

Separation of Society's professional and regulatory roles still to be resolved

The Royal Pharmaceutical Society's response to the so-called Foster and Donaldson reports on the future regulation of the health professions was published earlier this week. Dawn Connelly looks at the Society's reaction to some of the reports' proposals

This summer, the reports of the so-called Foster review of non-medical regulation and the Donaldson review of medical regulation proposed wide-ranging changes that will inevitably have a significant impact on all health professionals, their employers and their regulatory bodies (*PJ*, 22 July, p91). In particular, the Foster report made several suggestions about the structure and functions of the Royal Pharmaceutical Society. The consultation period for both reports ended last week.

Clarifying separation of functions

The Society's response is, perhaps surprisingly at this stage, lacking in detail about the Department of Health's recommendation that the Society needs to clarify the separation of its regulatory and professional leadership functions. Eileen Neilson, the Society's head of policy development, explains why. "The Council decided that it was not yet ready to go into detail, nor was this response the right vehicle for a dialogue with the Government about it. It is clearly an issue of huge importance with far-reaching consequences for the Society and the profession and it would not be wise to jump to conclusions about the Government's 'real' intentions or to make a snap judgement about it without having the necessary information on which to base a decision," she says.

In its response, the Society lists this issue as its main priority in terms of implementation and recognises that it needs to avoid protracted discussion about the way forward: "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." The Council will be considering a potential way forward in the first week of December and this will be discussed with the Government separately from the Society's Foster response, it adds.

However, the Society's response does indicate that some clarification of functions has already been achieved and ongoing reforms will strengthen this distinction further. For example, Ms Neilson explains, the most recent reorganisation of the Society's structure has achieved separation of its enforcement and standard-setting functions in the fitness-to-practise area. The recently strengthened policy team has provided additional capacity to support the Council in making policy. In addition, the Society is in the process of establishing national



boards to provide professional leadership and support for pharmacy practice development in England, Scotland and Wales. "The Council has also had to act as a de facto English national board because there has not been an English executive," says Ms Neilson. "So achieving the English National Board is important to getting that clarification [of roles]," she says.

The Society argues that the Foster report presents no evidence that the Society's integrated professional and regulatory roles have had a detrimental affect on public safety, the standards achieved by the pharmacy profession or the quality of pharmacy services. However, it says that if a regulatory board were to be established, then the Society can see advantages in creating a clear distinction between the regulatory board and other structures. The Society would accept the arguments for a lay majority on such a board. Ms Neilson explains that, by implication, the Council is saying that it would not want a lay majority on the Council itself. "What [the Council] has always objected to is the idea that you would have a lay majority on a structure that oversees the professional functions. The Government allowed us to have a smaller proportion of lay members on the Council than is the case with some of the other regulatory bodies for health professionals because it recognises that we have this professional role," says Ms Neilson.

Appointment of members of Council

In the Foster report, it says that there is a public perception that health care regulators are dominated by members of their profession, and this is reinforced by the election of pro-

fessional members to the councils of these bodies. To address this, the report suggests that it would be desirable to replace some or all of the elected members by appointed professional ones. The Society is not "entirely persuaded" by this argument.

"We do not believe an entirely appointed body would command the confidence and commitment of the whole profession, which the Government has acknowledged remains necessary for professional regulation, in its broadest sense, to work," it says. By this, the Society means 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.

According to Ms Neilson, some arguments put forward by members of Council were that the importance of professional representation outweighs public perception and that the public already has a strong voice through the 10 lay members on the Council.

Revalidation

The Society highlights that, 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. The Society is supportive of the principles of revalidation and is developing its own proposals. However, it is clear in its response that it does not support employer-driven regulation: "The regulator, not the employer, must determine the standards required for revalidation, and make the judgement about whether or not an individual has met them." Although the Society does not think that employers should be in charge of the process, it recognises that there is an important role for them in revalidation. "If there was not, the amount of activity that would be required by the Society to revalidate around 38,000 pharmacists on the practising register would be incredibly costly," Ms Neilson explains. "You would probably be talking about running a big assessment centre — revalidation is a lot more than continuing professional development," she adds. She says that the employer is in the best position to judge whether somebody is competent in their role. "If there is an employer, and they can provide the evidence, then that is likely to be the most cost-effective solution for the profession."

The Society agrees with the principle of risk-based revalidation proposed in the Foster report. "Individuals in similar jobs with com-

parable types and levels of risk should be subject to similar revalidation requirements," says the Society. However it points out that the methods by which the information is produced and submitted might differ according to a practitioner's employment situation.

The Society highlights several situations in which provision of information by an employer for revalidation purposes would either be unavailable or inappropriate: for example, locum pharmacists, single-handed independent pharmacists and pharmacists with combined job roles — a significant proportion of the community pharmacy workforce. These groups might have to be revalidated entirely by the regulator or the regulator could accredit other bodies to revalidate certain groups of practitioners, the Society suggests. It also proposes that the Healthcare Commission in England and Wales could inspect the appraisal systems of larger private-sector employers of pharmacists (as well as NHS appraisal systems). The Society's inspectorate, it suggests, could have a role in assessing the smaller community pharmacy employers' appraisal systems, with their consent, to see if they could produce valid information that could contribute to revalidation.

Merging societies

The Foster report recommends that the Pharmaceutical Society of Northern Ireland should share some functions with the Society with a view to eventually amalgamating to form a single UK body. Although the Society recognises the logic of consistency in regulating the pharmacy profession across the UK, it argues that the proposals require a detailed investigation regarding their potential benefits, risks, costs and feasibility.

The Society also believes that the views of the PSNI (Panel 1) are "paramount" and a joint approach to any potential merger would be essential.

Other regulators with dual roles

The General Chiropractic Council, the Royal Pharmaceutical Society, the Pharmaceutical Society of Northern Ireland and the General Osteopathic Council were the four regulators singled out in the Foster report as having a role outside the scope of regulation. The report said that although the roles of profes-

Panel 1: Pharmaceutical Society of Northern Ireland response

The Pharmaceutical Society of Northern Ireland accepts that it should continue to work closely with the Royal Pharmaceutical Society and other health care regulatory bodies but it opposes a merger with the Society (*PJ*, 21 October, p469).

In its response, the PSNI says that it already has a society with statutory functions defined, it has a structure in place which is clearly enshrined in legislation and it is working to define the costs and timelines to enact the changes enabling a reformed and fit-for-purpose regulatory function.

The primary legislation under which the functions of the PSNI are defined does not allow the society to appoint lay representation, to register support workers or non-practising members, or to apply a range of sanctions. "We fundamentally agree that we need to amend the current legislation," it says. Regarding lay membership, the PSNI says: "Our view is that appropriate appointment of lay representation would benefit the working of the society and would be welcomed." However, it adds that it does not believe a lay majority is necessary on either the council or the statutory committee, although it would accept that a third of the council should be made up of lay members.

On its professional leadership role, the PSNI says: "The promotion of the standards expected of the profession cannot be compromised to the degree that the public safety agenda is undermined. The representation aspect of our remit is understood clearly in this regard, and we would argue that it is appropriate that this degree of representation is retained." It adds that the society accepts it must work towards providing transparency and will do so as efficiently as is practicable in areas where it can be achieved without changes to primary legislation. "There could perhaps be a perceptual issue with reference to 'representation' and it is this aspect that the society would accept that we would need to address," it says.

The PSNI supports the principle of revalidation, which it says should be realistic and appropriate. However, it argues that revalidation should not detract from the core service of providing patient care.

sional leadership and promoting the profession do benefit the public there is a tension between their focus inwards on the professions' interests and the need for the regulators to be seen to be free from such influences. It suggested that the changes following the review would provide the opportunity to bring these regulators into line with the majority.

In its response to the Foster report (*PJ*, 21 October, p469), the General Osteopathic Council said that references to promoting the profession are likely to be removed from the Osteopaths Act 1993. In contrast the General Chiropractic Council makes no mention of the tensions referred to in the report (Panel 2) but does support appointment rather than election of council members.

The PSNI argues in its response that the two regulatory consultations do not detail adequately the areas that would be defined as "representation" and those that would be viewed as "regulatory". "We would be concerned if it became a requirement to establish a second professional body that this would dilute the authority of the regulatory function, and could result in a costly exercise that would produce limited benefits especially in

relation to public safety," it says (Panel 1).

Many other issues are addressed in the Society's response to the Foster and Donaldson reports (Panel 3). The full response is available on the Society's website at www.rpsgb.org and via *PJ Online* (www.pjonline.com/links/pj).

Panel 3: Society's views on other issues in the reports

- **Devolution of regulatory activity** The Society believes that its inspectorate could act as a model for developing a system for other regulators to resolve complaints locally.
- **Standard of proof** The Society currently applies a civil standard of proof with a sliding scale, ie, the more serious a case is the more cogent the evidence required to prove it. The Society encourages other regulators to adopt similar practices.
- **Adjudication panels** The Society supports the development of a shared pool of panellists to serve on adjudication committees across the professions alongside members of the professions regulated and lay panellists serving on the panels of only one regulator.
- **Common standards for all health professionals** The Society believes there would be value in having common standards in some areas but not all.
- **Registration of students** The Society believes that student/trainee registration should be considered for all health care disciplines.
- **Regulation of support workers** The Society urges the Government not to unravel its voluntary register of pharmacy technicians without properly evaluating its benefits.
- **Council for Healthcare Regulatory Excellence** The Society opposes the appointment of professional members to the CHRE's council.

Panel 2: General Chiropractic Council response

Appointment, rather than election, of professional members to its council is supported by the General Chiropractic Council in its response to the Foster and Donaldson reports.

The GCC agrees with the Foster report's suggestion that members of regulatory bodies should be appointed by the Public Appointments Commission. "Our view is that elections lead to a false assumption that some members have a professional constituency that they represent, rather than the duty common to all members to protect the public," says the GCC. This is unhelpful and confusing, it says, particularly to the extent that it may undermine public confidence in the regulatory process.

The GCC supports the possibility of a lay majority of one if there is evidence that this will increase public confidence in the regulatory process. "Currently, we are not aware of any such evidence," it says.

The GCC opposes the recommendation that an independent tribunal should be established to deal with fitness-to-practise cases, something it believes would undermine the statutory function of the regulator. It also opposes the devolution of regulatory activity to a local level and all recommendations associated with this.