

Response to call for evidence on the Opticians Act and consultation on associated GOC policies

July 2020

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
- 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 contribute to the General Optical Council's call for evidence on the Opticians Act and consultation on associated GOC policies.
- 2.2 As the scope of the call for evidence and consultation is broad, we have mainly limited our comments to those areas where we have a specific view or knowledge of the issues.

3. Answers to questions

Section 1: Objectives for reform

Q5: Are these the right objectives for the GOC for legislative reform?

- a) Yes
- b) No
- c) Not sure / no opinion

If no, please provide details.

- 3.1 a) Yes
- 3.2 The objectives laid out in the consultation document seem sensible. We suggest however that as the GOC's current overarching objective remains protection of the public it would make sense for this to be the primary consideration in the event that there is any conflict between the different objectives.
- 3.3 This would align with the direction suggested by the 2021 policy consultation on reform carried out by the Department for Health and Social Care (DHSC) which suggested that this overarching objective is likely to remain in place.¹
- 3.4 We support the approach by the GOC to develop an evidence base and build the case for reform. This approach should enable them to be on the front foot with regard to the planned Government reforms to the legislation of all of the professional regulators and should help to identify the key considerations for DHSC when taking forward reforms for the GOC.

Section 2: Protection of title, restricted activities and registers (sections 7, 8A, 9 and 24-30A of the Act)

Q6. What activities should non-registrants be restricted/prevented from doing?

- 3.5 In line with our position that decisions about whether to regulate a role should be based on risk of harm, it is our view that decisions about which activities should be protected should also be based on an assessment of risk.
- 3.6 Regulation should only be used when necessary and where there is no reasonable alternative for managing risk of harm. Used inappropriately, restriction of activity may constitute a barrier to competition and innovation. It may inhibit or prevent provision of services to the public.
- 3.7 We note that since the Opticians Act was first introduced the level of risk arising from different activities may well have shifted. We would expect the GOC to base any recommendation for change on available evidence.

Q7. What activities do you think must be restricted to our registrants?

- 3.8 See answer to question 6.

Q8. What are your views about continuing to restrict/prevent non-registrants from carrying out the following activities?

- a) *Testing of sight: should be restricted / not sure / should not be restricted*
- b) *Fitting of contact lenses: should be restricted / not sure / should not be restricted*

¹ The Department of Health and Social Care, *Regulating healthcare professionals, Protecting the public*, 2021. Available at: <https://www.gov.uk/government/consultations/regulating-healthcare-professionals-protecting-the-public>

c) Selling optical appliances to children under 16 and those registered visually impaired: should be restricted / not sure / should not be restricted

d) Selling zero powered contact lenses: should be restricted / not sure / should not be restricted

- 3.9 We do not have the evidence to give a view on whether these specific activities should remain restricted to registrants. As outlined in our answer to question 6, we think it is important for there to be a up to date assessment of whether the risks associated with these activities remain sufficient to justify limiting who can carry them out.

Q9. Are there any additional activities that you think should be restricted to registrants?

- 3.10 See answer to question 6.

Q10. Is there any evidence that any other post-registration skills, qualifications or training need to be accredited or approved by the GOC (above and beyond the existing contact lens optician and prescribing qualifications)?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.11 c) Not sure
- 3.12 We do not have evidence of any further specific post-registration skills that need to be accredited by the GOC. Annotation to the register should only be used for the purpose of public protection. We suggest therefore that further accreditation of training leading to an annotation should only be introduced where there is clear evidence of risk arising from the additional post-registration skills, training or qualifications.

Section 3: Regulation of businesses (sections 9 and 28 of the Act)

Q11. Does the basis for extension of business regulation outlined in our 2013 review of business regulation still apply?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.13 a) Yes

- 3.14 There remains a strong case for reforming business regulation. The increasing role of high street providers of health and care services and the growing importance of large corporate bodies and multi-nationals has raised a range of issues which current legislation may not be fully equipped to respond to.
- 3.15 The current system for regulating optical business is complex, piecemeal, and may not be fit for purpose. Further, the Government's current programme of reforms to professional regulation makes this an ideal time to consider how the system could be improved to work better for the public, registrants and businesses.

Q12. Are there any advantages, disadvantages and impacts (both positive and negative) of extending business regulation in addition to those identified in our 2013 review of business regulation? (Impacts can include financial and equality, diversity and inclusion.)

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.16 a) Yes
- 3.17 The current system where only businesses using certain protected titles and with particular management structures are required to register, is confusing and inequitable. It means that registration with the regulator is essentially 'optional'. We note that in 2013 the GOC estimated that only 2,200 of approximately 6,400 optical businesses were registered. This leaves customers without the assurance that all optical businesses are complying with the GOC's standards and means that optical businesses are not operating on a level playing field. Further, the current system is not risk-based, as it is not the case that those businesses required to register with the GOC have been deemed to be higher-risk than those that are not.
- 3.18 We support the GOC's proposal to extend business regulation to include all businesses providing restricted functions. This would end the disparity between businesses, and ensure they comply with minimum standards. We believe it would make the system fairer and safer.
- 3.19 It is our view that the powers of all regulators with a role in regulating businesses should be reviewed. The review should focus on the effectiveness and adequacy of current powers (e.g. 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.
- 3.20 We outlined in *Regulation rethought* our view that the Government should also consider extending business regulation powers to all regulators whose

individual registrants work in 'high street' practices² (the Government committed in their response to the *Promoting professionalism, Reforming regulation* consultation to considering "professional regulators' roles in regulating businesses and premises"³). In doing so, they should assess any regulatory gaps arising from the current system.

Q13. Do you think the GOC could more effectively regulate businesses if it had powers of inspection?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.21 a) Not sure
- 3.22 We see potential benefits in the GOC having powers of inspection and this is a model that works well for other regulators, allowing them to intervene early where there are concerns, and get 'upstream' of any potential problems.
- 3.23 Without inspection powers, regulators may be hampered in their ability to identify issues at an early stage and provide businesses with advice or conditions to help them improve. It is clearly preferable, both from the point of view of public safety, and for the business themselves, for any shortcomings to be dealt with in a prompt and proportionate manner, rather than waiting for them to escalate.
- 3.24 As with all additional regulation however, it would be important to clearly establish the unmanaged risk arising from the current model and whether inspection powers would be the appropriate mechanism to address this. Any proposals to introduce additional regulation, especially where this might impose costs on business, would of course need to be carefully considered.
- 3.25 As we have noted in our answer to question 12, we believe that a review of the adequacy and effectiveness of the powers of those regulators with a role in regulating businesses would help to establish what the most appropriate regulatory model should be.

Q14. Is there an alternative model of business regulation that we should consider?

- a) Yes, the GPhC model of a responsible pharmacist

² Professional Standards Authority 2016, *Regulation rethought*. Available at:
https://www.professionalstandards.org.uk/docs/default-source/publications/thought-paper/regulation-rethought.pdf?sfvrsn=c537120_20

³ Department for Health and Social Care 2019, *Promoting professionalism, Reforming regulation – Government response to the consultation*. Available at:
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/820566/Promoting_professionalism_reforming_regulation_consultation_reponse.pdf

b) Yes, another model (please specify)

c) No

d) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

3.26 d) Not sure

3.27 As highlighted, in our view it would be helpful for there to be a review of the powers of all those regulators with a role in regulating businesses to help to establish what the most appropriate regulatory model should be. This would include reviewing the strengths and weaknesses of the different models of business regulation in managing risks arising.

3.28 The Authority supports the the regulation of people and 'high street' premises being brought together within scope of the professional regulators, as with the General Pharmaceutical Council (GPhC) model. In our view this remains the most logical approach. However, we are aware that there are likely to be areas for improvement within this model also and consideration of whether existing powers are adequate to address the risks arising for consumers in a fast-moving landscape of healthcare service provision.

Section 4: Testing of sight (sections 24 and 26 of the Act)

Q15. Should dispensing opticians be able to undertake refraction for the purposes of the sight test? (NB This would be possible only if the GOC were to amend or remove its 2013 statement on refraction.)

a) Yes - with no restrictions

b) Yes - under the oversight of an optometrist or registered medical practitioner

c) No

d) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

3.29 d) Not sure

3.30 We do not have a view on this question. We recognise the benefits of using the workforce more flexibly and reducing unnecessary regulatory barriers. If any changes are to be made in this area public protection should remain the central consideration.

Q16. What would be the advantages, disadvantages and impacts (both positive and negative) of amending or removing our 2013 statement on refraction so that dispensing opticians can refract for the purposes of the sight test? (Impacts can include financial impacts and equality, diversity and inclusion impacts.)

Please give your reasons and provide any evidence to support these.

- 3.31 See answer to question 15.

Q17. Does the sight testing legislation create any unnecessary regulatory barriers (not including refraction by dispensing opticians)?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

- 3.32 c) Not sure
- 3.33 We do not have the evidence to suggest whether the sight-testing legislation should be changed to allow an eye health check to be carried out separately from a sight test. There may be a risk that the public would not understand the distinction and so any change would need to guard against patients taking false reassurance from a sight test.
- 3.34 In line with our overall view that any changes must prioritise public protection we welcome the GOC's intention to only consider changes in this area if it was clear from the evidence that this would not have a detrimental effect on public protection.

Q18. What would be the advantages, disadvantages and impacts (both positive and negative) of sight testing legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.35 No comments.

Q19. Do you have any data on the number/percentage of referrals that are made to secondary care following a sight test / eye examination?

- a) Yes
- b) No
- c) Not sure / no opinion

If yes, please provide details of the evidence and where it can be obtained.

- 3.36 b) No

Q20. Are you aware of any data to support or refute the case for separating the refraction from the eye health check?

- a) Yes
- b) No
- c) Not sure / no opinion

If yes, please provide details of the evidence and where it can be obtained.

- 3.37 b) No

Section 5: Fitting of contact lenses (section 25 of the Act)

Q21. Does the fitting of contact lenses legislation create any unnecessary regulatory barriers?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

- 3.38 c) Not sure
- 3.39 Whilst restricting the fitting of contact lenses to dispensing opticians, optometrists and registered medical practitioner is clearly a barrier to this service being provided more widely, if this is necessary for public protection then this is not an unnecessary barrier.

Q22. What would be the advantages, disadvantages and impacts (both positive and negative) of fitting of contact lenses legislation remaining as it is currently? (Impacts can include financial impacts and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.40 Whilst there may be benefits to removing this restriction on contact lens fitting which may increase competition in provision of this service there may be a negative effect on public protection if those that do not have the appropriate skills are able to do this. We note that the GOC do not refer to any evidence to suggest that the risk associated with this procedure has decreased therefore on this basis it would seem logical for the legislation to remain as it is.

Section 6: Sale and supply of optical appliances (section 27 of the Act)

Q23. Should the sale and supply of optical appliances be further restricted to certain groups of vulnerable patients?

- a) Yes - please specify which groups of patients

b) No

c) Not sure / no opinion

Please explain which group(s), give your reasons and provide any evidence to support these.

- 3.41 c) Not sure
- 3.42 We recognise the need for regulatory approach to take into account the vulnerability of patients and service users that professionals may have responsibility for, as we have outlined in *Right-touch assurance*.⁴ It is important to ensure that vulnerable patients are protected from harms arising. However, we do not have specific evidence to suggest that there are risks arising from the status quo which may need to be addressed.
- 3.43 We suggest that any decisions on further restrictions on the sale and supply of medical devices should be taken on the basis of evidence of risk of harm arising and a view that regulatory intervention would be the best way to address this. It would be important to consider any unintended consequences of introducing further restrictions of this nature.

Q24. If you answered yes to the previous question, what would be the advantages, disadvantages and impacts (both positive and negative) of further restricting the sale and supply of optical appliances to certain groups of vulnerable patients? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.44 No further comments.

Q25. Do the general direction / supervision legislative requirements relating to the sale of prescription contact lenses create any unnecessary regulatory barriers?

a) Yes

b) No

c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.45 c) Not sure
- 3.46 We agree with the GOC's assessment that the requirement for verification of electronic copies of the contact lens specification is outdated, and it is highly

⁴ Professional Standards Authority 2016, *Right-touch assurance: a 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)

likely that this requirement creates an unnecessary regulatory barrier. The requirement is also not 'future-proof' as it is likely that the use of electronic copies will continue to grow. The Covid-19 pandemic has accelerated what was already a growing shift towards online provision, with research suggesting that the pandemic brought forward digital adoption by up to seven years.

- 3.47 The Authority supports a risk-based approach to regulation, and therefore the fact that the GOC has noticed no detrimental effects from relaxing the verification rules during the pandemic would lend evidence to continuing with this approach. However, we would expect the GOC to undertake a risk-benefit analysis before advocating a permanent change to rules.

Q26. Would there be a risk of harm to patients if the general direction / supervision requirements relating to the sale of prescription contact lenses changed?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.48 c) Not sure
- 3.49 We do not have the necessary evidence to answer this question, and would expect the GOC to undertake a risk assessment of changing these requirements.

Q27. Do the legislative requirements for verification of contact lens specifications create any unnecessary regulatory barriers?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.50 c) Not sure
- 3.51 We do not have the necessary evidence to answer this question, and would expect the GOC to undertake a risk assessment of changing these requirements.

Q28. What would be the advantages, disadvantages and impacts (both positive and negative) of removing the requirement to verify a copy of or the particulars of a contact lens specification? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

3.52 We do not have the evidence required to answer this question.

Q29. Do you think the Act should specify a definition of aftercare?

- a) Yes
- b) No
- c) Not sure / no opinion

If yes, please specify what you think the definition of aftercare should be.

3.53 a) Yes

3.54 We do not have the expertise to suggest a definition of aftercare but would expect the GOC to base this of relevant evidence, views and expert opinion.

3.55 In order for regulations to be effective they must be clear and able to be understood by registrants and the public. If regulations are not sufficiently clear, the public are unable to insist upon the service to which they are entitled. Further, regulators may have difficulty holding registrants to account against standards that are ill-defined. We would therefore support increased clarity over what 'aftercare' means in practice, in order that this regulation can be as effective and workable as possible.

Q30. Does the zero powered contact lenses legislation create any unnecessary regulatory barriers?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

3.56 c) Not sure

3.57 We do not have the evidence required to answer this question. However, in line with our overall position, if there is limited evidence of harm arising from the sale of zero powered contact lenses then regulatory restrictions may need to be reviewed.

Q31. Would there be a risk of harm to patients if the requirements relating to the sale of zero powered contact lenses change?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.58 c) Not sure
- 3.59 See answer to question 30.

Q32. If you answered yes to the previous question, is legislation necessary to mitigate this risk?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.60 c) Not sure

Q33. What would be the advantages, disadvantages and impacts (both positive and negative) of zero powered contact lenses legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.61 We do not have the evidence to answer this question.

Q34. Are there any unnecessary regulatory barriers in the Act that would prevent current or future development in the sale of optical appliances or competition in the market?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

- 3.62 c) Not sure
- 3.63 The consultation document refers to the possibility of de-regulation as a means of achieving a level playing field. We are unsure what exactly is being proposed and how this would impact on consumers of optical services and on public protection. We would be keen to learn more about the GOC's policy thinking in this area. Any moves towards de-regulation would need to be made on the basis of risk, having undertaken a full assessment of the evidence.

Q35. If you answered yes to the previous question, what would be the risk on the consumer if these barriers were removed?

Please give your reasons and provide any evidence to support these. Please also include any advantages, disadvantages and impacts (both positive and negative) of any proposed changes.

- 3.64 We do not have the evidence to answer this question.

Q37. Is the two-year prescription restriction on purchase of spectacles from non-registrants an unnecessary regulatory barrier?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.65 c) Not sure

- 3.66 We do not have evidence to suggest that this regulatory requirement is unnecessary, however would expect the GOC to base any view on changing this requirement on evidence of risk of harm set alongside the potential consumer benefits in increased flexibility and choice.

Q38. What would be advantages, disadvantages and impacts (both positive and negative) of patients being able to purchase spectacles from non-registrants without a prescription dated in the previous two years? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.67 See previous answer.

Q39. What would be advantages, disadvantages and impacts (both positive and negative) of the legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.68 See answer to question 37.

Q40. Does the legislation in relation to the sale and supply of sportswear optical appliances for children under 16 create any unnecessary regulatory barriers?

- a) Yes
- b) No
- c) Not sure / no opinion

Please give your reasons and provide any evidence to support these.

- 3.69 c) Not sure

- 3.70 The consultation document refers to feedback from stakeholders suggesting that the restrictions on the sale of sportswear optical appliances may be overly restrictive, therefore we agree that this area which may warrant review. It will be important to consider any unintended consequences of changes to the legislation in this area and weight up the potential benefits of increased consumer choice with any potential risk of harm arising.
- 3.71 We do not have any specific evidence to contribute on this matter but would expect the GOC to take account of all evidence received.

Q41. What would be advantages, disadvantages and impacts (both positive and negative) of children under 16 being able to buy sportswear optical appliances outside the supervision of a registrant / registered medical practitioner? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.72 See previous answer.

Q42. What would be advantages, disadvantages and impacts (both positive and negative) of the legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.73 See answer to question 40.

Q43. Are there any other aspects of the sale and supply of optical appliances legislation that you think need changing or create unnecessary regulatory barriers?

- a) Yes
- b) No
- c) Not sure / no opinion

If yes, please give your reasons and provide any evidence to support these.

- 3.74 c) No opinion

Q44. What would be the advantages, disadvantages and impacts (both positive and negative) of the sale and supply of optical appliances legislation remaining as it is currently? (Impacts can include financial and equality, diversity and inclusion.)

Please give your reasons and provide any evidence to support these.

- 3.75 No comments.

Section 7: Delivery of remote care and technology

Q45. Do you have any knowledge or experience of areas of technological development that the GOC should be aware of when considering changes to the Act?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

- 3.76 a) Yes
- 3.77 We have no sector-specific knowledge of technological advancements in optometry, but are of the view that new technologies are likely to significantly reshape the provision of healthcare over the coming decades. As such, we strongly support the GOC giving consideration to these questions, and how regulations and regulators may need to adapt to respond to these changes.
- 3.78 We welcome the GOC's efforts to take a forward looking approach to this issue to ensure that they are properly equipped as a regulator to prepare for these challenges.

Q46. Is there any evidence that increased use of technology or remote care may have an impact on patient safety or care in the future?

- a) Yes - a mainly positive impact
- b) Yes - a mainly negative impact
- c) No
- d) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

- 3.79 d) Not sure
- 3.80 The increased use of technology and remote care is likely to have a range of impacts both positive and negative. For patients, the ability to access services from home has the potential to improve both accessibility and convenience. Online service provision is also likely to provide cost savings for both patient and provider.
- 3.81 However, there are also risks to patients and users in respect of virtual care, and the GOC is well aware of concerns that have been raised over online providers, particularly those operating from overseas. Overseas providers are outwith UK jurisdiction and therefore may sell unsafe or poorly fitting contact lenses without the threat of regulatory action.

- 3.82 Even in respect of regulated providers, there is evidence from other sectors (such as primary care and pharmacy) that online providers often fall below the standards expected by regulators, and perform significantly worse than their 'bricks and mortar' competitors. For example, inspection data shows that only 63% of online pharmacies meet the GPhC's standards, compared to the overall benchmark of 84%.

Q47. Are there any unnecessary regulatory barriers in the Act that would prevent any current or future technological development in the eye care sector or restrict innovative care delivery or competition in the market?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

- 3.83 We do not have the evidence required to answer this question, however we support the GOC in seeking views on this issue.

Q48. Are there any gaps within the Act or GOC policy relating to the regulation of technology or remote care that present a risk to patients?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details of what these are, including your reasons and provide any evidence to support these.

- 3.84 a) Yes
- 3.85 As the GOC acknowledges, it does not have the powers or the capacity to act against online providers located overseas which may result in a patient safety gap.
- 3.86 A further area that the GOC may wish to develop policy on (as acknowledged in the consultation) is the potential for new technologies, such as robotics and Artificial Intelligence (AI) to blur the lines of accountability should things go wrong. We know from other sectors such as medicine that procedures carried out with robotic assistance can and have resulted in legal action where the technology has failed. In such circumstances liability and accountability can be unclear.
- 3.87 Similarly with AI, issues can occur where inappropriate or unrepresentative data is used to produce algorithms. Biased or flawed algorithms may result in misdiagnosis or inappropriate treatment, but it is unclear what the role of the

registrant would be in such cases. Work by the MHRA to regulate AI as a medical device may alleviate this problem.

Q49. If you answered yes to the previous question, do you have any suggestions about how these gaps in the regulation of technology or remote care could be addressed?

Please include your reasons and any evidence or impacts of your suggestions.

- 3.88 We recommend that all regulators, including the GOC, review how they will determine lines of accountability for new technologies.
- 3.89 It will be important for regulators to collaborate both with other regulators and other stakeholders with involvement in this area to ensure a consistent approach which will be necessary to ensure clarity for professionals, patients and service users.

Q50. Are there any gaps in the Act or GOC policy relating to the regulation of online sales of optical appliances that present a risk to patients?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details of what these are, including your reasons and provide any evidence to support these.

- 3.90 a) Yes
- 3.91 As above, the GOC lacks the powers or resources to tackle illegal online sales, particularly where providers are operating from overseas.

Q51. If you answered yes to the previous question, do you have any suggestions about how these gaps in the regulation of online sales of optical appliances could be addressed?

Please include your reasons and any evidence or impacts of your suggestions.

- 3.92 We would like to see full consideration given to these questions as part of the Government's regulatory reform programme. This should include a full review of all regulatory powers and whether they are sufficient to address current and future challenges and protect the public.
- 3.93 All healthcare professional regulators should also be considering what education, training, and CPD registrants require to adequately prepares them to interact with new technology, including robotics, AI and any additional risks and challenges arising from online sales.

Section 8: Any other areas

Q52. Are there other areas of our current legislation that you think need to be amended (recognising that the Department of Health and Social Care review will cover our core functions)?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

3.94 b) No

Q53. Are there any other gaps in regulation where you think legislative change might be required?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

3.95 b) No

Q54. Are there any other policies or guidance that the GOC currently produces that should be reviewed or require amendments?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

3.96 a) Yes

3.97 We are aware that there may be additional and growing risks associated with optical services provided in domiciliary settings. This may be an area for the GOC to consider providing additional or amended guidance.

Q55. Are there any other impacts of our legislation that you would like to tell us about, including financial impact or impact on those with protected characteristics under the Equality Act 2010 (i.e. age, sex, race, religion or

belief, disability, sexual orientation, gender reassignment, pregnancy or maternity, caring responsibilities)?

- a) Yes
- b) No
- c) Not sure / no opinion

If you answered yes, please give details, including your reasons and provide any evidence to support these.

- 3.98 We do not have evidence of specific impacts on those with protected characteristics at this stage. However, we would expect the GOC or the DHSC to carry out full equality impact assessment of any specific changes taken forward.
- 3.99 We suggest that in advance of then, the GOC may wish to consider any broad equality impacts of the changing landscape of the provision of optical services, including the shift to online and distance provision of services.

Q56: Can we publish your response?

- 3.100 Yes

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
157-197 Buckingham Palace Road
London SW1W 9SP

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