
CHRE Policy Framework

November 2009

1. Introduction

- 1.1 CHRE's policy advice is provided in response to requests or commission from four sources:
- The Secretary of State for Health in England and the Health Ministers in the devolved administrations
 - From the Scrutiny and Quality team following the performance reviews and audits of the regulatory bodies
 - From Council following the identification of a matter where patients and the public maybe at risk or regulation might be improved.
 - At the request of the regulatory bodies we oversee.
- 1.2 The 2007 White Paper expressed a desire to see CHRE become 'an authoritative independent voice for patients on the regulation of professionals, providing expert advice on policy.'¹ This requires us to develop the knowledge and evidence base to be able to make authoritative, expert statements on policy and to have sufficient independence to determine areas in which we need to take on work to enhance patient safety and public protection.
- 1.3 This paper describes the policy development framework we have adopted in undertaking these commissions once they have been accepted, and outlines our interpretation of key regulatory concepts: risk, professionalism, and right-touch regulation. This paper was discussed and approved with minor changes by CHRE Council in September 2009.

2. The values and principles in our policy work

- 2.1 CHRE occupies a unique position in the world of health professional regulation, and this allows us to build and maintain expertise and experience in developing our policy work. Through our work we aim to provide a consistent message about good regulation and to help achieve this we build our work on two sets of overlapping values and principles:
- The values in our strategic plan:
 - Patient and public centred
 - Independent
 - Fair
 - Transparent
 - Proportionate
 - Outcome focussed.
 - The principles of good regulation that we have adopted:

¹ Department of Health, 2007. *Trust, Assurance and Safety: the regulation of healthcare professionals in the 21st century.*

- Proportionality
 - Accountability
 - Consistency
 - Targeting
 - Transparency
 - Agility.
- 2.2 The concept of agility as a sixth principle of good regulation was proposed in our advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council², in the context of rapid change in pharmacy practice expected over the next ten years. Agility in regulation means looking forward, rather than looking back and trying to prevent the last crisis from happening again. An agile regulator will:
- Anticipate the changes that are going to occur in its field, anticipate the risks that will arise as a result of those changes, and taking timely action to mitigate those risks
 - Not react to everything as changes may occur which do not require the regulator to respond.
- 2.3 This concept of agility in regulation has been generally welcomed by the health regulators and was recently supported by in the House of Commons Regulatory Reform Committee.³
- 2.4 These values and principles form an intellectual and ethical framework around which we begin to develop our policy. They help to identify the issues we tackle and the research questions we ask, and they shape the reports and consultation responses we publish. The interplay of these values and principles is an important aspect of our approach. For example, taken together they mean that while we strive to ensure that our work is centred on the needs of patients and the public, this is balanced by a commitment to the characteristics of good regulation. These values and principles also help us to be clear when regulation is not the appropriate way of promoting patient safety or improving quality. The views and experiences of patients and the public inform our work, directly and indirectly, but the opinions we express and the positions we adopt are independent of any particular group or stakeholder.
- 2.5 CHRE's main objective is to promote the health, safety and well-being of patients and other members of the public. In our policy work that means we demonstrate and express views on the impact and outcome of regulation on patients and the public. Sometimes this is straightforward, such as public views on registers or how complainants are involved in fitness to practise processes. Sometimes, however, regulatory activity is at a greater distance from the public, for example in quality assuring education programmes. Throughout our policy work we try to focus on the impact on patients and the public, and the risks that are presented, such as in our work on advanced practice and sexual boundaries. The learning from this work is

² CHRE, 2008. Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council

³ House of Commons Regulatory Reform Committee, 2009. Themes and Trends in Regulatory Reform. Ninth report of session 2008-09

then fed into the performance review, against which the regulators are assessed on an annual basis.

2.6 In practice, when we work with this framework to develop policy we:

- Seek to establish the views of patients and the public on matters relating to their experiences of healthcare and their thoughts about their needs from regulation, either through commissioned research, or through secondary sources
- Focus on the outcome and impact of regulatory activity rather than the processes that regulators may adopt in delivering these outcomes. Only when it becomes evident that the process is adversely affecting the outcome do we seek to comment.
- Retain a view of regulation that is independent of professional interests and of employment settings
- Seek to maintain good working relationships with the regulators, offering them early and late sight of our work, and involvement on a basis that suits their resources
- Make recommendations based on our understanding of the range of different stakeholders with a role and responsibility in promoting the health, safety and well-being of patients and the public. This can include employers, professionals and their peer groups, and patients themselves. This approach was supported by market research we commissioned in late 2008.
- Promote transparency in regulatory activity wherever possible to help promote and retain public confidence in health professional regulation
- Draw on the expertise and experience of regulators and other organisations with an interest in our work or our issues, building an evidence base for our recommendations and advice
- Be consistent in our approach and recommendations
- Write our reports in plain English, reflecting the public and patient-centred nature of our work, as well as our desire to be clearly understood.

3. Key regulatory concepts: Risk

3.1 There is an inherent risk in all interventions in healthcare, nothing can be said to be completely safe. For example there is no such thing as an absolutely safe medicine, since there will always be someone who will suffer an adverse reaction or side effect. The role of health professional regulation is to mitigate aspects of that inherent risk, through promotion of standards of safe practice and conduct, by taking action where these standards are breached, and by quality assuring the education of professionals. It does not seek to address all aspects of risk, and indeed regulation (of health professionals or in its other forms) is not the solution to prevent every possible thing that could go wrong.

- 3.2 The Risk and Regulation Advisory Council define public risk as ‘those risks that may affect any part of society and for which government is expected to respond’.⁴ They define six key features of public risk in general:
- Risk is a social phenomenon
 - Managing risk is about managing complexity
 - Managing risk is also about managing anxiety
 - Managing risk is a shared responsibility
 - Communications about risk should restore the voice of reason
 - An independent perspective can help communicate and manage risk.
- 3.3 Responsibility for risks in healthcare should be shared between all parties and not just borne by the health professional. Patients and the public also have some responsibility for managing risks, becoming involved in discussions about their treatment options, the different levels of risk involved, and the possible consequences for their health. Different patients will have different levels of risk that they are prepared to live with and this should be respected in those discussions. Regulation needs to help health professionals to take account of patients’ different appetites for risk.
- 3.4 In our policy development we work with the following core assumptions about risk:
- Risk and uncertainty is inherent in all transactions between health professionals and patients, their relatives and carers
 - Regulation does not seek to remove all risk, it seeks to mitigate some aspects of risk
 - Professionalism acts a risk-mitigating factor – the self-regulation of individuals by virtue of their professional attitudes
 - Taking too heavy-handed an approach to reducing risk would have unwanted and unintended consequences
 - Patients should be helped to understand the risks inherent in any procedure, and be part of the decision making on what procedures are done. The burden of risk should not all be on the health professional or the provider organisation but patients share in the risk in an informed manner
 - Things will always go wrong whatever risk-mitigation framework is in place. With right touch regulation things will go right far more often than they go wrong.

4. Key regulatory concepts: professionalism

- 4.1 Professionalism is the heart of good practice and the most important element in safety and quality. It is the professionalism of health professionals which prevents them from attempting procedures which are beyond their competence, and ensures

⁴ Risk and Regulation Advisory Council, 2009. Tackling Public Risk: a practical guide for policy makers

that they will involve colleagues with appropriate competence where necessary. It is professionalism which internalises appropriate behaviour and make virtue a habit.

- 4.2 There has been much debate in the health professions recently about the need to redefine professionalism for the 21st century. The Royal College of Physicians has proposed that medical professionalism should be seen as a set of 'values, behaviours and relationships' rather than as personal attributes.⁵ The issue of relationships as a core element of professionalism is thrown into further focus by the advent of appraisal and revalidation and the growing importance of teamwork. Being professional is expressed in what you do not in what you are.⁶
- 4.3 If high quality professionalism keeps patients safe, the role of regulation should be to support good professionals and allow them to flourish for the benefit of patient care. In our policy development we work on the basis that regulation exists to support and encourage good professionals, it provides a framework that outlines expectations and identifies when behaviour falls outside these boundaries of accepted norms.

5. Right-touch regulation and excellence

- 5.1 CHRE aims to develop right-touch regulation in healthcare. We need to find just the right balance of standard setting, professional development and revalidation which will help knowledgeable, talented, creative professionals to thrive and sufficient to command trust and confidence of patients and the public. We need to find simpler ways for remediating or eliminating dangerous practice or bad behaviour. Right-touch regulation will encourage professionalism and mitigate risk in a proportionate manner.
- 5.2 Right-touch regulation means doing more with less. We have already started to reduce the burden of our performance reviews on the regulators by addressing ourselves more clearly to outcomes. In making a judgement on how they perform we seek more insight with less oversight, we aim to ask less but understand more.
- 5.3 Right-touch regulation will mean always asking ourselves what risk we are trying to regulate; to be proportionate and targeted in regulating that risk or to find ways other than regulation to promote good practice and safety.
- 5.4 Right-touch regulation will mean anticipating the future. Healthcare is a rapidly changing global market. Technical innovations, changes in practice, mobility of patients and professionals, healthcare challenges such as hospital acquired infection or the 'flu' pandemic all test our ability to reassess risk and respond precisely. Regulation itself must be agile, anticipatory and innovative if it is to keep pace with developments in healthcare and to support not stifle improvements.
- 5.5 We recognise that over-regulation is costly and ineffective, and professional regulation must always be aware of its duty to be cost effective. While patients and the public have the right to expect to be treated safely, the expense of regulation may ultimately be passed onto patients and service users.

⁵ Royal College of Physicians *Doctors in Society: Medical professionalism in a changing world* Report of a Working Party 2005

⁶ Cayton, Harry, *Some Thoughts on Medical Professionalism* GMC 2005

- 5.6 Right-touch regulation might be seen as fulfilling CHRE's task to define excellence in regulation. Excellence we consider to be the habit of doing things well every time, all the time. In the Performance Review process document we define excellence as 'consistent performance of good practice combined with continuous improvement'.
- 5.7 Throughout our policy work we reflect on the context and delivery of healthcare across the many settings and environments that registrants work in. Regulators are only one of a number of influences on the care delivered by a health professional to patients and the public. Making changes to regulatory functions can be a solution, but we do not assume it is always the most appropriate or proportionate response to a problem. Alongside the regulators, employers, educators, individual professionals and their peer groups, and patients themselves have particular roles and responsibilities to fulfil. This view guides our analysis and any recommendations we may make in our policy work.

6. Conclusion

- 6.1 This paper sets out a framework which combines values and principles, an intellectually coherent approach to regulation and effective processes for commissioning, researching, reviewing and producing policy. Properly applied this will produce consistently high quality work and will enable the Council to have appropriate assurance and oversight.

