Department for Business & Trade

# SMARTER REGULATION AND THE REGULATORY LANDSCAPE:

## CALL FOR EVIDENCE

**This call for evidence closes 11:59pm on 17 January 2024**

Published 17 October 2023

A clear strategy for oversight the points

Single regulator under the international comparison, a general point about considating where it may bring benefits, common code.

Department for
Business & Trade

# Introduction

On 10 May 2023, the Government published Smarter Regulation to Grow the Economy. This introductory report set out our vision for regulation and committed to a series of regulatory reform announcements across the year to benefit businesses and drive innovation and growth.

When delivered effectively, regulation and the work of regulators plays a vital role in protecting consumers, the environment and setting the right frameworks for businesses to thrive. Smarter regulation is about only using regulation where necessary, implementing it well, and ensuring its use is proportionate and future-proof. Through this lens, the Smarter Regulation programme across government - led by the Department for Business and Trade - has three core pillars:

- **Minimising regulatory burden and future-proofing regulations**. We are reforming the existing stock of regulation to cut regulatory burdens and future-proof our approach. This spans both reforms to Retained EU Law (REUL) using the powers in the Retained EU Law Act, as well as wider domestic regulations. Regulations that are not needed will be removed, while those that are needed must be proportionate, contemporary and forward-looking.

- **Making regulation a last resort, not a first choice**. This means putting downward pressure on the flow of new regulation, with alternatives deployed wherever possible.

- **Ensuring a well-functioning landscape of regulators**. Regulators have a significant footprint on the economy, and as such it is essential that regulators work well for the UK. They should operate in an agile and outcome-driven fashion and help drive economic growth - while protecting consumers and ensuring that markets work as well as they can.

Since 10 May 2023, we have already announced reforms across each of these areas. First, on the stock of existing regulation, we have already reformed or revoked over 1,000 pieces of REUL with 1,000 more reforms and revocations underway. We have also launched consultations on reforming REUL employment law; wine sector reforms; and the product safety review and fire safety of domestic upholstered furniture. The latter two consultations will future-proof our approach to product regulation, alongside our announcement to indefinitely extend recognition of the CE mark. Second, our new Better Regulation Framework launched in the summer, to put downward pressure on the flow of new regulation; encourage alternatives as far as possible and allow for a wider consideration of impacts. Third, we launched a series of consultations aimed at improving the outcomes that independent regulation delivers - this includes a Strategic Steer for the Competition and Markets Authority; Strategy and Policy Statement for Energy regulation; most recently we consulted on extending the existing growth duty to Ofgem, Ofcom and Ofwat and published wider findings on efficiency and effectiveness of regulation in an independent review into the Civil Aviation Authority as part of the Cabinet Office Public Bodies Review programme.

A full collection of smarter regulation announcements can be found on the Smarter Regulation Landing page.

There are more opportunities to seize in both reforming the stock of regulation and in ensuring that the wider landscape of independent regulation delivers for the UK. This call for evidence is the next step that the Government is taking to ensure that we have a world-leading regulatory system.

# The Purpose and Scope of this Call for Evidence

Stakeholder feedback and views is essential to informing the Smarter Regulation programme of regulatory reform, to improve outcomes for businesses and consumers. The first and principal focus of this call for evidence is to understand what works well and what could be improved in how regulators operate to deliver for the sectors they serve.

We are particularly interested in success stories and areas for improvement on regulatory agility; proportionality; and consistency of approach. Second, we are also interested to understand any further steps we can take to reform the existing stock of regulation on the UK Statute book (both Retained EU Law and wider regulations) and ask a supplementary question on this.

The questions that we ask are general and not specific to any given regulators. However, we welcome, where helpful in your answer, specific examples or case studies from your experience of interacting with individual regulators. For the purpose of this call for evidence, we welcome hearing about any central government public bodies with a regulatory function and a territorial scope of the whole UK, Great Britain or England and Wales only.[1]

We welcome hearing from all stakeholders with views on regulatory reform and how independent regulation works. We are particularly interested in responses from small businesses and consumers.

We welcome responses from all stakeholders across all sectors in the economy, but note that we are not seeking views on financial services regulators and regulations. These are handled by HM Treasury, where there have been positive and industry-welcomed reforms in this space in recent years.

[1] This definition means the scope of this review broadly covers most independent regulatory authorities, but not local authorities. If there is a particular regulator that you feel should be applicable to this Call for Evidence but does meet this scope, please do let us know in your responses - setting out why, focusing for example on the significance of its impact.

# Audience of this Call for Evidence

The majority of the questions in this call for evidence are, unless otherwise stated, applicable to all stakeholders - businesses; consumers; regulatory bodies, and other bodies. We recognise that the lens through which you provide answers will differ:

- If you are a business, we want to hear about your experience of interacting with regulators, including both your perception of regulatory complexity and costs as well as the benefits. The more detail you can provide us, the better.
- If you are a regulator, we want to know about your experiences managing relationships with your regulated businesses; your sponsoring policy department; and the consumers you protect - or whoever the ultimate beneficiary of the regulatory activity is intended to be. We want to know what causes tension between your desire to help businesses grow; to secure good outcomes for consumers; and your need to discharge your statutory functions.
- If you are neither of those, tell us who you are and give us your views, making clear in what capacity you were involved in each example. For example, we welcome responses from consumers and consumer groups.

# Structure of this Call for Evidence

We encourage respondents to answers as many questions as possible, but also recognise that respondents may wish to be target responses to areas of interest. The call for evidence is structured as follows:

- **Section 1: Preliminary questions,** asks for some high-level views on the regulatory landscape. We ask that all respondents complete this section. (Questions 1 - 3)
- **Section 2: Complexity and Ease of Understanding the Regulatory System**, asks important questions on how easy it is to navigate the landscape of regulators and understand what their objectives are. We recommend that all respondents complete this section. (Questions 4 - 12)
- **Section 3: Regulator Agility, Responsiveness and Skills**, covers the speed with which regulators make decisions and whether they have the right balance of skills to deliver effectively. We particularly encourage regulatory authorities and regulated businesses to respond to this section. (Questions 13 - 19)
- **Section 4: Proportionality in Implementing Regulation**, is concerned with whether the approach of regulatory authorities to delivering outcomes is proportionate. We particularly welcome responses from regulated businesses and consumers. (Questions 20 - 27)
- **Section 5: Process and Governance**, is concerned with whether the governance structures of regulatory authorities are conducive to delivering the best outcomes and whether the rationale for decisions is well communicated. We particularly welcome responses from regulated businesses and regulatory authorities. (Questions 28 - 35)
- **Section 6: Regulator Performance**, asks for views on whether regulators are delivering on their objectives and whether there is sufficient performance monitoring in place. We particularly welcome responses from regulated businesses and consumers. (Questions 36 - 38)
- **Section 7: Concluding questions**, asks some general closing questions on regulation as a whole, including whether there are international examples of best practice that regulatory authorities could adopt. We encourage all respondents to answers these questions. (Questions 39 - 42)
- **Section 8: Closing Questions**, asks some background questions on the respondent, including the capacity in which they are responding to this Call for Evidence. We encourage all respondents to answer these questions. (Questions 43 - 49)

# Duration of this Call for Evidence

This Call for Evidence will last for 13 weeks and close on the 17th of January 2024

# Confidentiality of Responses

Information you provide in response to this consultation, including personal information, may be disclosed in accordance with UK legislation (the Freedom of Information Act 2000, the Data Protection Act 2018 and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please tell us, but be aware that we cannot guarantee confidentiality in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not be regarded by us as a confidentiality request.

We will process your personal data in accordance with all applicable UK and EU data protection laws. See our privacy policy.

We may summarise all responses and publish this summary on GOV.UK. The summary may include a high level list of respondents, but not people's personal names, addresses, e-mails, or other contact details

We do not intend to publish individual responses.

# Quality assurance

This consultation has been carried out in accordance with the government's consultation principles.

If you have any complaints about the way this consultation has been conducted, please email: smarter.regulation@businessandtrade.gov.uk

# Next Steps

Once the Call for Evidence has closed, the Review team will review and analyse the responses received.

# Section One: Questions on the Landscape of Regulation (Required)

There are around 90 regulators in the UK and they spend almost £5bn per year across regulatory activities and running costs, covering most sectors of the economy.[2] The scale and responsibility assigned to regulators makes the performance of these entities in delivering the best outcomes in the sectors/areas that they regulate key to the UK's economic success.

*Please note that any questions asked about a 'regulator' is pertaining to the relevant regulatory body to your answer. We are not seeking information about individual persons employed by regulatory bodies.*

*The Professional Standards Authority for Health and Social Care (PSA) 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*

*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.*

*We have set out the regulators we oversee in question two, but it is useful to describe the nature of the regulators we oversee to provided context to all the answers given. Most regulatory activity of the ten regulators we oversee is regulating people not business or products. Moreover, many of these individuals work partially or wholly within the NHS and public sector.*

*We understand the focus of this the focus of this call for evidence may be on the regulation of business.*

*Nevertheless insights from professional regulation may be relevant and there may be overlap across sectors. We are also aware that professional regulation may not always be central in considerations of the wider policy landscape, however we believe the unique considerations of regulating professionals are crucial to understanding the regulatory system as a whole*

*In responding to these questions, in the context of our oversight of the statutory regulators, some of our answers touch upon matters of regulatory policy that we have considered over a number of years, while others go to matters related to the current performance of regulators (which we assess through performance reviews), and other answers go to current issues within the policy context in which we operate.*

[2] See https://www.nao.org.uk/wp-content/uploads/2020/03/Overview-Regulation-2019.pdf.

*In so far as answers go to matters regarding regulatory policy, you may wish to review some of our previous statements. Examples of these are:*

- *Right touch regulation Revised*[3]
- *Right Touch Assurance*[4]
- *Regulation Rethought*[5]
- *Right touch reform*[6]

*Further policy statements can be found on our website. We provide some comment on regulatory performance and specific policy issues in answering the questions that follow.*

**Question 1:** Based on your experience, do you think that UK regulators are supportive of the individual businesses they regulate in a way that appropriately balances considerations of consumers and other businesses within the sector more broadly?

*In our report 'Safer Care For All'*[7] *we reflect emerging issues that regulators need to be able to respond to, with regard to balancing commercial interests and public protection. We describe a growing trend away from established models of provision of health and care, with 'the increasing role of for-profit providers and the conflicts of interest this presents, to the rise in online services, to the expansion of new and innovative models of care'*

*Below is our evaluation of regulators' ability to maintain the balance between commercial interests and public protection, and our associated recommendations for government.*

*'By and large, healthcare professional regulators are aware of the issues and are already taking action to manage risks and protect the public. However, they are sometimes reluctant to intervene (for example in matters relating to commercial practices) even where there is a legitimate case for doing so. This is partly due to the risk of challenge if there is no specific duty to act. They are also hampered by outdated and overly prescriptive legislation, and some lack the powers they need to protect the public effectively"*8

*We recommend that Governments use the current healthcare professional regulation reform programme to:*

*a. Review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses*

[3] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-regulation-2015.pdf?sfvrsn=eaf77f20_20
[4] 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
[5] https://www.professionalstandards.org.uk/docs/default-source/publications/regulation-rethoughtd6c718f761926971a151ff000072e7a6.pdf?sfvrsn=48557120_0
[6] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/right-touch-reform-2017.pdf?sfvrsn=2e517320_7
[7] Safer Care For All, The Professional Standards Authority, 2022 https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/safer-care-for-all-solutions-from-professional-regulation-and-beyond.pdf?sfvrsn=9364b20_7

*b. Consider whether there is a case for extending business regulation powers to all regulators whose registrants work in 'high street' practices*

*c. Ensure regulators have the agility to address the challenges brought about by new approaches to funding and delivering care, including the introduction of new technologies.*

*Reform should be considered on two fronts: firstly, the powers of those regulators with a role in regulating businesses should be reviewed. This should focus on the effectiveness and adequacy of current powers (for example, inspection powers, powers to require businesses to register, levels of fines etc), and whether they are sufficient to protect the public and hold businesses to account. Secondly, the UK Governments should consider extending business regulation powers to all regulators whose registrants work in 'high street' practices and, in doing so, should assess any regulatory gaps arising from the current system.*

*The Government committed to considering 'professional regulators' roles in regulating businesses and premises' in 2019.The Authority has previously called for healthcare professions and high street premises to be regulated together, and in our view this remains the most logical approach. The Governments should use the current programme of regulatory reform to review the adequacy and effectiveness of the powers of regulators with a role in regulating businesses. It should also consider whether there is a case for extending business regulation powers to other regulators whose individual registrants work in 'high street' practices. As the Governments have already set out their view that 'regulators should have broadly equivalent powers to maintain a level of consistency and effective public protection', we hope these recommendations will support reform in this area.'*

**Question 2:** Please name the UK regulator(s) you engage with most frequently:

*Our role includes the oversight of ten statutory regulators:*

*General Chiropractic Council*

*General Dental Council*

*General Medical Council*

*General Optical Council*

*General Osteopathic Council*

*Health and Care Professions Council*

*Nursing and Midwifery Council*

*Pharmaceutical Society of Northern Ireland*

*General Pharmaceutical Council*

*Social Work England*

*In addition to this, we independently assess organisations that hold non-statutory registers using our Standards for Accredited Registers. We award a 'Quality Mark' to organisations that meet all of*

*these standards, to show that an organisation is committed to protecting the public and is working to good practice.*

*You can see the full list of Accredited Registers, and the occupations they cover on our website.*[9]

**Question 3:** What do you consider to be the most positive and/or negative aspect of how the UK regulators that you engage with operate?

*We conduct regulator performance reviews of the regulators we oversee, and publish our findings*[10]*.*

*As set out in law, the regulators we oversee have an overarching duty to protect the public.*

*According to the law, this involves:*

*• protecting, promoting and maintaining the health, safety and wellbeing of the public*

*• promoting and maintaining public confidence in the professions regulated by the regulatory bodies*

*• promoting and maintaining proper professional standards and conduct for members of those professions. In regulation, simplicity is key. We believe this clear focus and purpose is advantageous to the functioning of regulators. There is a risk in giving them multiple, possibly competing objectives that they may find it increasingly difficult to know what to prioritise This focus on public protection provides a clear remit for the regulators to fulfil their functions.*

*For example, in Safer Care For All*[11]*, we outlined our support for steps taken by regulators to cultivate trust with profession. However, we did point out that 'there is a fine line between cultivating trust, and getting too close to the profession; the latter comes with the risk of becoming a less effective regulator, insufficiently focused on all three limbs of public protection. The PSA and the regulators we oversee will need to stay vigilant to ensure that the cumulative effect of these initiatives does not compromise our ability to protect the public effectively.'*

*A vital component of public protection must be listening to the experiences and feedback of patients, service users and the public. It remains essential that the regulators that we oversee continue to make the effort to listen to patients and the public, including listening to the voices of those typically underserved.*

[9] https://www.professionalstandards.org.uk/what-we-do/accredited-registers/find-a-register
[10] https://www.professionalstandards.org.uk/what-we-do/our-work-with-regulators/read-performance-reviews
[11] Safer Care For All, The Professional Standards Authority, 2022 https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/safer-care-for-all-solutions-from-professional-regulation-and-beyond.pdf?sfvrsn=9364b20_7

# Section Two: Complexity and Ease of Understanding the Regulatory System

The large number of regulators in the UK is driven in part by the scale of our economy and the range of different sectors and activities that require some form of regulation, whether to ensure markets work well or to otherwise protect workers, consumers, and other members of the public. While this structure may have advantages in terms of scope, we also recognise that it creates risks of overlaps or duplications between the mandates of different - potentially increasing complexity for those being regulated and the burden of regulation.

Statutory duties are placed on the regulators through legislation. Regulators often have a set of duties across different primary and secondary legislation which they must fulfil in carrying out their core functions. They also frequently have wider objectives, for instance as set out in statutory guidance.

*We are aware that not all questions will be relevant to all respondents. Please address as many questions as are relevant to your experience.*

**Question 4**: Based on your experience or understanding of UK regulators, do you find it clear what the overall purpose and objectives of individual regulators are?

*As discussed in response to question three, the regulators we oversee, and the PSA itself, all share the same overarching objective to protect the public. This is a relatively recent development, having been introduced in 2015, and has helped to bring some coherence to the framework of professional regulation in health and care, which is formed of multiple bodies. We understand that this objective will be carried over to the new legislative framework for these regulators, under the current set of reforms to professional regulation.*

*However, in a number of our policy statements over recent years, for example Rethinking regulation12, we have described the complexity of the regulatory landscape in the health and care sector as a whole, and the difficulties this creates for those wishing to engage with regulation . For example, to understand the functions and duties of the regulator, and how these interact with those of other organisations with responsibilities to patient safety.*

**Question 5:** Within these overall objectives (as considered in the preceding question), do you find it clear what the specific statutory duties (i.e required by legislation) of individual UK regulators are?

*See questions 3 and 4.*

[12] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf

**Question 6:** Do you think that the statutory duties (i.e required by legislation) imposed on UK regulators:

1. Cover the right issues?
2. Are clearly stated in relevant statute, including where supplemented by relevant guidance?; and
3. Are sufficiently consistent across regulators, where this is relevant?

*No response*

**Question 7:** As set out above, UK regulators have a remit that is set through legislation and guidance. Which of the below do you consider best applies?

1. Regulators always act within the scope of their remit;
2. Regulators go beyond their remit in a way that may negatively impact the outcomes that they are required to deliver; or
3. Regulators go beyond their remit in a way that supports the outcomes they are required to deliver

*We have not seen evidence which indicates the regulators we oversee go beyond their remit in a way which negatively impacts the outcomes they are required to deliver. Rather, we are seeing positive examples of regulators working at the boundaries of their remit, alongside stakeholders, to maximise their contribution to the safety of care.*

**Question 8:** Do you often have to engage multiple UK regulators on the same issue or area?

1. Yes
2. No

*Yes, we oversee 10 professional regulators of professions in health and care. We play a convening role to facilitate and encourage collaboration between regulators, hosting fora and conferences to support discussion of current and future issues and policy concerns, and to share learning and research.*

*While each of these regulators regulates different professions, these professionals often work in similar contexts, in the same premises and multi-disciplinary teams.*

**Question 9:** Do you consider that UK regulators collaborate effectively with each other and their international counterparts?

**Question 10:** Where you engage with multiple UK regulators, do you find it clear which regulator is responsible for a specific issue or area, and how regulator mandates interact?

**Question 11:** Do you consider there to be underregulated areas of the economy, or gaps in regulatory responsibility between UK regulators?

*We have taken the answers to questions 9,10 and 11 together.*

*The PSA is one of a number of bodies to have highlighted the complexity of the regulatory framework in both health and social care.* [13] *The multitude of regulators in the sector has been found to be an obstacle to effective harm prevention by a number of public inquiries and reviews*[14]*. People both within and outside the system are unsure about where to direct complaints or information. We know that regulators are committed to working together, as evidenced by the existence of a range of cross-regulator working groups. But however committed organisations may be to joint working, the boundaries between them are necessarily obstacles to the free transfer of data and information. In addition, no one has oversight of the system as a whole, to ensure that it is working effectively to protect patients.*

*Among the regulators we oversee – 10 professional regulators (listed above) – we do not see much overlap, as they have clear remits relating to the different professions they regulate. The bigger concerns relate to the complexity, gaps and silo working that are a necessary consequence of having multiple regulators operating within the same sector regulating different aspects of health and care.*

*. We should point out though that professional regulators are only one part of the regulatory framework, which is itself only one part of the patient safety system. A recent study identified 126 different organisations that exerted a regulatory influence over the provision of care in the NHS.* [15] *Any reform of regulation in healthcare would ideally be part of a broad review of the safety system, such as has been called for by the Parliamentary and Health Service Ombudsman.*[16]

*We would like to see the creation of a role with oversight of the patient safety system as a whole, to ensure that it is working effectively to avert and address risks of harm. We would expect it to consider the effectiveness of regulatory and non-regulatory mechanisms for keeping patients safe, and to make recommendations for improvements, to include remit gaps and overlaps. For England, we would like to see this broader role taken on by the Patient Safety Commissioner, whose current jurisdiction is limited to medicines and medical devices. More information on our Commissioner proposal can be found within Safer Care For All.*[17]

[13] https://www.professionalstandards.org.uk/safer-care-for-all
https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/rethinking-regulation-2015.pdf
https://www.ombudsman.org.uk/publications/broken-trust-making-patient-safety-more-just-promise-0
[14] Such as Mid-Staffordshire https://assets.publishing.service.gov.uk/media/5a7ba0faed915d13110607c8/0947.pdf, Paterson Paterson Inquiry report - GOV.UK (www.gov.uk), and Cumberlege First Do No Harm (immdsreview.org.uk)
[15] Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare - PMC (nih.gov)
[16] https://www.ombudsman.org.uk/publications/broken-trust-making-patient-safety-more-just-promise-0
[17] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/safer-care-for-all-solutions-from-professional-regulation-and-beyond.pdf?sfvrsn=9364b20_7

**Question 12:** Do you consider that guidance issued by UK regulatory bodies makes the regulatory system clearer and easier to understand?

*No response*

# Section Three: Regulator Agility, Responsiveness and Skills

Regulators need to be responsive to change and wider systemic factors. As new issues and novel technologies emerge, regulators must be adaptive, coherent and coordinated to ensure that issues do not fall through the cracks and that responses are timely. Regulator agility means quick and effective implementation of current rules, as well as adapting rules when circumstances change and it is appropriate to do so.

*We are aware that not all questions will be relevant to all respondents. Please address as many questions as are relevant to your experience.*

**Question 13:** Do you find UK regulators to be agile and responsive to new and emerging issues?

**Question 14:** What factors do you think work for and against UK regulators' ability to respond sufficiently rapidly?

*We have taken question 13 and 14 together:*

*We have previously raised concerns of the ability of regulators, with constrained legislation to respond to the pace of change, in the context of changing models in the funding and delivery of care.*

*Emerging technology, and artificial intelligence specifically, provides an example of this. It is a challenge for regulators to keep pace with developments, their implications for the professionals they regulate, and how best to evaluate and address the risks arising. With the use of AI and technology in our sector, the management of risks is spread across a number of regulatory bodies, making it a particularly challenging area to respond to – and one where a central risk function, such as that of the Commissioner (see above) would be helpful. We wrote about the risks of AI in Safer Care For All[18].*

*We were pleased to see the Government proposals on regulation of AI earlier in the year[19], however, we noted that there had been little engagement with, or consideration of professional regulation in the development of the proposals. We have since sought to bring together officials and regulators to bridge this gap.*

*We noted in our response to the White Paper consultation the need for expertise and support for regulators on AI, noting that they may struggle to keep pace. Our response to the Government White Paper consultation can be found on our website[20].*

[18] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/safer-care-for-all-solutions-from-professional-regulation-and-beyond.pdf?sfvrsn=9364b20_7
[19] A pro-innovation approach to AI regulation - amended (web-ready PDF) (publishing.service.gov.uk)
[20] https://www.professionalstandards.org.uk/docs/default-source/publications/consultation-response/others-consultations/2023/psa-response-to-government-consultation-on-white-paper-on-artificial-intelligence-regulation.pdf?sfvrsn=e4a14a20_3

*With regard to the Government's proposals for the regulation of AI, we would like to draw attention to points 19, 20 and 21 of the Connected tech: AI and creative technology report, produced by the Culture, Media and Sport Committee Select Committee*[21] *. These recommendations mirror our concern with regard to expertise required for regulation of AI among professional regulators.*

**Question 15:** Do you consider the processes that UK regulators have in place allow them to make decisions in an appropriate time frame?

*We review the performance of the regulators we oversee against our Standards of Good Regulation*[22]*. Standard fifteen includes "The regulator's process for examining and investigating cases is fair, proportionate, deals with cases as quickly as is consistent with a fair resolution of the case…". In the most recent round of reviews, five of the regulators we oversee (GDC, HCPC, GPhC, SWE and NMC) did not meet this standard.*

*Specific factors contributing to underperformance in this area vary between regulators, and may include processes, staffing issues and other external and internal factors. The proposed reforms to fitness to practise are expected to enable regulators to conclude cases more quickly.*

**Question 16:** In the sector(s) that you operate in, do you think there are specific improvements that UK regulators and / or the Government could make to facilitate a more agile implementation of rules and regulations?

*Existing legislation (whether the GMC's, or that of other health professional regulators) tends to be prescriptive, setting out in detail the regulator's processes and procedures – and changing it requires further legislation. This is both inefficient and inflexible, and prevents the regulator from making improvements to its processes, and adapting to changing circumstances.*

*This current reforms to professional regulation, of which The Anaesthesia Associates and Physician Associates Order are 'enabling legislation' – essentially a set of powers and duties, for the GMC to implement as it sees fit, through rules that it will sign off itself. This is another departure from the current model, which requires rules to be approved by the Privy Council.*

*With this newfound flexibility and autonomy, the GMC, and other regulators in due course, will be taking greater responsibility for how they operate. This should allow them to become more agile.*

**Question 17:** Do you think UK regulators have the appropriate mix of skills to deliver their objectives?

*No response*

*No response*

[21] https://committees.parliament.uk/publications/41145/documents/201678/default/
[22] https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-of-good-regulation145e23f761926971a151ff000072e7a6.pdf?sfvrsn=ce597520_17

**Question 19:** Do you think existing processes enable UK regulators to test new regulatory reform proposals?

*This is currently limited because the regulators' legislation is prescriptive, however the proposed new model of legislation to be rolled out sequentially by regulator, starting with partial reform of the GMC, will change this. New enabling legislation should give regulators much more scope to change their regulatory approaches. We would have liked to see some testing of the new legislation itself, however, the plans to reform the regulators in sequence would allow for a review stage and possible course-correction if necessary.*

# Section Four: Proportionality in Implementing Regulation

The methods regulators employ to meet their objectives can increase or decrease the burden on those they regulate. A proportionate approach to managing risk is key to balancing important protections with an environment that fosters innovation and accelerates economic growth and technological development.

*We are aware that not all questions will be relevant to all respondents. Please address as many questions as are relevant to your experience.*

**Question 20:** Do you consider UK regulators to be proportionate in the measures they take, e.g. in applying regulations or responding to emerging issues?

*No response*

**Question 21:** In making decisions that involve risk, which of the below do you consider most accurate?

1. UK regulators are too risk averse in their decision making
2. UK regulators achieve the right balance of risk in their decision making
3. UK regulators allow for too much risk in their decision making

*No response*

**Question 22:** Do you consider that individual UK regulators have the appropriate level of discretion when taking decisions that involve risk?

*No response*

**Question 23:** If you are a business or consumer, how does the approach that UK regulators take to risk impact your own decision-making?

*No response*

**Question 24:** UK regulators often need to balance delivery across a range of different legislative duties or regulatory requirements, some of which may involve trade-offs. Do you consider that they balance these trade-offs effectively and transparently?

*As outlined in question one, avoiding trade-off between multiple competing objectives, and maintaining a steady focus on the three limbs of public protection, allows the regulators to perform their role most effectively.*

**Question 25:** If you are a UK regulator, are there specific areas where you consider it would be beneficial to seek further steer or guidance from the Government?

*In our view, the professional regulators we oversee should retain independence in deciding between different objectives and priorities.*

*That said, on these matters, we would expect regulators to continue to seek out and consider the views and perspectives of key stakeholders, among whom the UK Governments should feature.*

*In our view, it would be extremely valuable for Government to outline its strategic approach to and use of regulation as a tool for achieving its policy objectives.*

*For example, we would like to see each UK Government adopt a regulatory strategy to support its workforce strategy for health and care, so that workforce change and innovation can be implemented smoothly and safely, with appropriate safeguards in place from the outset. The recent concerns about the expansion and regulation of the Medical Associate Professions[23] (physician associates and anaesthesia associates) illustrate the problems that can arise when workforce changes and the related mechanisms for assurance are not developed in tandem.*

*Such a strategy should set out principles and objectives for what the regulatory framework as a whole should achieve, and anticipate the regulatory needs of changes in the workforce. It should be risk-based, and consider the full range of regulatory tools, from different forms of statutory regulation, which are the subject of this inquiry, down to voluntary registers accredited by our statutory programme[24], and the local management of risk. It should be developed in partnership with existing regulatory bodies, to ensure that plans for changes to existing regulatory frameworks can be achieved without compromising public safety.*

*More information on our regulatory strategy proposal can be found in Safer Care For All.*

**Question 26:** In general, do you consider the approach that UK regulators take to requests for information to be proportionate to any burden they may impose on you?

1. Yes
2. No
3. N/A

*No response*

**Question 27:** Do you ever receive duplicative requests for information from the same or multiple UK regulators? (i.e., requests asking for essentially the same information)?

1. Yes
2. No

[23] https://www.bma.org.uk/news-and-opinion/bma-position-statement-on-physician-associates-and-anaesthesia-associates
[24] https://www.professionalstandards.org.uk/what-we-do/accredited-registers

3. N/A

*No response*

# Section Five: Process and Governance

Regulators have a variety of governance structures (for example decision making boards or external advisory committees) which underpin their decision making. Responsibility is also assigned throughout the regulatory system between Government departments and regulators. The balance of this relationship is vital for the successful delivery of regulatory outcomes. Regulators are in place to deliver certain outcomes, as set out in their duties and guidance. As in any organisation, internal processes need to be put in place to operate effectively and consistently. It is however crucial that those processes drive rather than limit outcomes.

*We are aware that not all questions will be relevant to all respondents, please address as many questions as are relevant to your experience.*

**Question 28:** Do you consider that UK regulators have in place the right governance structures to deliver the best outcomes? If not, how can they be improved?

*The regulators we oversee have a range of accountability mechanisms. They are accountable first and foremost to their Councils, through their internal governance arrangements, which are set out in legislation. Since the early 2000s, reforms have ensured that Councils are populated by both professional and lay members in equal number. This was seen as an essential modernising reform to ensure that the public interest was central to decision-making. Appointments to Councils are made by the Privy Council, on advice from the PSA on whether the appointments process (rather than the decision itself) has met its standards.*

*Regulatory reform will introduce unitary Boards instead of Councils. As that part of the legislation is not yet proceeding for the GMC, it is not yet clear what the template will look like, but in outline it is likely to take the same approach: to define less in legislation, remove the requirement for Privy Council to oversee rulemaking, and give more autonomy to the regulator. We are in favour of increased flexibility but it will be important for it to be balanced with meaningful and timely accountability, to ensure public protection remains at the heart of regulators' activity.*

**Question 29:** Do you consider that UK regulators use digital systems in their interactions with you in an efficient fashion? (e.g. data transfer or other digitised methods)?

*No response*

**Question 30:** Do UK regulators sufficiently communicate the processes they follow to make decisions?

1. Yes

2. No
3. N/A

*We review regulators' performance against the Standards of Good Regulation[25]. Standard one is: The regulator provides accurate, fully accessible information about its registrants, regulatory requirements, guidance, processes and decisions. While meeting a standard does not mean all aspects of a regulator's performance in relation to that standard are performed optimally, all the regulators we oversee met standard one in the latest round of reviews.*

**Question 31:** Are you provided sufficient opportunity to input into decision making by UK regulators processes (e.g., via consultations, workshops etc)? If not, how would you suggest improving the process?

*Under the current regime, regulators routinely consult on proposed changes to their processes. They also engage with us informally on other proposed changes. Regulatory reform will give regulators more freedom to decide when and how they need to consult. Consultation and engagement, particularly with patients and service users, is an important part of effective regulation in the public interest, and we will expect regulators to use their new powers to ensure they engage appropriately about proposed process changes.*

**Question 32:** Do you consider the processes that UK regulators follow deliver reasonable outcomes?

*We assess the performance of the regulators through a cycle of performance reviews focused on regulatory outcomes. In 22/23, Across all the regulators we oversee an average of 92% of the standards were met and four of the regulators met all the standards.*

*Additionally, we review regulators' final hearing decisions about whether individuals on their registers are fit to practise. In 2022/23 we reviewed 2,335 such decisions26; overall, we find that the bulk of cases are managed to a high standard, with findings and sanctions that protect the public appropriately. However, every decision counts and there is room for further improvement. During 2022/23, 13 appeals under our Section 29 powers were completed. All but one of these appeals were either upheld or settled. One case could not be heard on the basis of jurisdiction – the court decided that Section 29 did not apply to the particular circumstances of the case.*

**Question 33:** Do you think UK regulators treat those that they regulate consistently?

*As part of standard three of our standards of good regulation, we review whether regulators' processes disadvantage people on the basis of protected characteristics – Standard three: "The regulator understands the diversity of its registrants and their patients and service users and of others who interact with the regulator and ensures that its processes do not impose inappropriate barriers or otherwise disadvantage people with protected characteristics." In 2022/23, all the regulators we oversee met standard three, but they and we are aware that inequalities persist in the health and care systems and their regulation; this year, we have revised our approach to focus on outcomes and drive further improvement across the sector, introducing a revised evidence framework and accompanying guidance.*

[25] https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-of-good-regulation145e23f761926971a151ff000072e7a6.pdf?sfvrsn=ce597520_17
[26] https://www.professionalstandards.org.uk/publications/detail/professional-standards-authority-annual-report-and-accounts-2022-23

*In SCFA, we describe areas where governing legislation hampers the ability of regulators to regulate the sector fully and consistently[27]. The GOC's legislation is also restrictive in terms of which business it oversees, meaning certain businesses fall outside the requirement for mandatory registration with the regulator. Registration with the GOC is only required for 'bodies corporate' with particular management structures; and even then, only if they use certain protected titles such as 'optometrist' or 'dispensing optician' in their company or trading name.*

*We also raised the difficulty of imposing meaningful sanctions, where the maximum fine from the GOC to corporations is limited to £50,000. In Safer Care For All, we noted "regulators outstripped financially by large businesses, there is also the question of how feasible it would be, in practice, for regulators to impose the most serious sanction of erasure on a large chain"*

**Question 34:** As a business, do you think the process to challenge a UK regulator you interact with is sufficiently clear, robust and fair?

*No response*

**Question 35:** What steps, if any, do you think could be taken to further improve the effectiveness and clarity of the reviews and appeals processes?

*We know the process for challenging the decisions at the early stages can appear opaque from the perspectives of the public. The issues and experiences of those who seek to raise concerns with regulators has been studied through the NIHR-funded Witness to Harm Project[28]. The findings of the various strands of this research will be disseminated this year.*

*With regard to ongoing regulatory reform, we are concerned the process for the Revision of fitness to practise decisions has lost those features that made it a public protection mechanism, as opposed to just an efficient means of rectifying 'errors' that disadvantage the registrant.*

*We would like to see the following in the legislation for wider reform of professional regulation:*

- *Change the test to enable a decision to be challenged because it is deemed insufficient to protect the public. An 'error of fact or law' is significantly narrower than the test that was originally proposed of a 'material flaw' combined with reference to public protection*
- *Remove the restriction on possible outcomes of the revision when it comes to conditions and suspensions so that an outcome that is insufficient to protect the public can be rectified*
- *Make it mandatory for the power to revise to be available for case examiner decisions*
- *Amend the PSA's legislation to enable it to challenge an article 15 decision through Judicial Review for the purposes of public protection.*

[27] https://www.professionalstandards.org.uk/docs/default-source/publications/standards/standards-of-good-regulation145e23f761926971a151ff000072e7a6.pdf?sfvrsn=ce597520_17
[28] https://wels.open.ac.uk/research/witness-harm-holding-account

# Section Six: Regulator Performance

How regulators seek to meet their objectives, implement and enforce regulation is just as important as regulatory structures. Regulation is only effective if it achieves its desired outcome and tackles the problems that it is trying to solve.

*We are aware that not all questions will be relevant to all respondents, please address as many questions as are relevant to your experience.*

**Question 36:** In your experience, have UK regulators that you interact with delivered on their stated objectives in that interaction?

*Please see the overview, taken from our 22/23 annual report[29]:*

*In our scrutiny reviews of regulators' performance over the year, we have found that they have generally performed well against the standards we set. Across all the regulators an average of 92% of the standards were met and four of the regulators met all the standards. Six of the regulators did not meet Standard 15 of the Standards of Good Regulation. This is a fitness to practise standard and the primary reason for it not being met is that it is taking too long to complete cases. This is not good for regulators, registrants, and patients and service users. We are monitoring this situation very closely in 2023/24*

**Question 37:** Do you think UK regulator performance reporting is proportionate, objective and transparent?

**Question 38:** Do you think UK regulators report on the right set of criteria and metrics to monitor their performance and ensure accountability?

*We have answered question 37 and 38 together: We would like to draw the Committee's attention to the oversight model embodied by the PSA. We were created to address the problem of regulatory capture – and perception thereof – and to increase public confidence in professional regulation. We also hear from stakeholders that the work we do helps to give professionals themselves greater confidence in their regulator.*

*We are an oversight body as opposed to a regulator – we do not have any regulatory powers to address poor performance. However, we can shine a light on issues, and escalate to ministers if necessary. We do have direct powers to challenge, through the courts, individual regulatory decisions about professionals, if they are insufficient to protect the public. We can also be commissioned by the Secretary of State to investigate a specific concerns relating to a regulator, and advise on possible ways of addressing them.*

*This model is unlikely to be appropriate for all sectors. In our opinion though, in our sector it is both effective and necessary, given the risks to the public of a regulatory framework that is not fully focused on public protection, and the history of failures of 'self-regulation'. A similar body, the Legal Services Board, exists to oversee the multiple professional regulators in the legal services sector.*

[29] https://www.professionalstandards.org.uk/publications/detail/professional-standards-authority-annual-report-and-accounts-2022-23

*For our performance reviews, we draw together a wide range of evidence to assess performance, seeking out and listening to feedback from third parties including patients and complainants. We continue to strive to improve the effectiveness of our engagement, and intelligence gathering from a range of voices informs the performance review process.*

*We assess against the standards of good regulation, this is under review for next year. With the sector undergoing reforms, we will be reviewing regulators' functions with the new model of professional regulation.*

# Section Seven: Concluding Questions (Required)

**Question 39:** If you could suggest a single reform to improve how UK regulators operate, what would it be?

*We would like to see each UK Government adopt a regulatory strategy to support its workforce strategy for health and care, so that workforce change and innovation can be implemented smoothly and safely, with appropriate safeguards in place from the outset. The recent concerns about the expansion of the Medical Associate Professions (physician associates and anaesthesia associates) illustrate the problems that can arise when workforce changes and the related mechanisms for assurance are not developed in tandem.*

*Such a strategy should set out principles and objectives for what the regulatory framework as a whole should achieve, and anticipate the regulatory needs of changes in the workforce. It should be risk-based, and consider the full range of regulatory tools, from different forms of statutory regulation, which are the subject of this inquiry, down to voluntary registers accredited by our statutory programme, and the local management of risk. It should be developed in partnership with existing regulatory bodies, to ensure that plans for changes to existing regulatory frameworks can be achieved without compromising public safety.*

*More information on our regulatory strategy proposal can be found within Safer Care For All[30].*

**Question 40:** Are there any examples of international approaches to regulation that you think set best practice that UK regulators could learn from?

*The PSA has been commissioned to work in a number of countries to assess regulatory performance and effectiveness This work can be found on our website[31].Some other countries have adopted innovative approaches, such as the Australian model of merging together large numbers of regulatory institutions and the creation of the Australian Health Practitioner Regulation Authority. However, very careful benefits analysis and assessment would be required to transfer regulatory innovations from one context to another.*

**Question 41:** What is the best designed regulation you face, and why?

*The PSA believes that all regulatory policy should follow the right-touch regulatory approach.*

*The concept of Right-touch regulation[32] emerges from the application of the principles of good regulation identified by the Better Regulation Executive in 2002, to which the Professional Standards Authority has added agility as a sixth principle. With this addition, the principles state that regulation should aim to be:*

*• Proportionate: regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised.*

[30] https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/safer-care-for-all-solutions-from-professional-regulation-and-beyond.pdf?sfvrsn=9364b20_7
[31] https://www.professionalstandards.org.uk/publications/international-reports
[32] https://www.professionalstandards.org.uk/what-we-do/improving-regulation/right-touch-regulation

*• Consistent: rules and standards must be joined up and implemented fairly*

*• Targeted: regulation should be focused on the problem, and minimise side effects*

*• Transparent: regulators should be open, and keep regulations simple and user friendly*

*• Accountable: regulators must be able to justify decisions, and be subject to public scrutiny*

*• Agile: regulation must look forward and be able to adapt to anticipate change.*

*These principles provide the foundation for thinking on regulatory policy in all sectors of society. We see the concept of Right touch regulation emerging naturally from the application of these six principles: bringing together commonly agreed principles of good regulation with understanding of a sector, and a quantified and qualified assessment of risk of harm. It is intended for those making decisions about the design of an assurance framework.*

**Question 42:** Are there any further points you would raise about regulation, including the functioning of the regulatory system or any recommendations you have on the stock of regulations from the Government which should be removed or reformed and modernised?

*The PSA supports the four UK Country Governments' legislative reform programme for the regulators it oversees, of which the Anaesthesia Associates and Physician Associates Order (AAPAO) is a first step.*

*This piece of legislation which is intended as a blueprint for reform of all the regulators we oversee would replace the outdated and inflexible legislation that we believe is holding our sector back from adapting to changing times and pressures. We support:*

*• The greater flexibility and adaptability it would give regulators by removing detail from the legislation itself, and granting regulators powers to make the rules that would cover this detail*

*• The new, consensual fitness to practise process that would be quicker and less adversarial.*

*However, there are elements of the blueprint that we would like to see reconsidered before the legislation is rolled out to larger groups of professionals, such as doctors, nurses and allied health professionals:*

*• More checks and balances on powers allowing the regulators to override adjudication decisions about the conduct and competence of professionals*

*• An effective public protection mechanism for challenging decisions made under the new consensual fitness to practise process.*

*Ideally, we would have liked these changes to appear in the AAPAO, however, given the small number of registrants affected by this piece of legislation, we are focusing our efforts now on the potential impacts of this blueprint being applied to much larger groups of registrants.*

# Section Eight: Closing Questions (Required)

**Question 43:** In what capacity do you interact with UK regulators or regulated businesses? (Please select the most appropriate option that represents you, and respond according to your primary responsibilities)

- Other

Independent Oversight Body of regulators

**Question 44:** If you are a business, how many employees do you have?

- **Not Applicable – not a business**

**Question 45:** Please name the Sector(s) that you operate in - you may wish to reference Standard Industrial Classifications

*Health and Care (Professionals)*

**Question 46:** If you are a regulated business, how much as a percentage of turnover does demonstrating compliance with regulation cost your business?

- **Not Applicable**
- Less than 1% of turnover
- 1 to 5% of turnover
- More than 5% and up to 10% of turnover
- Over 10% of turnover

**Question 47:** What is your name, or the name of your organisation?

*The Professional Standards Authority For Health And Social Care*

**Question 48:** What is your e-mail address (optional response)?

*policy@professionalstandards.org.uk*

**Question 49:** We usually publish a summary of all responses, but sometimes we are asked to publish the individual responses too. Would you be happy for your response to be published in full?

- **Yes**
- Yes, but without identifying information
- No, I want my response to be treated as confidential

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