Response to the Government consultation on the White Paper: *A pro-innovation approach to AI regulation*

1. Introduction

1.1 The Professional Standards Authority for Health and Social Care (the 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 social 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.

1.2 As part of our work we:

- Oversee the 10 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 Science, Innovation, and Technology (DSIT) consultation on the White Paper, *A pro-innovation approach to AI regulation*. We are not experts in AI, and gaining this expertise should undoubtedly be a priority for our sector. We would like however to draw your attention to what we think could be structural challenges to the success of the White Paper proposals.

2.2 We understand the need for a flexible approach to regulation of this very fast-moving technology. We conclude however that further work is needed to understand the regulatory landscape for AI, at least – and we cannot speak for other sectors – within the sectors of healthcare and social care. It was not clear to us that the White Paper had considered the complexity of the regulatory landscape in health and care generally, including how the proposals would apply to regulators and registers of people, as opposed to places or products. We understand that there has been little engagement with professional regulators or accredited registers in our sector on development of the proposals in the White Paper. In addition to submitting this response, we will be writing to DSIT officials with an offer to coordinate contacts with the regulators we oversee, to facilitate greater levels of engagement going forward.

2.3 We are nonetheless concerned that the approach to date may have created a policy gap in relation to professional regulation, particularly in the light of the

decision to regulate the *use of* AI rather than the technology itself. Professionals are accountable to their professional regulator, which sets the standards of conduct and practice, approves education and training provision, holds registers of professionals, and can take action in response to concerns about conduct or practice. There is the potential for AI to transform health and care practitioners' work, their training, and even how they are regulated. The White Paper highlights the need to consider actors and processes across the AI lifecycle, so addressing how AI is and could be used by professionals and their regulators – and what this means for how AI itself is regulated – is, in our view, essential.

2.4 To illustrate some of the challenges of understanding what the proposed framework could mean for professional regulators and registers, it may be worth explaining that their registrants may be employees in the public sector (NHS or local authorities), or in the private and independent sectors (e.g. private hospitals, large private health clinics); or they may be self-employed or themselves business owners; two of the regulators we oversee also regulate 'places' – the General Pharmaceutical Council with pharmacies (including very large companies like Boots) and the General Optical Council with opticians (including for example Specsavers), under different models.

2.5 Furthermore, we suggest that the principles-based approach may place too much reliance on the capacity of multiple regulatory bodies to adapt and work together. We know from experience, and from the findings of major inquiries[1] that joint working presents a challenge for regulators operating in health and social care. Generally, it is not motivation that is lacking, rather the structures and legislation are not conducive to joint working, particularly in such a complex landscape with numerous regulatory bodies. In our view, it may not be feasible to expect regulators in health and care to agree amongst themselves how to apply the principles, and to do so in a way that is consistent, coherent, and leaves no gaps.

2.6 The rapid changes in health and care will require flexibility from regulators. We highlighted the need for such flexibility in the face of changing funding and delivery of health and care in *Safer Care for All*.[2] We also called for the establishment of a Health and Social Care Safety Commissioner to look across the sectors and identify emerging risks and possible mitigations. We believe the need for such a role increases with the acceleration of changes to the funding and delivery of care.

2.7 The Department of Health and Social Care (DHSC) is currently reforming professional regulation, having initially consulted on the reforms in 2017. As DSIT develops the government's regulatory strategy for AI, this would need to be in line with the new model of professional regulation, and we would welcome close collaboration between DSIT and DHSC to ensure this.

2.8 That said, with the reforms likely to take a number of years to be rolled out to all the regulators, the current rigid and overly prescriptive legislation is likely to continue to present a barrier to the necessary evolution of regulation, as health

[1] See for example the Inquiry into Ian Paterson, the rogue breast surgeon, or the Cumberlege review into the use of harmful medicines and devices.
[2] https://www.professionalstandards.org.uk/safer-care-for-all

and care roles are rapidly altered by AI capabilities. Considering the demands placed on the regulatory system to adapt to the implications of AI, there may also be a desire to expedite the pace of reform.[3]

3. Responses to questions

Q7: Do you agree that introducing a statutory duty on regulators to have due regard to the principles would clarify and strengthen regulators' mandates to implement our principles while retaining a flexible approach to implementation?

3.1 It would have been helpful if the consultation document had specified which bodies – or types of body – with regulatory responsibilities are meant to be in scope for the statutory duty. As noted above, it is not clear to us that the DSIT had in mind, when drafting the proposals, the important role played by professional regulators in our sector, or the voluntary registers under the PSA's statutory accreditation scheme.

3.2 In addition, we find there is a lack of clarity over the regulated entities intended to be in scope. The consultation documents refer frequently to businesses, but little reference is made to public sector bodies such as the NHS and local authorities. Then we have the ten statutory regulators and the registers under the aforementioned PSA accreditation scheme, which may themselves decide to use AI as part of their regulatory functions. It would be helpful to know whether these bodies could also be considered in scope as entities 'regulated' by the PSA, that could themselves be using AI in the future. Consequently, would *we* be expected to have due regard to the principles in our oversight functions?

3.3 Not having a clear understanding of which regulators and regulated entities are in scope of the proposals presents a challenge in understanding the policy intent of the principles, and in commenting on whether a statutory duty would be effective.

3.4 On a separate point, if the regulators we oversee are affected by the White paper proposals, it might be helpful for DSIT to discuss with the DHSC how any AI regulation statutory duties might interact with proposed new statutory duties for the healthcare professional regulators, under the reforms referred to above.

3.5 There is also the question of how these new AI-related duties might sit alongside existing duties. For example, the assurance of fairness and mitigation of bias is likely to interact with existing legal duties in the Equality Act 2010, which it is the responsibility of the Equality and Human Rights Commission to enforce. Principles relating to data are covered by the GDPR, with enforcement of these duties falling within the remit of the ICO. Indeed, the feedback from the Information Commissioners' Office (ICO) highlighted the potential for the AI regulation principles to cut across existing data protection principles.[4] It would

[3] https://www.gov.uk/government/consultations/regulating-anaesthesia-associates-and-physician-associates

[4] https://ico.org.uk/media/about-the-ico/consultation-responses/4024792/ico-response-ai-white-paper-20230304.pdf

have been helpful to understand more about how overlap and duplication could be avoided here.

Question 15: Do you agree with our overall approach to monitoring and evaluation?

Question 18. Do you agree that regulators are best placed to apply the principles and government is best placed to provide oversight and deliver central functions?

3.6 We welcome the proposal for a central function to consider new cross-cutting risks and broker agreement on which regulators should address them. We note also the reliance on regulators to identify and respond to sector-specific risks, and to apply the principles. We have taken questions 15 and 18 together, in order to highlight two issues that may present a challenge to the proposals.

The challenges of collaboration

3.7 The health and care regulatory system is complex. One study identified 126 bodies that have some kind of regulatory role over NHS providers.[5]

3.8 As we identified in Safer Care for All,[6] there is no single body responsible for oversight of the regulatory system in health and social care safety. This leads to regulatory gaps, unclear lines of accountability, and remit apathy. We concluded that expectations that joint working, co-ordination, or collaboration would address safety issues were often misplaced.

3.9 We see much laudable joint working among the bodies we oversee, and try to facilitate and encourage these endeavours as much as possible. However, achieving a consistent and coherent approach to regulating AI may be beyond what can be achieved through these sorts of initiatives.

3.10 As may be the case here, there are sometimes barriers that are beyond the capability of any one body, or even the group collectively, to address. We agree with Deloitte's analysis of the White Paper proposals, which identified the challenges of achieving coherent application of the principles when regulators are already bound by different duties, legislation, etc that might affect how they apply the duties.[7] This kind of regulatory friction could cause problems for regulated entities, particularly if compliance with one regulator's requirements meant they were not complying with those of another.

3.11 A system that relies on bottom-up, organic collaboration has the potential to be slow, piecemeal, and lacking in coherence – but more concerningly, it may actually fail to address structural and legislative barriers to its successful implementation. We recommend that the Government consider in greater detail the regulatory and legislative architecture in health and care, with a view to testing whether the proposed collaborative approach and principles would be likely to result in the effective regulation of AI.

---

[5] https://bmjopen.bmj.com/content/9/7/e028663
[6] https://www.professionalstandards.org.uk/safer-care-for-all
[7] https://emearegulatorystrategy.deloitte.com/post/102ie0o/regulating-ai-can-the-uks-proposed-approach-achieve-both-flexibility-and-clarit

3.12 We at the PSA could play a role in supporting the bodies we oversee to develop a consistent approach to application of the AI regulation principles across professional regulation. This would not however address the potential for overlap, duplication, gaps, friction and inconsistencies across the wider regulatory and legislative landscape.

The skills gap

3.13 Relatedly, with this structure there is a risk that individual bodies could find themselves unable to pre-empt and respond to gaps in the face of rapidly changing care delivery. This issue is described in the pre-print research paper *Sociotechnical sources of risk and resilience in the management, Implementation and regulation of artificial intelligence in healthcare* that we would like to draw to the DSIT's attention.[8]

3.14 The paper describes the concerns of those involved in the 'implementation, management and regulation of artificial intelligence'. One such concern is that a 'regulatory void' may emerge between regulatory approval of a particular AI-based product or device, and its practical implementation and use in a clinical setting. In line with the focus on the AI lifecycle, consideration of the human factors of the application AI in a clinical context is essential. This may be particularly pertinent where AI is performing more complex, generative functions. The paper suggests this should include regulatory clarity and standards around what else needs to be included within that supported environment, and how AI is actually used in services. In line with this, the research paper recommends clearly allocated responsibility for regulatory requirements, performance standards and associated oversight activities that can assure the safety of AI systems across the full range of development, testing and deployment.

3.15 We agree with this research paper that there are very likely skills and expertise gaps across the regulatory landscape in responding to the challenge and opportunities of AI. The paper argues that regulation needs to change so that the same amount of rigour that goes into the development of a product is applied to its deployment. To even understand – and crucially, anticipate – the harms or missed opportunities that may be occurring across the system, our sector will need to develop skills, expertise, and possibly systems, that it currently does not have.

3.16 We would welcome any technical support for regulators in our sector. As the DSIT continues to develop its technical guidance expertise, we would like to highlight the need to equip all regulators, including professional regulators, with the capabilities for proactively identifying areas of risk and determining policy responses.

[8] https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4299419

Question 22: Do you have any other thoughts on our overall approach? Please include any missed opportunities, flaws, and gaps in our framework?

3.17 We have three further comments.

3.18 Firstly, clinical oversight of AI-related changes to training of health and care professionals, and use of AI in providing care, will remain essential. In developing such competencies across the wider workforce, Accredited Registers could offer a way for employers to identify capabilities and gain assurance that those offering services on a contract basis are qualified, even if they do not operate under a registered title. With the benefit of a voluntary, flexible approach to education and training, we would encourage the Government to consider the Accredited Register programme as a means of providing assurance across the AI life cycle. For example, the Government may want to ensure that those developing generative AI for use in health and care are members of an Accredited Register, as a flexible way to ensure adherence to the five principles without statutory regulation.

3.19 Secondly, in *Safer Care for All*, we called for regulators to tackle business practices that fail to put patients first, risk undermining confidence in the professions, or fail to allow registrants to exercise their professional judgement. We also called for the Government to conduct a cross-sector review of the effectiveness of arrangements to address financial conflicts of interest among healthcare professionals. The development of AI is likely to require the input of professionals who may be otherwise employed in the provision of care – and as we explained in our report, this can give rise to conflicts of interest that can affect the safety and quality of care. We should be alert to the heightened potential for these risks to occur through the rapidly developing deployment of AI in our sector.

3.20 Finally, a further point from *Safer Care for All*, that helps to illustrate the complexity we have alluded to throughout our response. We highlighted in the report that there is a need for greater clarity about responsibility and accountability when AI is used in care. This complex question is central to how professional regulators consider the use of AI by their registrants, but it is not one they can take a unilateral view on. It is inextricably linked to decisions about how AI is regulated as a product, liability schemes, the regulation of systems and places, any relevant aspects of the law – including a possible need for further legislation in this area – and so on. This may be an example of an area where a clearer Government steer is needed.

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:

Professional Standards Authority for Health and Social Care
16-18, New Bridge St
Blackfriars

London EC4V 6AG

Email: policy@professionalstandards.org.uk
Website: www.professionalstandards.org.uk
Telephone: 020 7389 8030