

# TRUST, ACCOUNTABILITY AND REGULATION — CHANGING EXPECTATIONS

*This article is based on a presentation given by Philip Green, the Royal Pharmaceutical Society's deputy secretary and registrar and director of education and registration, to the International Pharmaceutical Federation Congress in Sydney on 8 September*

Some important messages about modern regulation can be gleaned from a look at the strands and themes that emerge from the history of the Royal Pharmaceutical Society, other health professions and the National Health service, and current events.

## PUBLIC ACCOUNTABILITY

Accountability needs to be considered alongside the development and evolution of health policy and broader social policy. Change needs to be viewed not just in the light of recent events but over the past 30 years or so if we are to get a real sense of perspective. It is perhaps only now, with the benefit of hindsight, that the trends and events can be pieced together. If one looks at the histories of medicine, nursing and pharmacy, at the reports, the conflicts and the issues, a picture begins to emerge.

## HEALTH REGULATION

The contract between the professions and society dates back to the 19th century. In Britain, it has always been characterised by a strong element of professional self-regulation, based in part on a belief in the twin pillars of unique professional competence (no one else knows enough to regulate them), and the professional and ethical commitment to the interests of the client.

## HEALTH REGULATION: THE "PLAYERS"

In the context of health, the state (in the form of successive governments) has, since the 1980s, sought to wrestle with the fundamental impact of economic constraints on the almost unlimited demands for health care. The fact that the UK government fulfils the roles of insurer, provider and regulator of final resort has further complicated its objectives.

This has been compounded by growing public disquiet and anger at obvious examples of lack of professional knowledge and commitment. Public reaction to these scandals was difficult for politicians to handle — it was unpredictable, powerful and unaccepting of excuses. The "rolling snowball" effect of successive scandals (taken alongside other events) accumulated to such an extent that the pressure to reform, and be seen to reform, professional regulation became irresistible. The watershed was the death of a number of babies during heart surgery in Bristol.

In terms of the professions themselves, there has been serious questioning of medical and nursing performance and regulation

in particular, and doubt about how much it is in the public interest that professions regulate themselves. Until the early 1990s, there was near universal denial among the professions that the old notion of self-regulation might be becoming untenable or misplaced. Some more visionary leaders began to realise that a sea change was occurring. But it was not until government forced their hands after the Bristol scandal that attitudes really began to change.

For most of the 20th century, the statutory self-regulation of professions has been fairly stable. It was seen as the business of the elite within the professions, aided by a small numbers of others.

The other participant in all this was of course the Government through the Department of Health (in its various guises) whose interventions might have been said to limit the professions' claim to completely independent decision taking.

It may seem to those working in the regulatory arenas that change is recent. But a longer historical perspective indicates that professional self-regulation was being challenged much earlier. A train of events was building — just waiting for a "tipping point".

## REGULATION IN 1975

An inquiry into the regulation of the medical profession (Merrison) in 1975 said: "An instructive way of looking at regulation is to see it as a contract between public and the profession, by which the public go to the profession because the medical profession has made sure it will provide satisfactory treatment. Such a contract has the characteristics of all freely made contracts — mutual advantage."

It is interesting to look at the origins of the Merrison inquiry. The General Medical Council was in financial difficulties and had proposed that a retention fee be paid annually by all doctors, which would be a condition of remaining on the register. Not surprisingly, this generated considerable unrest. Some doctors objected on the grounds that they had already paid for life and should therefore not be asked for more money. Others put the point that if they paid, they should be directly represented and thus have more of a say in the running of the GMC.

This presented a problem for the government of the day: if doctors did not pay and the regulator removed their names from the register for non-payment, how would the National Health Service function? The government intervened and established the inquiry. Merrison took the opportunity to

review what professional regulation meant and who should be involved.

It was self-evident to the inquiry committee that the medical profession itself should keep the register because it was only members of the profession who had the knowledge and experience to decide on the competence of their peers.

A register, essential for public protection, could only be maintained, the committee believed, by those with knowledge of the issues involved. To maintain standards, a regulatory body needed to be thoroughly independent of government and of employers, although the public interest dictated that parliament should have the power to intervene if the profession was not doing its job.

A lay contribution was also acknowledged as valuable. The Merrison recommendations began to widen involvement of the rank and file practitioner. Further, the inclusion of 10 places for lay members was also significant. Possibly unintentionally, it paved the way for the much stronger user voices that would follow in the next decade.

## LAY VOICES

During the mid and late 1980s the GMC, in particular, experienced growing criticism over the perceived deficiency of its disciplinary system. Lay voices, especially those representing consumers of health services, were getting stronger.

The starting point was a case where the behaviour of a doctor was regarded by the GMC's professional conduct committee, as "below the standard which can be regarded as acceptable in a medical man", but not deemed to constitute serious professional misconduct.

This triggered a member of parliament to seek to change the law to enable the GMC to incorporate the lesser charge of unacceptable conduct within its disciplinary process.

The nurse's disciplinary process was at this time regarded as healthier than that of the doctors. The nurses had a charge of "professional misconduct" as opposed to the doctors' "serious professional misconduct". But the absence of an explicit requirement to include a lay member on the nurses' conduct committee was a serious cause for concern.

In the intervening years all the regulatory bodies have faced public questioning, not only of the decisions they have made on matters such as educational requirement for entry but particularly on the rulings that they have made on removing names from and restoring them to the register.

If the rationale for the registration of professions is protection of the public, should professions themselves play such a strong part? Can they really always be trusted to work in the public interest?

These questions grew in importance in the 1980s and erupted on to the public agenda at the end of the 1990s with a whole series of cases.

### CHANGING ATTITUDES

There were increasing public and political demands that regulatory systems should be more open, accountable and responsive, and a greater questioning of how others — allied professionals, non-professionals, employers, service users — might become more fully involved in regulation.

To understand the whole picture it is useful to look across all the regulatory bodies in the health field and to explore how their interests and concerns meshed or failed to mesh with government agendas.

It was certainly possible for the government in the 1970s — and, more surprisingly perhaps, it continued to be possible for governments in the 1980s — to assume that professional self-regulation could by and large be left alone.

### THE POLITICAL STRAND

The 1980s Conservative governments were less content to defer to professions or to hold them in high regard. New right philosophies hostile towards the welfare state distrusted the public sector professions for their drain on the public purse. They were looking for ways to control health care and its costs more closely. They questioned the monopolistic character of all professions, not just in health care. Lawyers, for example, also came under attack.

Attention first focused on new business style general managers who it was hoped would question professional practice and introduce greater efficiency and value for money. The focus then shifted towards establishing an internal market, which it was hoped would create new incentives to change practice through consumer choice. Performance criteria were written into job contracts.

### REGULATION

A number of issues relating to the regulation of health professions began to appear and converge on the legislative agenda in the early years of the 1990s.

New professional groups were emerging; time was found for legislation to create registers for both osteopaths and chiropractors. And the workforce was changing. Demographic trends showed an aging population, a shrinking workforce and dramatic changes in working patterns.

Questions of poor performance of doctors were the subject of a Department of Health inquiry and new procedures for dealing with poor performance in medicine were enshrined in law.

But all this took valuable parliamentary time. When others started to press to be included in the list of professions regulated

under the Council for Professions Supplementary to Medicine, the Government called a halt.

In 1995, a decision was taken to commission a firm of management consultants to undertake an overall review of the regulatory machinery for the professions supplementary to medicine.

The Government then commissioned the same consultants to look at the regulation of nursing and midwifery. They listened not only to those working inside the regulatory machinery but also to civil servants, employers, trade unions and professional associations.

They concluded that the law had failed to put public protection explicitly as its paramount purpose. What was needed, they said, was new legislation and a culture change to go with it. This needed to be based on a clearer understanding of the central purpose of regulation: "The purpose of the statutory body is to protect the public through setting and monitoring standards of professional practice, education and conduct for nurses and midwives and to influence the development of those professions in the public interest. The accountability of the council in all these matters is to the public first, and secondly to the professions that establishes and funds it".

The consultants started from first principles and in doing so, brought public protection to the fore as the single and central purpose of professional self-regulation.

The public should be able to distinguish between a practitioner who is appropriately qualified and one who is not. Anyone could offer services as a physiotherapist, for example. It was clear to the consultants that public protection required the legislation to be changed to give, for example, an unambiguous protection of job title.

A regulatory body, they believed, had to get involved not only in removing practitioners not fit to practise but in administering lesser penalties to bring practitioners back into line. They suggested guidelines on offences and sanctions, more collaboration with other regulatory bodies and new powers including a power of mediation in matters of professional conduct.

The consultants considered whether lay members should actually be in the majority on the new councils believing this could be a more logical development of current trends in public policy on professional regulation. However, this was rejected as too radical a change.

But 20 years on from the Merrison Inquiry, in a distinctly different climate, the management consultants offered an entirely new consideration of what professional self-regulation was and what it should entail. The contrast is a sharp one. Merrison's view of professional self-regulation had been one where the profession itself took on the responsibility of administering the register, policing standards of entry and removal from it in order to protect the public.

The management consultants turned this on its head. A register was vital but they had an altogether less benign view of the disinterest of the professions. Public protec-

tion requires a balancing of the interest of the profession with those of employers, service users, educationalists and others.

The view on the respective roles of regulatory and professional bodies was that what advanced the profession did not necessarily advance the public. Advancing the profession was the business of professional associations not the regulatory body. This was a view that would itself evolve later, after the Bristol inquiry, as the role of "modern regulator" took shape.

The recommendations and the rationale underlying them amounted to a radical repositioning of statutory regulation. In effect, though, the consultants were too politically aware to put it this way. The new model almost amounted to taking the "self" out of "self-regulation".

### THE LEGAL FRAMEWORK — THE HEALTH ACT 1999

The consultants' report disappeared into the Department of Health in the summer of 1998. Thanks to the lack of parliamentary time and a queue of health professions wanting or needing legislative amendment, the government proposed to insert a clause into an Act of Parliament (the Health Bill) that would give it flexible powers to amend primary legislation by order, that is, without full scale parliamentary debate.

Despite assurances that the government's intentions were benign the regulatory bodies in the health field were uneasy. Was the aim to quietly erode the fundamentals principles of professional self-regulation?

As the Health Bill was being debated in early 1999, the report on the review of nurses, midwives and health visitors was released (February 1999) and the public inquiry into the Bristol babies scandal was well under way.

At the same time the National Consumer Council issued a report that spoke of "a patchwork of varying arrangements with different professions which have not caught up with the changes in public demand or with current health care practices".

It noted problems with regulation in relation to team care, lack of regulation in the private sector, the continuation of unregulated groups, the grey area where practitioners who should not do so nonetheless continued to practise and, not least, the sheer difficulty for consumers in finding their way around the system.

It recommended better links between regulators and considered a one door complaints system, more open business and more participation of lay members.

The regulators lobbied for limits on the scope of this new power and by the time the Bill became an Act in June 1999, it was confirmed that the core functions of regulation could not be transferred between bodies or to any new body that was created, that a lay majority would not be imposed on the council of any of the regulatory bodies, and that the existing lines of accountability that many of the regulators had with Parliament rather than, say, a ministry of the government would remain unaltered.

But the Government had nevertheless acquired a way to reform self-regulation rapidly. And there were other developments that would have an impact on regulation as well.

### QUALITY/SAFETY TRIANGLE

When Labour came into power after 18 years of opposition, it was clear that it wished to distance itself from the “market” form of health and welfare service delivery of the previous government and to institute something new.

Modernising government, social services and the NHS were all on the agenda. The aim was to implement a new kind of culture across the whole range of public services and a much stronger commitment to quality on the part of all those delivering and managing care.

The Government’s framework for quality for the NHS was founded on the establishment of national standards. National service frameworks for clinical care delivery, mechanisms for strong, clinical governance at local level and new kinds of inspection and monitoring of clinical performance were unveiled. A central plank of this framework for quality was the concept of clinical governance.

### MODERNISATION AND CLINICAL GOVERNANCE

So where did professional self-regulation stand as a result of all this? Modification of professional self-regulation was not, at first, at the top of the Government’s agenda but questioning of the institution of professional self-regulation started to build by the late 1990s and the Labour Government integrated these issues into its determination to “modernise” and to raise the quality of public services.

Professional self-regulation was preserved as part of the framework but with an inter-relationship with clinical governance and a partnership between each of the professions and the Government for a programme of reform. Life-long learning for all health care professionals was recognised as an essential element of the quality framework.

Crucially, in all of these processes there is patient and public involvement and the objective of national standards setting is to define clear standards of service to produce dependable local delivery and put in place quality assurance mechanisms which monitor the standards and confirm that they are delivered.

### WHAT HAPPENED NEXT?

In 1999, after the considerable media attention on the failures in clinical care (particularly by doctors) the Government published “Supporting doctors, protecting patients” — a consultation paper on preventing, recognising and dealing with poor clinical performance of doctors in the NHS in England. The paper discussed the expectations of a modern, open, responsive and publicly accountable system of self-regulation in the

health field. Two broad functions were defined.

The first was to determine which individuals should enter and remain members of a health profession at different levels and at different fields of practice.

The second, through the above, was to support health organisations in achieving high standards of quality through clinical governance at local level and through other structures and processes at national level.

The paper expanded on the five principles outlined by the Better Regulation Taskforce, setting out “Modern principles of self-regulation in the health field”, which all health regulatory bodies could be expected to fulfil. These were transparency, accountability, targeting, consistency and proportionality.

It set out an agenda for broadening the remit of professional self-regulation and the expectation of a consistent approach across all health professions.

It said: “The organisation of professional self-regulation still owes more to history than the needs of patients in a modern NHS. The challenge now is for the Government and clinical professionals to work together to modernise that framework so that it is fit for the new century”.

It was clear that professional self-regulation was not going to be allowed to hamper the projected overall change.

### THE BALANCE HAS SHIFTED

The public enquiry, chaired by Professor Ian Kennedy, into the deaths of children at Bristol Royal Infirmary heard from nearly 600 witnesses and looked at almost 200 medical records. It was published in July 2001 and the Government’s response to it appeared later in the year, accepting most of its recommendations.

The timing was critical since the Government was putting together its policies for reform, and the public expected reform. Public opinion, political will and “events” all came together.

The report said: “The culture of the future must be a culture of safety and quality; a culture of public service; a culture in which collaborative teamwork is prized; and a culture of flexibility in which innovation can flourish in response to patients’ needs.”

It challenged the “club culture” and the imbalance of power, with too much control in the hands of too few people. It highlighted “system” failures as well as individual failure.

In the light of both the specifics in Bristol and the history and events described in this article, the Bristol report reviewed professional regulation in its widest sense.

The whole culture of regulation was challenged from initial qualification right through to removal from registers, and was found wanting.

If registration could not give the public a real assurance that practitioners were competent and fit for purpose then things would have to change and be seen to have changed.

The Bristol inquiry effectively redefined regulation and accountability. It said: “Regulation of health professionals is not just

about disciplinary matters. It should be understood as encapsulating all of the systems which combine to assure the competence of health care professionals: education, registration, training, continuing professional development and revalidation as well as disciplinary matters.”

### KENNEDY PRINCIPLES

Professor Kennedy set out the components that should apply to all health professional regulators:

- Poor performance needs to be identified and dealt with
- There needs to be support for improvement and a focus on performance as well as misconduct
- The cultural change needs to go right back to the recruitment and training phases, with registration understood as living, dynamic and relevant
- Standards for education, conduct and practice should be set and raised, good practice and innovative practice promoted, and there should be a programme of lifelong learning and training with regular revalidation for continuing practice rights

This is not a pipe dream — it is happening now. Medical, dental, nursing and now pharmacy regulation is being reformed.

We are accountable and we have to work hard to ensure that we keep up with and fully meet the expectations of us.

### CULTURE IS THE KEY

It is evident that, above all, culture is the key to good regulation. Professional culture reflects professional ethics, values and standards. But professions do not exist in isolation from each other, the public they serve or the Government.

In the UK, regulators, professional bodies and governments have in the past effectively colluded because of cost, power play, and sometimes benign (but nonetheless unacceptable) ignorance to give the public a less than good service.

The professions should welcome this change: it offers the prospect of real improvement in the quality of care, and hence renewed public confidence, while still conceding substantial autonomy to the professions.

But paradoxically, it is the reaction of the professions themselves that remains a potential barrier. There is significant resistance, including within the pharmacy profession, to key elements of this reform process. Pharmacy is struggling to cope with major changes in professional roles and acceptance of new regulatory regimes is difficult in such a climate.

It remains a major challenge for us all to deliver effective, workable, modern regulation, and retain the confidence of the public and support of our colleagues in pharmacy.

But this is the only route on offer if we are to renew and sustain the contract with the public.