

## Response to Department for Business, Energy and Industrial Strategy consultation 'Reforming the Framework for Better Regulation'

October 2021

### 1. Introduction

- 1.1 The Professional Standards Authority for Health and Social Care promotes the health, safety and wellbeing of patients, service users and the public by raising standards of regulation and registration of people working in health and care. We are an independent body, accountable to the UK Parliament. More information about our work and the approach we take is available at [www.professionalstandards.org.uk](http://www.professionalstandards.org.uk)
- 1.2 As part of our work we:
- Oversee the ten health and care professional regulators and report annually to Parliament on their performance
  - Accredit registers of healthcare practitioners working in occupations not regulated by law through the Accredited Registers programme
  - Conduct research and advise the four UK governments on improvements in regulation
  - Promote right-touch regulation and publish papers on regulatory policy and practice.

### 2. General comments

- 2.1 We welcome the opportunity to respond to the Department for Business Energy and Industrial Strategy (BEIS) consultation on reforming the framework for better regulation.
- 2.2 We support the intention to ensure that the Better Regulation Framework supports proportionate, agile regulation with a focus on outcomes. It is important that regulation can respond and adapt to new and emerging challenges and opportunities. We welcome the continuing commitment to ensure public safety.
- 2.3 When taking forward changes to the Better Regulation Framework, Government should keep in mind that not all regulators directly regulate businesses. Of the regulators under our oversight, eight regulate individuals and two regulate both individuals and businesses. Health and social care are safety critical sectors where lack of regulation or poor regulation can mean serious harm or death to patients or service users.

- 2.4 The principles of good regulation<sup>1</sup> and the Better Regulation Framework that flows from them is well established and well understood within health regulation and across other regulated sectors. We built on these principles when developing our own approach of 'right-touch regulation'. This states that regulation should aim to be:
- Proportionate
  - Accountable
  - Consistent
  - Transparent
  - Targeted
  - Agile (our addition).<sup>2</sup>
- 2.5 *Right-touch regulation* outlines eight steps to take when considering whether to regulate.<sup>3</sup> It describes the approach we take in our own work and that we encourage the ten regulators we oversee and others to adopt.
- 2.6 The organisations that we oversee regulate health and care professionals across the UK as well as optical and pharmaceutical businesses. There is already much change underway for healthcare professional regulation.<sup>4</sup> Some of the reforms proposed by the Department of Health and Social Care (DHSC) echo proposals in this consultation in aiming to remove prescriptive detail from legislation and devolve greater responsibility to regulators. As outlined in our response to the DHSC consultation earlier this year, we support this, providing this additional flexibility is balanced by enhanced accountability.<sup>5</sup>
- 2.7 Any changes to the Better Regulation Framework must balance the desire to reduce regulatory burden with the need to ensure public safety. Regulators may come under pressure to amend or reduce regulatory requirements for many different reasons. In healthcare this may arise from workforce pressures or because of professional interests. Regulators should be sufficiently independent of government and operate within a framework that allows them to do what is necessary keep the public safe.

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<sup>1</sup> Better Regulation Task Force, *Principles of Good Regulation*. Available at: <https://webarchive.nationalarchives.gov.uk/ukgwa/20100407173247/http://archive.cabinetoffice.gov.uk/brc/upload/assets/www.brc.gov.uk/principlesleaflet.pdf>

<sup>2</sup> Professional Standards Authority 2015, *Right-touch regulation*. Available at: <https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=16>

<sup>3</sup> The eight steps of right-touch regulation are: 1) Identify the problem before the solution, 2) Quantify and qualify the risks, 3) Get as close to the problem as possible, 4) Focus on the outcome, 5) Use regulation only when necessary, 6) Keep it simple, 7) Check for unintended consequences, 8) Review and respond to change.

<sup>4</sup> Department of Health and Social Care, *Regulating healthcare professionals, Protecting the public*. Available at: <https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public>

<sup>5</sup> Professional Standards Authority response to 'Regulating healthcare professionals, Protecting the public'. Available at: [https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2021/authority-response-to-consultation-on-regulating-healthcare-professionals-protecting-the-public.pdf?sfvrsn=7a1a4920\\_4](https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2021/authority-response-to-consultation-on-regulating-healthcare-professionals-protecting-the-public.pdf?sfvrsn=7a1a4920_4)

- 2.8 We support the inclusion of proportionality as a core principle so long as this means proportionate to the risk of harm. Whilst competition and innovation are important considerations, they may not apply in the same way to regulators across different sectors. We therefore suggest that Government consider keeping the principles within the Better Regulation Framework higher level to allow it to continue to have relevance to regulators in different sectors. Other specific considerations for regulators operating in particular sectors could instead be built into guidance or any impact assessment requirements.
- 2.9 Government may wish to consider including ‘agility’ as an overarching principle as we have done within the right-touch regulation principles to reflect that regulation should look forward to anticipate change and adapt as required.
- 2.10 We are unclear from the consultation whether Government is proposing to scrap the existing principles of good regulation and replace them with the principles and duties outlined or whether it intends these to sit alongside the existing principles. If the former we are not aware of evidence to suggest that the other existing principles are no longer needed.
- 2.11 In its unique oversight role the Authority is well placed to ensure that professional regulators remain focussed on their objective of protecting the public but also take account of other key considerations. We would be happy to discuss our role further with colleagues within BEIS and whether there is more that we can do to support Government objectives in this area.
- 2.12 Our answers to the consultation questions are outlined below.

### **3. Detailed comments**

#### **The common law approach to regulation**

*Question 1: What areas of law (particularly retained EU law) would benefit from reform to adopt a less codified, more common law-focused approach?*

- 3.1 We have called for reforms to reforms to health professional regulation. Change is currently underway to move towards less prescriptive legislation with more detail within rules and guidance. We support this, provided that a less prescriptive approach is accompanied by enhanced accountability.

*Question 2: Please provide an explanation for any answers given.*

- 3.2 We are aware that professional regulators have struggled with prescriptive legislation which may become outdated and obstruct their ability to respond in an agile manner to new and emerging risks and opportunities.

*Question 3: Are there any areas of law where the Government should be cautious about adopting this approach?*

- 3.3 As the consultation document recognises, reforms should not compromise public safety. We therefore suggest that Government consider taking a more cautious approach in areas of regulation covering safety critical sectors such as healthcare where lack of regulation may result in severe harm or death.

Increased flexibility may still be desirable overall; however safety must remain paramount.

*Question 4: Please provide an explanation for any answers given.*

- 3.4 Whilst we do not suggest that healthcare regulation is unique, there are likely to be different considerations in sectors where the consequences are particularly serious.

*Question 5: Should a proportionality principle be mandated at the heart of all UK regulation?*

- 3.5 We agree that proportionality to risk should be a key consideration in deciding whether regulation is required. However, this is already captured through the existing principles for good regulation and in our own right-touch regulation approach which builds on these.
- 3.6 These principles are well known and established across different areas of regulation. It is unclear from the consultation document whether Government intends to replace these or add a further set of principles and duties to guide the regulatory approach in the UK.
- 3.7 If the intention is to replace them, we suggest further clarity on why the other principles outlined ('accountable', 'consistent', 'transparent', 'targeted') are no longer deemed valid for the purposes of reshaping the UK's regulatory approach post EU-Exit.
- 3.8 If the intention is to lay out an additional set of principles for consideration, we note that having multiple sets of principles for regulators may prove confusing, particularly where there is partial overlap.

*Question 6: Should a proportionality principle be designed to 1) ensure that regulations are proportionate with the level of risk being addressed and 2) focus on reaching the right outcome?*

- 3.9 Yes.

*Question 7: If no, please explain alternative suggestions.*

- 3.10 N/A

### **The role of regulators**

*Question 8: Should competition be embedded into existing guidance for regulators or embedded into regulators' statutory objectives?*

- a. Embedded into existing guidance*
- b. Embedded into statutory objectives*
- c. Creating reporting requirements for regulators*
- d. Other (please explain)*

- 3.11 We support the intention to promote competition which if implemented in the right way may ultimately increase choice and support a higher quality of care for patients and service users. Although only two regulators that we oversee (the General Optical Council and the General Pharmaceutical Council) regulate businesses, many individual professionals run or operate businesses, for example dental and GP practices. Furthermore competition has relevance to workforce which is a key issue within health and care.
- 3.12 However competition is likely to apply in different ways to regulators across different sectors. The regulators that we oversee share an overarching objective of public protection and each regulate one or multiple health or care professions. In most cases they are the sole regulator of each profession within the UK and are responsible for setting the standards of practice and controlling access to the Register. Whilst competition is not always at odds with public protection in certain circumstances there may be a tension between the two.
- 3.13 It therefore may not be appropriate to embed a duty to promote competition within the statutory objectives for healthcare professional regulators. It may instead be possible to reflect this as a consideration in guidance. It is important that this is framed to ensure that it is clear that in a sector such as healthcare safety must come first.

*Question 9: Should innovation be embedded into existing guidance for regulators or embedded into regulators' statutory objectives?*

*a. Embedded into existing guidance*

*b. Embedded into statutory objectives*

*c. Creating reporting requirements for regulators*

*d. Other (please explain)*

- 3.14 We agree that there is a need for regulators to consider innovation and ensure that their approach and processes support innovation within the health sector. We have observed that regulators have sometimes been slow to respond to technological and other developments within healthcare and to find agile ways to support flexible delivery of care and manage emerging areas of risk in a proportionate way. Recent health sector innovations which have required creative regulatory approaches include provision of online services such as prescriptions, contact lenses and online health consultations.
- 3.15 However, as with competition innovation is likely to apply to different sectors in different ways. As noted under our answer to question 8, professional regulators are all bound by an overarching duty of public protection. It may therefore not be appropriate to embed a duty to promote innovation within statutory objectives but instead reflect within guidance as appropriate or consider introducing as a reporting requirement whilst being mindful of the potential burden on regulators.

- 3.16 We also note a potential role for the Authority as oversight body in reviewing the approach of regulators in taking account of these considerations.

*Question 10: Are there any other factors that should be embedded into framework conditions for regulators?*

- 3.17 We developed our right-touch regulation approach which builds on the principles of good regulation and added 'agility' as a sixth principle. This is intended to ensure that regulation can look forward to anticipate change and adapt as required. Agility may be a suitable concept for inclusion within overarching principles for regulators across all sectors which could capture the need to be forward looking and conscious of external developments.

*Question 11: Should the Government delegate greater flexibility to regulators to put the principles of agile regulation into practice, allowing more to be done through decisions, guidance and rules rather than legislation?*

- 3.18 In principle we support allowing regulators greater flexibility to be agile. Reform is already underway within healthcare professional regulation where the Department of Health and Social Care (DHSC) has recently consulted on removing much of the prescriptive detail from legislation with the intention for regulators to have the ability shape their own operating procedures through rules. This is positive as we are aware that professional regulators have struggled with legislation that does not easily support agile regulation.
- 3.19 However, additional flexibility, particularly where there are multiple regulators as in professional regulation, may increase the risk of unjustifiable inconsistencies arising, which may make it more difficult for regulators to collaborate including on areas such as innovation.
- 3.20 We also believe that in a safety critical sector such as healthcare it is important to maintain an appropriate balance between prescription and flexibility. For example, it may be appropriate for the core regulatory duties to continue to be laid out consistently in legislation, but greater flexibility permitted over how these are delivered.
- 3.21 We also believe that where greater flexibility and autonomy is delegated to regulators it may be appropriate to review arrangements for accountability. This could also encompass arrangements to ensure that regulators are continuing to take account of key considerations such as competition and innovation.

*Question 12: Which of these options, if any, do you think would increase the number and impact of regulatory sandboxes?*

*a. legislating to give regulators the same powers, subject to safeguarding duties*

*b. regulators given a legal duty*

*c. presumption of sandboxing for businesses*

- 3.22 We note that the concept of regulatory sandboxing has been used within healthcare in the UK however it is likely to have more limited application than within other sectors where the focus is on business or financial services regulation.
- 3.23 The consequences of suspending or altering regulatory requirements intended to protect patients may be significant and therefore we do not believe a presumption of sandboxing is necessarily appropriate. However, there may be a place for further use of this as a mechanism to develop new approaches to managing emerging areas of risk.
- 3.24 In professional regulation it is important to note that for new roles there is already an alternative to statutory regulation in the form of the Accredited Registers programme. This can help to manage risks whilst a new role is being brought into the workforce.

*Question 13: Are there alternative options the Government should be considering to increase the number and impact of regulatory sandboxes?*

- 3.25 No view.

*Question 14: If greater flexibility is delegated to regulators, do you agree that they should be more directly accountable to Government and Parliament?*

- 3.26 We agree that if greater flexibility is delegated to regulators this should be balanced with enhanced accountability. Within healthcare professional regulation, professional regulators are already accountable to Parliament.
- 3.27 It is our view that accountability to Parliament is more appropriate for regulators and oversight bodies as this reduces the risk that regulatory objectives such as public protection are compromised by any closer political control by Government and helps to maintain the independence of regulators.
- 3.28 In the context of the current planned reforms to healthcare professional regulation we suggested, in our response to the public consultation by the DHSC earlier this year, that it would be appropriate to consider enhanced powers for the Authority as the oversight body to counterbalance the additional flexibility proposed. This included a formal role for the Authority to advise on whether regulators have following an appropriate process when making or amending rules.<sup>6</sup> We are currently awaiting the Government response to the consultation.
- 3.29 Whilst we recognise that oversight bodies are not in existence across all regulated sectors we suggest that BEIS may wish to consider the role that bodies such as ourselves can play in encouraging regulators to have regard to the considerations outlined in this consultation.

*Question 15: If you agree, what is the best way to achieve this accountability? If you disagree, please explain why?*

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<sup>6</sup> Professional Standards Authority response to 'Regulating healthcare professionals, Protecting the public'. Available at: <https://www.professionalstandards.org.uk/publications/detail/professional-standards-authority-response-to-regulating-healthcare-professionals-protecting-the-public>

3.30 See answer to question 14.

*Question 16: Should regulators be invited to survey those they regulate regarding options for regulatory reform and changes to the regulator's approach?*

3.31 Yes. Within health professional regulation there is already an active programme of reform underway including the recent DHSC consultation which has had wide involvement from professional bodies representing regulated professionals as well as bodies representing the interests of patients and service users.

3.32 We agree that Government, when making changes to regulations, and regulators themselves should always engage with those they regulate on reform and any changes proposed. However, it is equally important that regulators engage with or seek the views of the beneficiaries of robust regulation, in most cases the public.

3.33 As part of the reforms to professional regulator governance DHSC proposed to require regulators to consult on 'significant changes to rules and standards'. We support this but have commented that this should include the full range of stakeholders who may be affected by such changes.

*Question 17: Should there be independent deep dives of individual regulators to understand where change could be introduced to improve processes for the regulated businesses?*

3.34 It would be helpful to understand how this proposal might differ from tailored reviews. We think that regulators should be responsible for reviewing their own processes on an ongoing basis to consider where improvements could be made. There may also be a role for the Authority as the oversight body for the professional regulators to monitor how effectively they do this.

3.35 However, if this is taken forward, we think that a review of any individual regulator should take into account not only where change could be introduced to improve processes for those that are regulated but also where change could improve outcomes for those that are protected by regulation. BEIS should also consider the range of different mechanisms that may be in place for reviewing processes for particular groups of regulators.

### **Revising the process and requirements of better regulation**

*Question 18: Do you think that the early scrutiny of policy proposals will encourage alternatives to regulation to be considered?*

3.36 Yes, however a shift away from a binary approach to regulation will be needed in some sectors.

3.37 In healthcare professional regulation we have called for non-regulatory approaches to assurance for lower risk occupations to be actively considered ahead of pursuing statutory regulation. We have developed a tool which advises on the most appropriate form of oversight for healthcare occupations



based on a thorough assessment of the nature and level of risks arising from practice.<sup>7</sup>

- 3.38 The Authority operates the Accredited Registers programme which accredits voluntary registers of health and care practitioners not regulated by law. This provides an alternative mechanism for managing moderate levels of risk however requires buy in from stakeholders to ensure sufficient awareness and participation.

*Question 19: If no, what would you suggest instead?*

- 3.39 N/A

*Question 20: Should the consideration of standards as an alternative or complement to regulation be embedded into this early scrutiny process?*

- 3.40 Yes, we think there should be a range of different methods for managing risk.
- 3.41 In the context of healthcare professional regulation we have described a 'continuum of assurance' for healthcare occupations ranging from employer controls for lower risk occupations through to statutory professional regulation for higher risk roles.
- 3.42 A clear and thorough assessment of the risk of harm arising at the outset should allow consideration of the different mechanisms available to effectively manage the risk. *Right-touch assurance* outlines our tool for assessing occupational risk and determining the best way to manage it.

*Question 21: Do you think that a new streamlined process for assessing regulatory impacts would ensure that enough information on impacts is captured?*

- 3.43 Yes, but as previously stated, this should consider the impact of regulation both on those that are regulated and also those who benefit from regulation.

*Question 22: If no, what would you suggest instead?*

- 3.44 N/A

*Question 23: Are there any other changes you would suggest to improve impact assessments?*

- 3.45 No.

*Question 24: What impacts should be captured in the Better Regulation framework? Select all which apply:*

*a. Innovation*

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<sup>7</sup> Professional Standards Authority 2016, *Right-touch assurance - methodology for assessing and assuring occupational risk of harm*. Available at: [https://www.professionalstandards.org.uk/docs/default-source/publications/right-touch-assurance---a-methodology-for-assessing-and-assuring-occupational-risk-of-harm-\(october-2016\).pdf?sfvrsn=f21a7020\\_0](https://www.professionalstandards.org.uk/docs/default-source/publications/right-touch-assurance---a-methodology-for-assessing-and-assuring-occupational-risk-of-harm-(october-2016).pdf?sfvrsn=f21a7020_0)

*b. Trade and Investment*

*c. Competition*

*d. Environment*

3.46 We suggest 'safety' or similar as a way of capturing the benefits of a regulatory intervention would be useful.

*Question 25: How can these objectives be embedded into the Better Regulation Framework? Can this be achieved via:*

*a. A requirement to consider these impacts,*

*b. Ensuring regulatory impacts continue to feature in impact assessments,*

*c. Encouragement and guidance to consider these impacts, but outside of IAs,*

*d. Other? (please explain)*

3.47 No view.

### **Scrutiny of regulatory proposals**

*Question 26: The current system requires a mandatory PIR to be completed after 5 years. Do you think an earlier mandated review point, after 2 years, would encourage more effective review practices?*

3.48 No view.

*Question 27: If no, what would you suggest instead?*

3.49 N/A

*Question 28: Which of the options described in paragraph 3.4.10 would ensure a robust and effective framework for scrutinising regulatory proposals?*

*a. Option 1*

*b. Option 2*

*c. Option 3*

*d. Other (please explain)*

3.50 We suggest that either Option 2 or Option 3 are likely to ensure that scrutiny of regulatory proposals is sufficiently robust and benefit from advice independent of Government processes.

### **Measuring the impact of regulation**

*Question 29: Which of the four options presented under paragraph 3.5.4 would be better to achieve the objective of striking a balance between economic growth and public protections?*

- a. Adjust
- b. Change
- c. Replace
- d. Remove
- e. Other (please explain)

3.51 No view.

### **Regulatory offsetting: One-in, X-out**

*Question 30: Should the One-in, X-out approach be reintroduced in the UK?*

- 3.52 As we note in our answers to previous questions, regulation should only be used when it is the best way of managing risks therefore it follows that it should only need to be removed where the risk has significantly diminished or changed. This should be on a case-by-case basis and shouldn't be within the scope of any arbitrary deregulation target.
- 3.53 It may be valuable instead to build in regular reviews of different regulations to ensure they remain necessary and justified.

*Question 31: What do you think are the advantages of this approach?*

3.54 No view.

*Question 32: What do you think are the disadvantages of this approach?*

- 3.55 If this was to cover regulation in safety critical sectors such as health this may lead to the arbitrary reduction or removal of measures designed to keep patients and service users safe.

*Question 33: How important do you think it is to baseline regulatory burdens in the UK?*

- a. Very important
- b. Somewhat important
- c. Somewhat unimportant
- d. Not very important

3.56 No view.

*Question 34: How best can One-in, X-out be delivered?*

3.57 No view.

## Further comments

*Question 35: Are there any other matters not mentioned above you would suggest the Government does to improve the UK regulatory framework?*

- 3.58 In October 2020 we responded to the BEIS call for evidence on recognition of qualifications and regulation of professions in the UK. Part of this has now been addressed through the Professional Qualifications Bill which seeks to introduce a new framework for recognition of international professional qualifications and experience.
- 3.59 However, the call or evidence and subsequent communications from BEIS indicated that Government were also seeking to introduce a new approach to domestic regulation of professions across the UK to support a strengthened internal market and support free movement of workforce across the UK.
- 3.60 In this response we have also mentioned the ongoing programme of work by DHSC to reform health professional regulation which includes the introduction of a new set of duties for regulators.
- 3.61 We would welcome any further details from BEIS on how these other areas of work link with the review of the better regulation framework.

## 4. Further information

- 4.1 Please get in touch if you would like to discuss any aspect of this response in further detail. You can contact us at:

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