



The Community Pharmacy Wales response

to

Healthcare professional regulation: Public consultation on proposals for change

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Part 1: Introduction

Community Pharmacy Wales is the body whose function is to represent and negotiate NHS contractual matters on behalf of all of the pharmacy contractors in Wales and seeks to secure the best possible NHS services provided by pharmacy contractors in Wales.

CPW has worked closely with the PSNC in the drafting of this response and CPW does not demur from the submission by PSNC to this consultation.

CPW has considered the three questions posed in the consultation and the 11 common themes running through the Donaldson and Foster reports.

The three questions are very broad, and whilst we provide brief responses to those, we believe that comments on the common themes may be more valuable to the Welsh Assembly Government in developing the future policies.

As the consultation and our responses are highly relevant to the Welsh Executive of the Royal Pharmaceutical Society of Great Britain (RPSGB) in the work it is itself carrying out in responding to the reports and developing future strategy, we have sent a copy of this response to the Welsh Executive of the Society.

Part 2: The consultation questions

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

It is vital, in order to maintain and develop public confidence in all healthcare professions that there are common principles applied to the regulation of the professions across the devolved administrations. The disparity between regulation of the different professions has led to some professions being 'over-regulated' and others 'under-regulated' and public confidence has been impaired. Whilst the Donaldson and Foster reports dealt with the regulation of doctors and the other healthcare professions separately, there is no reason why the regulation of all healthcare professions should not follow similar core principles, and CPW welcomes the opportunity to propose that the regulation of community pharmacy should follow the same principles as all other regulated professionals, including doctors.

2. Do stakeholders support the approach advocated in the two reports?

The identification of the 11 core themes is useful in identifying areas where the regulation of healthcare professionals can be harmonised.

3. What are the priorities for stakeholders in terms of implementation?

CPW proposes a cautious stepwise approach, first to identify areas of commonality in regulation, secondly to modify these common areas to embrace the recommendations of the reports that are agreed, and finally by working towards removing disparity between the regulators.

For the pharmacy profession, the extended period of uncertainty during the evolution of the Royal Pharmaceutical Society of Great Britain has been unhelpful. The Pharmacists (Fitness to Practise) Act 1997 is almost a decade old, but the Regulations necessary to implement the provisions are yet to be laid. Delays have

been caused by the review by the Society of its Charter and also the formulation of Regulations under s60 of the Health Act 1999. It is our hope that the publication of the Donaldson and Foster Reports will provide a new impetus to developing a regulatory body for pharmacy that is fit for purpose.

Part 3: The common themes

CPW now wishes to comment on the common themes running through the two reports, as follows:

1. Changes to the governance and accountability of regulators.

The PSNC commented on the consultation carried out by the Department of Health on the Pharmacists and Pharmacy Technicians Order, which addressed many of the issues relating to the Royal Pharmaceutical Society as regulator and CPW fully endorse this response. See <http://www.psn.org.uk/resources>

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

CPW is supportive of this theme.

3. The appropriate standard of proof.

CPW disagrees with the proposal to adopt the civil standard of proof in fitness to practise cases.

We accept that the need to meet the criminal standard of proof has, in some cases, led to injustice, but we believe that a health professional should not have their right to practise their chosen profession removed by allowing evidence to meet only the civil standard of proof.

The Chairman of the Statutory Committee of the Royal Pharmaceutical Society of Great Britain, Lord Fraser, QC., has considered the standard of proof in a number of decisions made by the Committee, and has stated that the Committee will consider the standard of proof on a sliding scale, with the most serious of allegations having to satisfy not the civil standard, but a higher standard approaching the criminal standard.

We would propose that a sliding scale is adopted, similar to that adopted by the current Statutory Committee.

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

CPW supports the proposal of a risk based spectrum of revalidation.

5. Devolution of some regulatory activity to a local level.

It is the CPW position that local resolution of complaints or untoward incidents should take place where appropriate.

The first level contact for any person who is dissatisfied with a service provided by a healthcare professional should be with the healthcare professional himself. This allows any misunderstandings to be remedied, as well as providing the opportunity for the healthcare professional to correct any deficiency in his service both for the dissatisfied patient and for future patients.

Where this contact with the healthcare professional does not satisfy the patient, then the next level should involve other local organisations. Both Local Health Boards and the local Inspectors of the Royal Pharmaceutical Society have participated in local resolution of complaints, and the RPSGB Inspectors have well developed investigation experience. The aim of local resolution, particularly in simple, non repeated, and relatively minor breaches, whether 'terms of service' or of professional or legal provisions should aim to identify mechanisms for improvement and provide local support.

Local Health Boards (LHBs) have not usually had access to trained investigators, and so their response to complaints have been variable. If LHBs are to attempt local resolution, it is essential that they have access to investigators who have adequate knowledge and experience of the sector in which the healthcare professional under investigation works. Any local resolution should aim to remedy any poor performance identified and provide confidence to the public about the healthcare services generally. Escalation to formal investigation and disciplinary action should be contemplated only on rare occasions.

Until about five years ago, the Inspectors of the RPSGB were able to deal with simple, non repeated relatively minor matters such as uncomplicated dispensing errors, by reviewing systems with the pharmacist and offering advice on improvements. That would normally be the end of the matter, unless there were further incidents. Unfortunately, the RPSGB has modified the way in which such incidents are dealt with, and all complaints are now referred for formal decision by a screening committee at the RPSGB, often after an interview of the pharmacist 'under caution'. CPW strongly believes that this is the wrong way in which to deal with minor breaches. The RPSGB Inspectorate has demonstrated over the years its ability to deal quickly and effectively with minor matters in a way that improves the service, provides greater public confidence, whilst minimising the bureaucracy of investigating and dealing with the incident.

CPW suggests that the RPSGB Inspectors are given back their discretion to deal with minor issues on a local basis. They can be relied upon to escalate the investigation where a more formal response is needed.

In putting forward this suggestion, we draw attention to the fact that pharmacy is the only healthcare profession where the registrants fund, through statutory registration fees, an inspectorate that undertakes regular, routine monitoring of premises and services. CPW believes that pharmacy should be regulated in the same way as the other healthcare professions, and therefore that there should be no regular routine inspections of pharmacy by an inspectorate funded through registration fees. We believe that the objective of the Donaldson and Foster Reports to harmonise the role of regulators supports our view that there should be no routine monitoring by the regulatory body.

LHBs have a duty to monitor NHS services, and since October 2005 have been undertaking a monitoring role in community pharmacy premises. The monitoring provisions include powers to take action where the 'Terms of Service' are not adhered to. In the last year, experience has shown that where the LHB and pharmacy contractors co-operate to identify areas needing improvement, remedial action can be taken quickly, which benefits the LHB, the pharmacy and the public using pharmaceutical services. This local resolution prior to the point at which the public are affected, is beneficial to all parties.

CPW therefore suggests that to bring pharmacy into line with the other healthcare professions, the routine monitoring (and associated remedial action where necessary) should be carried out by LHBs, with investigations into complaints and adverse

incidents mainly being carried out by the RPSGB Inspectorate, which should have discretion to deal with minor matters on a local basis.

Where it is felt that the complaint requires a more formal investigation, or where a dispute requires resolution, CPW would support publication, by the Welsh Assembly Government, of guidance to LHBs on the establishment of formal structures and processes to resolve these issues at a local level.

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

There could be some scope for greater flexibility and better use of resources, but at the present time the priority should be standardisation of procedures across all the professions.

In due course, a panel of lay members who could sit on all the regulatory bodies may be useful.

7. The requirement to record post-registration qualifications.

CPW supports this principle.

8. The role of regulation for student healthcare professionals.

CPW supports this principle.

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

CPW supports this principle.

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

CPW supports this principle, but only where it is risk and role based. This would be consistent with the point made in response to theme 4, in which revalidation should be risk based.

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

There is a great advantage in terms of public confidence in a regulator, if lay members are in the majority. But this public confidence must be balanced with the credibility of the lay person to the healthcare professional who is to be 'judged' by the lay person. CPW suggests that all lay members should have an appropriate level of specialist knowledge. All healthcare regulators should continue to have access to the necessary input and expertise of professional members.

Each regulatory body will also have different needs on their committees, and the necessary skills and qualities of members, whether lay or professional, should be identified. CPW suggests that all of the professional members of Councils should be appointed, rather than elected, since this ensures that the skills and qualities of candidates can be assessed against the agreed criteria.