

Call for evidence on the Opticians Act and consultation on associated GOC policies

28 March 2022

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Overview

What we're doing

- 1. This call for evidence seeks views, information and factual evidence on the need for change to the Opticians Act 1989 ('the Act') (the legislation that underpins the regulatory work of the GOC, as well as defining some aspects of optometry and dispensing optics practice). At the same time we are also seeking views through a consultation on associated GOC policies.
- 2. The information and evidence we collect from this call for evidence will inform the development of any business case for future change to the Act, as well as inform whether we should consider making more immediate changes to our associated policies. We are also seeking views on our objectives for legislative reform.
- 3. The call for evidence and consultation contains questions and requests for information, which may include factual evidence, insight or evidence of impact (positive or negative) and/or evidence of experience. We are very much focussed on engaging stakeholders and gaining evidence for what needs to change in the future to ensure that regulation remains relevant and fit for the future. However, there are some actions that we consider ought to be undertaken sooner, so as well as asking for evidence of the need for future change, we are also asking for your views and evidence of impact on our proposals for immediate change in some areas.
- 4. This document contains two aspects:
 - a call for evidence which seeks views, information and factual evidence on the impact (including evidence of risks and impact to the public) and stakeholders' experience of the Act to help us to decide whether the Act and associated GOC policies should remain as they are or whether there is any evidence to support a case for change. There will need to be strong evidence to argue for change and stakeholders may wish to give examples of what works in other fields, as well as evidence from within the optical sector. We recognise that there may be gaps in evidence and we would be grateful to stakeholders for drawing these to our attention; and
 - a consultation (paragraphs 31-34) which will concentrate on an area
 where we have already started to develop our policy thinking and are
 interested in stakeholders' views and evidence of impact on how to move
 forward, particularly where stakeholders have already told us that there is
 a need to take action now.
- 5. This call for evidence and consultation is separate to the <u>Regulating healthcare</u> professionals, protecting the public consultation and related programme of work

currently being carried out by the Department of Health and Social Care (DHSC) to ensure consistency between the powers that all healthcare regulators have to deliver their regulatory functions of registration, education, fitness to practise, standards and the overall governance and operating framework of the regulator.

6. We are focussing this call for evidence and consultation on the aspects of the Act that are unique to the GOC or the practice of optometry and dispensing optics, as well as associated GOC policies and/or guidance. The call for evidence and consultation is centred on two parts of the Act: part II (sections 7, 8A and 9) and part IV (sections 24-30A). Part II of the Act outlines how individuals and businesses are registered by the GOC. Part IV outlines the regulation of the practice of optometry and dispensing optics. You can access these sections via the links below.

Part II Registration and Training of Opticians

Section 7: Registers of opticians

Section 8A: Register of students

Section 9: List of bodies corporate carrying on business as opticians

Part IV Restrictions On Testing Of Sight, Fitting Of Contact Lenses, Sale And Supply Of Optical Appliances And Use Of Titles And Descriptions

Section 24: Testing of sight

Section 25: Fitting of contact lenses

Section 26: Duties to be performed on sight testing

Section 27: Sale and supply of optical appliances

Section 28: Penalty for pretending to be registered etc

Section 29: Provision as to death or bankruptcy of registered optician

Section 30: Offences by bodies corporate

Section 30A: Legal proceedings

7. For more information about the GOC and our <u>legislation</u>, please see our website.

Why we're doing this now

8. The original Opticians Act was published in 1958. This was replaced by the Opticians Act 1989, but still retained large sections of the 1958 Act. There have been various amendments since 1989 such as introducing Continuing Professional Development (CPD). During this time, the sector has evolved significantly with the roles of optometrists and dispensing opticians developing to realise their full professional capability as well as occupying different roles, including enhanced clinical roles, across each nation of the UK. Technological

developments including remote care have also impacted on the way optical services are delivered to patients. We are keen to gather evidence and insight to better understand how our regulatory activity needs to develop to match advances in technology, service delivery and professional capability, and associated risks to patient care and public benefit.

- 9. In addition, the Act contains other areas that may require reform, such as protecting both function (i.e. activities such as sight testing) and professional title. We need to ensure the Act is fit for purpose and does not create unnecessary restrictions that limit the ability of registrants to fully utilise their professional capability to the benefit of patients. We are also keen to understand where the limit of such changes should be and their impact, so as to not unnecessarily restrict competition in the market. These factors must be balanced against the need to maintain patient care, safety and public benefit.
- 10. We plan to use the opportunity offered by the DHSC in their review of certain aspects of the Act to propose, on the basis of the evidence and insight gathered through this call for evidence, whether further changes are required to the aspects of the Act that apply only to the optical sector (such as sight testing, fitting of contact lenses, sale and supply of optical appliances, and business regulation).

What will happen next

- 11. The public call for evidence and consultation will be open for 16 weeks.
- 12. This is the first step in a programme of work to ensure that our legislation and associated policies are fit for the future. We will analyse the responses received and consider the need and strength of the case for change and/or whether further research and/or analysis of impact is required. If, as a result of the call for evidence and/or the consultation, we consider changes to legislation or GOC policy are necessary and can be evidenced, we will carry out further public and targeted stakeholder consultation activities on our proposals.
- 13. Although we are leading engagement with stakeholders and the sector through this call for evidence, responsibility for agreeing changes to the Act does not rest with us but with Parliament, and the pace and outcome of any changes sought will be determined by other stakeholders such as DHSC, devolved administrations and/or NHS commissioners.

Section 1: Objectives for legislative reform

- 14. A successful case for change will need robust and compelling evidence. In establishing the evidence base and case for change, and in assessing the weight and impact of evidence and insight provided through this call for evidence and consultation, we propose to use the following (non-hierarchical) objectives:
 - objective 1: maintaining patient and public safety our primary objective in everything we do as a regulator;
 - objective 2: ensuring that legislation reflects current and future context of healthcare delivery and is more flexible to accommodate changes going forward;
 - objective 3: ensuring that our legislation is flexible enough to accommodate future workforce needs and does not unnecessarily restrict the development of different roles needed to deliver the eye care needs of the UK;
 - objective 4: the GOC has sufficient powers to regulate a changing landscape in terms of developments within technology and the potential increase of care delivered into the UK;
 - objective 5: ensuring that there is consistency in the regulation of optometry/optician practices/businesses, i.e. the regulation of the system in which our optometrists and dispensing opticians work;
 - objective 6: regulatory interventions should take account of the national objective to reduce healthcare inequalities where possible and not put up any unnecessary regulatory barriers to this aim;
 - objective 7: reform should take the path of least resistance where this is appropriate, i.e. considering other regulatory levers, such as standards and guidance if these would be more effective than changing legislation; and
 - objective 8: ensuring that any changes do not impose disproportionate administrative or financial impacts on patients, the sector and our stakeholders.
- 15. We are interested in stakeholders' views about whether these are the right objectives for the GOC in establishing the evidence base and any case for changing the Act.

Q51: 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.

¹ These question numbers deliberately start at '5' to account for the fact that our <u>consultation hub</u> will ask four preliminary questions about who is completing the consultation. Only the substantive questions are included in this document.

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

- 16. Sections 7, 8A and 9 of the Opticians Act outline that we will maintain a register of optometrists and dispensing opticians, students (persons training as optometrists and dispensing opticians) and bodies corporate carrying on business as opticians.
- 17. Protection of title means that certain titles in <u>section 28</u> of the Act are reserved for individual or business registrants of the GOC and it is unlawful for anyone else to use them. These include optometrist, dispensing optician, registered optician and ophthalmic optician. All health and social care regulators protect titles as this is a key aspect of public protection and provides assurance to the public that someone using that title is competent and safe to practise.
- 18. Our Act goes further than protection of title and also restricts the activities of non-registrants². For example, part IV of the Act restricts the testing of sight (section 24), fitting of contact lenses (section 25), and the sale and supply of optical appliances (with specific exemptions) and zero powered contact lenses³ (section 27). It is unlawful for a non-registrant (or non-registered medical practitioner) to carry out these activities. This is similar to other healthcare professions where certain activities or practice is restricted in legislation.
- 19. In effect, the Act outlines both what our registrants can do and what non-registrants cannot do. The Act protects the public from unregistered persons who are not bound by the GOC's standards, as well as from dishonest individuals who mislead people as to their registration status. We are interested in understanding what you think should and should not be restricted to registrants. These are introductory high-level questions about your thoughts and we will ask you for further detail in later sections of this document you do not need to provide detailed reasoning or evidence at this stage.

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

. . .

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

. .

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

² Non-registrants are those persons who are not registered with the GOC as dispensing opticians or optometrists.

³ Zero powered contact lenses are cosmetic, non-corrective lenses (i.e. without a prescription) to change the colour or appearance of the eye.

- b) Fitting of contact lenses: should be restricted / not sure / should not be restricted
- 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

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

. . .

20. As part of changes to the Act being implemented separately by DHSC, the registers of all health and social care regulators will change. In the future, all regulators will keep a register of primary qualifications to practise (e.g. optometry and dispensing optics) and can then annotate the register with any post-registration skills, qualifications or training which they feel needs to be regulated. Currently we recognise four post-registration qualifications: 'contact lens optician' for dispensing opticians and three prescribing categories of 'additional supply', 'supplementary prescribing' and 'independent prescribing' for optometrists. We are keen to hear whether there is evidence for any further skills, qualifications or training to be recognised under this new system in the future.

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.

. . . .

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

- 21. The legislation around GOC business regulation is complex and does not currently provide for a clear and consistent system of regulation for optical businesses.
- 22. Section 9 of the Act provides for the GOC to register bodies corporate that meet certain eligibility requirements (including around its directors' registration and the nature of its activities). Under section 28 of the Act, it is an offence for an unregistered business to use a title, addition or description that falsely implies GOC registration, i.e. GOC registration is mandatory for bodies corporate using a protected title (etc).
- 23. It is not possible to register businesses that are sole practitioners or partnerships, and it is not mandatory for bodies corporate to register unless they use a protected title. In addition, bodies corporate can voluntarily register if they are not using a protected title but have a majority of registrant directors. This results in an inconsistent application to our regulatory powers for businesses. Previous estimates suggest that there are over 4,000 businesses that are not registered with us. Further information about the legal requirements can be found in section 1 of our Review of business regulation: consultation.
- 24. Following <u>public consultation</u> in 2013 where we consulted on a number of different options for regulation of businesses, we confirmed in our <u>Statement on the outcome of the review of business regulation</u> to extend business regulation to all businesses providing restricted functions (referred to in this call for evidence as restricted activities) to ensure a "consistent and equitable approach to regulation that provides a level playing field for all optical businesses".
- 25. We re-stated our desire to extend business regulation in our <u>Strategic Plan</u> <u>2020-25</u> where we said that we want to "better protect the public by introducing a comprehensive, simpler and more effective system of business regulation that covers all UK businesses providing eye care services and/or supplying spectacles or contact lenses where this must involve registered practitioners, and which promotes rather than hinders the growth of these businesses".
- 26. We are interested in stakeholders' views about whether the basis for this decision to extend business regulation still applies or if there is any further evidence that they wish us to consider.
- 27. We also said in our Strategic Plan 2020-25 that we would "consider what powers are necessary to ensure compliance with our business standards, including the merit of seeking inspection powers in line with some other professional regulators".

- 28. Some examples of other models involving inspection powers include the Care Quality Commission (CQC) regulation of some health and social care services in England (which includes an inspection process) and the General Pharmaceutical Council's (GPhC) regulation of pharmacy premises. Both the GPhC and the CQC have proactive powers of inspection which mean they can intervene at an earlier stage if areas of concern are identified during an inspection visit to a practice or premises.
- 29. The regulation of retail pharmacy premises is an interesting model that we could learn from. A <u>responsible pharmacist</u> (a pharmacist registered with the GPhC) is appointed by the owner of a pharmacy to be in charge of the pharmacy and to ensure its safe and effective running. This is a legal requirement. We previously consulted on proposals for change in 2013, which included an option of a dedicated 'practice principal', similar to a responsible pharmacist more detail can be found in <u>Review of business regulation</u>: <u>consultation</u> as to the background of the consultation and the detail of the different options.
- 30. A majority of optical businesses will provide services for the NHS through a contract or service level agreement for General Ophthalmic Services (GOS). A system of contract performance review exists to improve the quality of the services provided, which includes initial review, self-declaration and/or random inspections. Approaches vary throughout the four UK nations and it is not clear whether the system is sufficient for the purposes of regulation, when this is not the sole intention of the inspection.

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.

. . .

Q12. Are there any advantages, disadvantages and impacts (both positive and negative) of extending business regulation in addition to those identified in our 2013 <u>review of business regulation</u>? (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.

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.

. . .

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

- a) Yes, the GPhC model of a responsible pharmacist
- b) Yes, another model (please specify)
- c) No
- d) Not sure / no opinion

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

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

- 31. Restrictions in relation to testing of sight are set out in section 24 of the Act, and only optometrists or registered medical practitioners can test sight (with special provision for students). Testing of sight is a restricted activity as outlined in section 2 of this document. We have heard from some stakeholders that the Act is too prescriptive, for example, in terms of who can carry out a sight test and how this must be done.
- 32. Currently, no part of the sight test can be delegated to a dispensing optician or contact lens optician, even under supervision. However, aspects of sight testing (i.e. refraction⁴) can be undertaken by others for purposes other than the sight test, for example, dispensing opticians undertaking refraction to check accuracy of lenses, or optical assistants completing triage checks prior to the sight test. We issued a <u>statement in 2013</u> setting out our position on this.
- 33. We have seen the roles of optometrists and dispensing opticians evolve and expand, particularly over the last few years, along with increasing pressures in ophthalmology departments. GOC registrants could help alleviate these pressures if they have the right clinical skills and the legislation does not create unnecessary barriers as to who can deliver care if dispensing opticians were able to carry out part of the sight test, it could free up the time of optometrists to support a wider range of clinical activities. In addition, technological innovation may also impact on the way the sight test is carried out in future and we should be mindful that the Act does not restrict this either.
- 34. Whilst we are looking to the future, we feel that we need to take action now in respect of our 2013 statement, as we feel that it creates an unnecessary regulatory barrier we think that dispensing opticians could undertake refraction for the purposes of the sight test if they are appropriately trained, competent, overseen and indemnified. We are therefore **consulting** with you to obtain your views on this area.

CONSULTATION

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 <u>statement on refraction</u>.)

- a) Yes with no restrictions
- b) Yes under the oversight of an optometrist or registered medical practitioner
- c) No

d) Not sure / no opinion

⁴ Refraction as part of the sight test refers to a check of the patient's visual acuity i.e. how well they can see, and whether any corrective measures such as spectacles or contact lenses are required.

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

. . .

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.

. . .

Duties to be performed on sight testing

- 35. Section 26 of the Act sets out the duties to be performed on sight testing, which are commonly known as the refraction and the eye health check. The difference between these two areas is not always clearly understood by patients and the public. Current practice is that the refraction and the eye health check must be undertaken at the same time or within a reasonable time period of each other. Our interpretation is that the Act does not specifically prohibit separation of the elements of the sight test by time, place or person.
- 36. We have heard arguments for retaining the sight testing regulations as they are, because the patient will automatically get an eye health check as well as their sight being tested (refraction) on a regular basis. We have also heard from stakeholders that there should be flexibility to completely separate the eye health check from the refraction to allow patients more choice and access to the care that they need, i.e. not prohibiting patients from accessing spectacles and contact lenses by having to pay for an eye health check. However, there is concern from some stakeholders that if these were to be separated, some members of the public would not attend for an eye health check and therefore pathology may go undetected or picked up at a late stage, thereby potentially leading to avoidable sight loss and an increase in serious eye conditions impacting on the secondary care sector.
- 37. Both of these models apply in different countries around the world and there is no consistency of approach at a worldwide level. If the approach to the testing of sight were to change, we would need a firm evidence base to justify that patient care was not being compromised. We are interested in your views on the advantages and disadvantages of the current sight testing legislation and what the impact of any changes might be. We are also interested in data to support or refute the need to maintain the link between the refraction and eye health check we are specifically interested in eye health referrals resulting from the standard sight test because this would indicate whether there might be an impact on public health and safety.

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.

. . .

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.

. . .

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.

. . .

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.

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

- 38. Section 25 of the Act provides that contact lenses can only be fitted by a dispensing optician⁵, optometrist or registered medical practitioner, with special provision for students. Fitting must begin before the re-examination date specified in a valid prescription (dated less than two years ago).
- 39. We understand the fitting of contact lenses is restricted because of the risk profile of contact lenses as medical devices and the complications that can arise from contact lens wear.
- 40. We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

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.

⁵ Dispensing opticians need to have completed an additional contact lens speciality and be on the contact lens speciality register in order to be able to fit contact lenses.

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

41. <u>Section 27</u> of the Act covers the sale and supply of optical appliances and zero powered contact lenses.

Supply to under 16s and those registered visually impaired

- 42. Under section 27 of the Act, only dispensing opticians, optometrists and registered medical practitioners (or those acting under their supervision) can supply certain optical appliances to children under 16 or those registered visually impaired. We have heard from some stakeholders that they would like these groups to be extended to vulnerable patients including older people in domiciliary care or those with disabilities other than visual disabilities, such as learning disabilities. We have heard from some stakeholders that those who are not dispensing opticians, optometrists or registered medical practitioners do not have the necessary skills and knowledge to understand and address the specific needs of these types of patient. GOC registrants have the necessary clinical and communication skills to effectively manage, understand and treat these patients by virtue of their education and continuing professional development.
- 43. We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

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.

Prescription contact lenses and verification

- 44. Prescription contact lenses can be sold:
 - by or under the supervision of a dispensing optician, optometrist or registered medical practitioner; or
 - (as long as the user is not under 16 or registered visually impaired) under the general direction of a dispensing optician, optometrist or registered medical practitioner, who need not be on the premises at the time, if the supplier first receives the original specification or verifies the specification with the prescriber.
- 45. In order to be supplied with prescription contact lenses, a patient must have an in-date contact lens specification which has been issued following a contact lens fitting/check. Where the sale is being made under the general direction (rather than supervision) of a registrant, and an original of the contact lens specification is not provided, section 27(3)(ii) of the Act requires the specification information (referred to as 'particulars of the specification') or a copy of the specification to be verified with the person who provided the original specification.
- 46. We have heard from stakeholders that electronic copies should now be accepted without the need for verification, provided that they can be clearly read. We think the requirement for verification of both electronic copies and particulars is outdated and we understand the risks associated originally with this may have changed. During the COVID-19 pandemic we relaxed enforcement of this requirement, with no detrimental effects to our knowledge.
- 47. In addition, section 27(3B) of the Act requires the seller to make arrangements for the user to receive reasonable 'aftercare' in so far as, and for as long as, may be reasonable in that individual's case. There is no definition of aftercare in the Act and we have heard from stakeholders that it would be helpful for this to be provided.

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.

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.

. . .

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.

. . .

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.

. . .

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.

. .

Zero powered contact lenses

- 48. Section 27(1)(b) of the Act provides that zero powered contact lenses can be sold only by or under the supervision of a dispensing optician, optometrist or registered medical practitioner. Case law and our <u>standards of practice</u> requires that the supervisor must be on the premises at the time of the sale, exercising their professional judgement as a clinician and in a position to intervene in the patient's interests.
- 49. We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

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.

. . .

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.

. . .

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.

. . .

Offences under the Act

- 50. The Act creates the following criminal offences:
 - unlawfully conducting sight tests (<u>section 24</u>);
 - unlawfully fitting contact lenses (<u>section 25</u>);
 - unlawfully supplying spectacles (<u>section 27</u>);
 - unlawfully supplying prescription contact lenses (section 27);

- unlawfully supplying zero powered contact lenses (section 27); and
- misuse of protected title or misrepresentation of registration status with the GOC (section 28).
- 51. Professional bodies and registrants have said in responses to our recent <u>illegal practice strategy review consultation</u> that we should do more to protect the public from illegal online sales, both UK and non-UK, and that the Act requires reform to address the consumer shift to online purchases. Responses have also levelled criticism that in failing to tackle illegal online sellers we are allowing an unlevel playing field.
- 52. The reality is that the enforcement of our legislation relating to sales bringing a private prosecution in the magistrates' court is not practicable for an organisation the size of the GOC or in relation to sales in a global online market. Moreover, it is not realistic to expect the GOC to achieve legislative reform that enables us to routinely act against non-UK sellers. De-regulation could be a way to achieve a level playing field if transferring the onus of compliance to the consumer, except for restricted categories, does not expose the consumer to a level of risk that is necessary to be mitigated by legislation.
- 53. The call for evidence is an opportunity to start to build a case to match our legislation relating to the sale of optical appliances to the realities of the market and ascertain the risk if the onus is on the consumer (except for restricted categories). We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

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.

Q36. Is legislation regarding the sale of optical appliances necessary to protect consumers (except restricted categories)?

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

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

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Sale and supply of spectacles by non-registrants

- 54. Currently the Act does not restrict the supply of spectacles by (or under the supervision of) optometrists and dispensing opticians, including for users aged under 16 or registered visually impaired. However, article 3 of The Sale of Optical Appliances Order 1984 requires (among other matters) that non-registrants may supply spectacles only in accordance with a written prescription issued within the previous two years.
- 55. We have heard from some patients that they are not happy with this requirement as they feel that it restricts their consumer choice and do not wish to have a sight test every two years.
- 56. We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

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.

. . .

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.

...

Supply of sportswear optical appliances to children under 16

- 57. The restrictions under the Act relating to supply of optical appliances to children under 16 apply to sportswear such as swimming goggles and dive masks, not just spectacles and contact lenses. This means that this type of sportswear cannot be provided over the internet by non-registrants as the supervision required cannot be exercised over the internet.
- 58. We have heard from some stakeholders that they think these supervision requirements are overly restrictive as these types of sportswear are usually only worn for short periods and the fitting process is not as complex as with spectacles or contact lenses. Section 27(2)(b) of the Act creates an exemption for "an optical appliance intended for use as protection or cover for the eyes in sports" provided (among other matters) that "the appliance falls within any category of appliance specified in an order made by the Privy Council for the purposes of this section". As yet, the Privy Council has not made any order specifying categories of sportswear optical appliances.
- 59. We are interested in evidence to support any case for retaining or changing legislation.

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.

. . .

Q41. What would be advantages, disadvantages and impacts (both positive and negative) of children under 16 being able to buy sportwear 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.

. . .

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.

. . .

Other

60. We have covered most of the areas in <u>section 27</u> of the Act above, but would encourage stakeholders to tell us about any other areas of the sale and supply of optical appliances legislation that they think needs changing.

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.

. . .

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.

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Section 7: Delivery of remote care and technology

- 61. We are increasingly aware that as technology moves on and develops, remote care (i.e. care that is not carried out in the same location as the patient, such as by telephone or video call) will become more central to healthcare practice. In our sector there are moves in Scotland for optometrists to start using a digital patient record sharing service. In England, NHS Digital is looking to expand the use of digital technologies for the eye care sector, including use of digital platforms to share consultation information and the use of apps for patients to manage long term conditions. We are aware that this offers the opportunity for care to be delivered remotely into the UK, either by supply of products or supply of consultations/care. UK legislation, including the Act, applies only to UK based individuals and businesses, so the Act does not extend to non-UK practitioners providing remote care to UK patients. We wish to understand potential options for ensuring patient safety in this area.
- 62. Currently our regulatory powers are based on a face-to-face model of care delivery where patients are seen in the practice and all care is delivered within the UK. As technology develops, and we have seen this through the recent COVID-19 pandemic, it is likely that more care will be delivered remotely, either as part of a triaging process or when the technology improves, remote refraction and healthcare checks using auto-refractors as standard⁶.
- 63. We are not a regulator of products or technology this is the remit of the Medicines and Healthcare products Regulatory Agency (MHRA). However, as healthcare relies more and more on artificial intelligence to perform the diagnostic and technical roles of the optometrist and dispensing optician, we want to explore how a regulator can ensure that this technology is safe, that patients are protected, and who is responsible should things go wrong in these circumstances.
- 64. We are keen to explore whether there is a necessity for increased regulation of technology, remote care or care delivered from outside of the UK, but again there must be evidence that this is required and we would not want to impose any regulatory barriers to the development of innovative care delivery or competition in the market. We would be interested in any evidence of risk or harm in this area or the potential for this given future developments. The sector itself is best placed to inform the regulator of how developments in technology may impact regulation going forward.

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⁶ 2020health (2016), 'Foresight Project Report', London: The Optical Confederation and The College of Optometrists.

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.

. . .

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.

. . .

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.

. . .

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.

. . .

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.

. . .

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.

. . .

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.

Section 8: Any other areas

- 65. We would like stakeholders to let us know about any other areas that we have not specified in this document where they think that legislative change might be required due to gaps in regulation.
- 66. We are also keen to explore where our other policies, guidance or standards may need to be amended or used instead of legislative reform. For example, we publish a number of <u>position statements</u> on various aspects of optometry and dispensing optics practice.

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 <u>core functions</u>)?

- 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.

. . .

Q53. Are they 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.

. . .

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.

. . .

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.

. . .

NB This document is an aide for you to see all the substantive questions at once and to draft responses. We would be grateful if you could input your responses into our <u>consultation hub</u> so that we can collect information about you or your organisation and whether your response can be published.