submissions to the Foster review that the case for amalgamating some or all of the existing regulators had not been made on cost or

other grounds. It argued that some of the benefits claimed for amalgamation could be achieved through closer working relationships between the regulators.

Eileen Neilson, Head of Policy Development  
Rob Darracott, Director of Corporate & Strategic Development  
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