Call for Views on Right-touch regulation

Reviewing its impact, currency, and key concepts

November 2014

1. Background

Right-touch regulation describes our approach to regulation. The 'right touch' is the minimum regulatory force required to achieve the desired result. It is a risk-based, outcome-focused approach that challenges the common misconception that more regulation is often the best way to reduce harm. Our ultimate aim is to foster a more considered, intelligent approach to regulation, and reduce the prevalence of unnecessary and ineffective regulatory action.

When we published it in August 2010, we billed *Right-touch regulation* as 'the approach we adopt in the work we do.' In the foreword, we explained that we wanted to make our approach explicit, and invite discussion on the topic.

In the four years since its publication, we have stimulated debate on *Right-touch regulation* and listened to feedback, and as a result have developed some awareness of how it has been received in the UK and abroad. We know that it has been adopted and adapted – in a number of different ways and not always as we had foreseen – by the regulators we oversee. We are also aware through the international commissions we undertake that it has had some impact internationally.

We are now engaged in a project to assess its impact, bring it up-to-date, and clarify and expand on some of the key concepts. We hope that in doing so, we might be able to further extend its usefulness both within the UK and abroad. This Call for Views forms part of the first of three project phases.

2. About the Call for Views

We would like to hear from regulators, accredited register holders, policy-makers, professional bodies, academics, patient groups, and any other interested bodies both across the UK and internationally. We would be grateful if you could **forward this Call for Views to any organisations or colleagues who may be interested**.

We will use the responses to this Call for Views to develop case studies, direct our focus on areas that require clarifying or amending, and inform our understanding of key areas and concepts, such as risk and proportionality. This will enable us to gauge who *Right-touch regulation* has reached, how it has been interpreted and applied, and how it could be further developed and improved.

Responses will be collated and analysed, and a summary published as part of the round-up of phase 1 activities in the new year.

We would like to be able to quote and attribute material from your responses in our published summary and final reports – please tick the boxes at the end of the form to opt out of this. Please note, however, that we may be obliged to disclose your response under Freedom of Information legislation.

3. How to respond

You can respond by email to policy@professionalstandards.org.uk using the Word form at the end of this document.

The deadline for responses is **31 December 2014**.

Annex A: Call for Views on Right-touch regulation – questionnaire

We will use the responses to this questionnaire to inform our review.

It would be helpful to us if you could be specific when referring to particular sections of the Right-touch regulation paper, and provide examples where relevant.

Please note that we do not expect all respondents to answer every question.

PART I: Questions about you

1. Your name and/or the name of your organisation

General Pharmaceutical Council (GPhC)

2. Postal address

25 Canada Square

London

E14 5LQ

3. Email address

Hugh.Simpson@pharmacyregulation.org

4. Phone number

0203 713 7803 (Hugh Simpson, Director of Policy and Communications)

5. How would you describe your organisation (or your own role if more relevant)?

Health professional and systems regulator

Part II: Questions about Right-touch regulation

6. Where did you first hear about *Right-touch regulation*?

The GPhC first heard about Right-touch regulation when it was published in 2010.

7. What use have you or has your organisation made of *Right-touch regulation*, if any?
(Please illustrate with specific examples if relevant)

PSA's publication, *Right-touch regulation (August 2010),* has particular significance for the GPhC given that the concepts within it were first aired by PSA in response to the Government's decision to establish the GPhC as the pharmacy regulator.

In particular the recommendation from PSA to add a sixth principle, *agility,* to the well-established five principles of good regulation[1] is something that has significantly influenced the work of the GPhC in the four years since we were established. At the heart of the GPhCs approach to regulation is a recognition that the people and sectors we regulate are dynamic, and as such, for regulation to be effective, we too need to be responsive but also forward looking.

As PSA acknowledges, *right-touch regulation,* is very much an addition to earlier work led by the Better Regulation Executive in 2000 to identify the principles of good regulation. Our Council has, from the outset, established a clear and strategic approach to regulatory development which is consistent with the six principles. In particular they have sought to focus on what we are seeking to achieve for patients; describe our standards where possible in terms of outcomes; and to consider the most effective regulatory tools and intervention to achieve those outcomes. In doing so we have drawn on the work of BRE, PSA but also from Sir Philip Hampton's report, *Reducing administrative burdens: effective inspection and enforcement*; as well as Government's response paper*, Implementing Hampton: from enforcement to compliance (2006).*

Each of these publications were helpful contributions to the debate about regulation. But there have been many further developments, both in the UK and internationally, which have influenced our own thinking and regulatory policy development which is set out in our Strategic Plan for 2015-18 and is also embedded both in our new standards for registered pharmacies and our approach to the inspection of pharmacies.

The GPhC regulatory policy development for regulation of pharmacies has been heavily influenced by our desire to be agile, to reflect the changing nature of pharmacy, the dynamic public policy environment and our Council's desire to look purposefully at the role that regulation can play in improving quality, of which we see safety as a critical element.

In accordance with the Agility principle, the GPhC has recognised the context of change in pharmacy practice, with pharmacists and pharmacy technicians delivering new services across all sectors and settings. The functions and powers of the GPhC are designed to continually improve patient and public safety.

[1] Five principles of good regulation, Better Regulation Executive (www.bis.gov.uk)

8. More generally, what impact do you think *Right-touch regulation* has had, if any, on your area of work?
(Please illustrate with specific examples if relevant)

We are unable to separate the impact of *right-touch regulation* from all the other principles on the "better regulation" landscape – listed by Sir Philip Hampton and the Better Regulation Executive, among others.

However, we do think *agility* as a sixth principle is particularly important in the pharmacy sector where there is a growing divergence in some aspects of public policy across Great Britain. The retail pharmacy market is developing at a rapid rate, in response to consumer demands but also heavily influenced by government, both domestically and at a European level. We continue to prioritise horizon scanning to ensure we are regulating in a way which considers future trends, not just keeping up to date with current activity. This is reflected in our guidance development work for pharmacies undertaking distance selling of medicines.

9. Which aspects of *Right-touch regulation* do you think are most important and why?
(Please refer to specific sections from the document if possible, and illustrate with examples)

Please refer to the answer below.

10. Which parts of *Right-touch regulation* do you find most useful and why?
(Please refer to specific sections from the document if possible, and illustrate with examples)

Right-touch regulation touches on some of the fundamental questions and challenges facing all regulators. We have discussed briefly the principles above but all regulators need to continue to focus on key issues highlighted by the original publication. These include: the concept of risk; how risk is evaluated and measured; what outcomes regulation is seeking to achieve; and, the decision making framework deployed.

11. Which parts of *Right-touch regulation* do you find least useful and why?
(Please refer to specific sections from the document if possible, and illustrate with examples)

All aspects of the publication provide a helpful contribution to debates about regulatory development.

12. Which elements or concepts do you think would be most suitable for further development?

As referenced above (response to question 10), the original publication touched on important and significant concepts. We think these could be developed further in light of some of the high profile failures of care seen in the UK health and care system in recent years. For the GPhC we have taken a fresh look over the last few years at how we consider some of these issues and concepts which are underpinned by our Council's strategy for our regulatory work. These are briefly touched on below:

Outcomes: We have developed our regulatory approach which is focussed on outcomes but which also recognises that we may need proxy measurement given the complexity of measuring patient outcomes in our particular regulated sector.

Risk: We continue to consider whether risk should be seen in narrow patient safety terms, or whether it is important to consider opportunity cost and failure to intervene for the benefit of patients and wider quality of care. We also see it important to be open where risk is hard to quantify or measure and in those circumstances what alternative approaches might look like and how they are communicated.

Evaluation: We think evaluation should not be just about evaluation of risk, but evaluation of regulatory impact. This is fundamental in our view to being an agile and transparent regulator.

Impact: Linked to the above point, nearly all regulatory interventions will have consequences, intended or otherwise. These need to be kept under regular review so that any model is flexible and evidence based.

13. Which elements do you think require updating and how?

Building on the points above, there are inevitable limitations to principle-based regulation. To take one example, interpretations of what is proportionate may be as numerous as the number of regulators. Therefore it is critical that any regulator describes not only their intention to be proportionate, but also how they are doing so, and be willing to describe what they are seeking to achieve and how others will be able to judge success.

This may be pertinent to consideration of risk and the use of data, information and intelligence. What recent history has shown is that intelligence needs to be informed in part by data, but also be people – both professionals and patients who are best placed to view the delivery and receipt of care.

To some, regulatory theory is two-dimensional; an assessment of risk on the one hand and regulatory intervention on the other. We see this as increasingly limiting in our particular context and believe it should be seen as three dimensional, considering much wider issues around quality and improvement.

As such, the *right-touch regulation* decision tree may need reviewing or updating.

14. Are there any other ways in which we could build on Right-touch regulation?

Please see above responses.

15. We would like to start to position *Right-touch regulation* within the relevant literature. In your view, how does it link to other published work?

We see *right-touch regulation* as a helpful contribution to the ongoing debate about the role of regulation.

16. Have you referenced it in any academic or other work?

We have referenced Right-touch regulation, both directly and indirectly, in our policy publications and reports. For example, it was referenced directly in our Annual report; annual accounts; and annual fitness to practise report for 2010, as well as in Modernising pharmacy regulation: A consultation on the draft standards for registered pharmacies. Its principles are also referenced in different parts of our website and enshrined in our strategic and corporate publications.

17. Are there any other comments you would like to make about *Right-touch regulation*?

Not at this stage.

We would like to be able to quote and attribute material from your response in our published summary and final reports.

☐ Please tick this box if you do not want us to quote your response.

☐ Please tick this box if you are happy for us to quote your response but do not want us to attribute the quote to you.

If you have ticked either of these boxes, please explain why you regard the information you have provided in this questionnaire as confidential.

We will manage the information you provide in response to this consultation paper in accordance with our information security policies which can be found on our website (www.professionalstandards.org.uk).

Any information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA) the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential.

If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality will be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Professional Standards Authority.

The Professional Standards Authority will process any personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.