

COUNCIL

Illegal practice strategy project

Meeting: 29 July 2015

Status: for decision

Lead responsibility: Alistair Bridge
(Director of Strategy)

Paper author: Marie Bunby (Project
manager)

Purpose

1. The purpose of the paper is to update Council on the implementation of the illegal practice strategy.
2. Council is asked to:
 - 2.1 **consider** and **approve** for consultation the draft voluntary code of practice for online contact lens supply (Annex 1), subject to incorporation of any comments it may have;
 - 2.2 **consider** and **approve** a consultation period of ten weeks for the voluntary code of practice;
 - 2.3 **consider** and **approve** the draft appendix to the protocol for criminal prosecutions (Annex 3); and
 - 2.4 **delegate** authority to the Chair and the Chief Executive and Registrar to sign off the final versions of the consultation document and draft appendix to the protocol for criminal prosecutions incorporating Council's comments.

Strategic Objective

3. The specific purpose of this project is to 'develop a clear strategy for preventing and addressing illegal practice'.
4. This project contributes to our mission of protecting and promoting public health and safety by helping to achieve our strategic objectives in the 2014-17 Strategic Plan to raise public trust and awareness, handle complaints more effectively and implement a targeted and proportionate system of regulation.
5. Alistair Bridge, Director of Strategy, is the Project Sponsor for this work. Marie Bunby, Policy Manager, is the Project Manager. Rob Hogan is the Council Champion. Rosie Glazebrook, Council Member, is also involved in this project through her work with the stakeholder working group (see paragraph 17) and brings particular expertise in relation to the workstream on producing guidance for the public. Lisa Davis, Director of Fitness to Practise, is leading the workstream on how we review our approach to complaints handling.

Risks

6. There is a risk that we are not able to meet stakeholders' expectations in relation to the actions we take and the results we achieve. We will continue to engage closely with stakeholders to maintain support for the strategy and spread awareness of the limitations on our ability to take formal enforcement action, particularly when contact lens suppliers are based overseas.
7. If the requirements of the code of practice are too onerous, there will be a risk of only limited support, thus reducing its effectiveness. Conversely, if the requirements are insufficiently demanding, compliance might not be sufficient to improve public protection. The consultation will enable us to test the draft code with stakeholders generally.
8. There is also a risk of legal challenge from suppliers who feel disadvantaged by the code of practice and might object to the GOC's role in developing the code. To minimise this risk we have made clear that the rationale for the code is to reduce the risks to the public identified by the Europe Economics research, taking into account the constraints on our ability to take enforcement action against suppliers who are based overseas and therefore do not have to comply with UK law.
9. There is the risk that consulting on the code of practice for only ten weeks will result in criticism from the Professional Standards Authority or other stakeholders who might have preferred us to consult for the full 12 weeks. We feel that this would be appropriate as we have already carried out a 12 week consultation on our proposed illegal practice strategy allowing stakeholders to consider the Europe Economics research and comment on our proposed strategy; this consultation focuses more narrowly on the implementation of one aspect of the strategy.

Background

10. In 2013 the General Optical Council (GOC) began a review of its strategy for tackling illegal practice. Illegal practice is defined as criminal offences under the Opticians Act 1989 (the Act). The Act creates criminal offences in relation to:
 - 10.1 unlawfully conducting sight tests;
 - 10.2 unlawfully supplying spectacles;
 - 10.3 unlawfully fitting contact lenses;
 - 10.4 unlawfully supplying prescription contact lenses;
 - 10.5 unlawfully supplying zero-powered contact lenses; and
 - 10.6 misuse of protected titles.
11. We commissioned Europe Economics to carry out a study into the risks associated with illegal practice. They examined both the likelihood of an adverse event occurring as a result of each type of illegal practice, and the likely

harm that would arise from the adverse event. Europe Economics produced a report¹ and made recommendations on the areas that carry the greatest risk to public health and safety.

12. We held a consultation on our strategy for tackling illegal practice between March and June 2014. During the consultation we sought views on our proposed approach to addressing the different types of illegal practice. Our preferred option was a proactive, multi-pronged approach to reducing public harm based on the following five areas:
 - 12.1 continuing to handle complaints in line with our prosecution protocol for all types of illegal practice (workstream 1);
 - 12.2 collaboration with other enforcement bodies to address high-risk areas of illegal practice (workstream 2);
 - 12.3 guidance for the public on the safe purchase and use of contact lenses (prescription and cosmetic) (workstream 3);
 - 12.4 development of a voluntary code of practice on the supply of contact lenses (prescription and cosmetic) online that would address the risks to the public identified by the Europe Economics research (workstream 4); and
 - 12.5 further research and intelligence-gathering (workstream 5).
13. In July 2014, following the consultation period and consideration of feedback from our stakeholders, Council approved our strategy for tackling illegal practice in the optical sector. In doing so, we decided not to look at online supply of spectacles as part of the code of practice for online suppliers as this area was found to be of lower risk in the Europe Economics research, but we will consider extending the code of practice to cover spectacles if we assess that it has been a success for contact lenses.
14. Since the end of the consultation period, we have been concentrating our efforts on workstreams 1, 3 and 4 outlined above. We have also made progress on workstreams 2 and 5 in recent months.

Workstream 1: Continuing to handle complaints in line with our prosecution protocol

15. Our prosecution protocol was published in June 2011 (Annex 2), following approval by Council in May 2011. We also have internal guidance for the Registrar in applying the protocol. The outcome of the illegal practice strategy consultation was that we decided to review the way in which we handle complaints in line with our protocol.

Workstream 2: Collaboration with other enforcement bodies to address high-risk areas of illegal practice

¹ Europe Economics (2013), *Health Risk Assessment of Illegal Optical Practice: Final report for the General Optical Council* [add link please]

16. We have been engaging with Trading Standards Officers over the past year to raise awareness of the law around zero powered contact lenses. We exhibited at the Trading Standards Institute Conferences in 2014 and 2015 and met the lead officer for product safety to discuss how we can strengthen our links, including using the channels the Trading Standards Institute has for communicating information to its members.

Workstreams 3 and 4: Guidance for the public on the safe purchase and use of contact lenses and Development of a voluntary code of practice

17. Illegal online supply of contact lenses and illegal contact lens supply where there is a lack of aftercare advice were identified by Europe Economics as two areas that presented some of the highest level of risk in relation to illegal practice. We decided to work in collaboration with stakeholders to minimise the risks to the public, by making customers more aware of how they can safely buy and wear contact lenses and making it easier for them to choose a supplier that follows good practice by developing and promoting a voluntary code of practice for online suppliers.
18. The GOC sees its role as to act as a catalyst to bring together stakeholders and develop a shared view of what constitutes good practice in the online supply of contact lenses. Having led the work to develop the code of practice with our stakeholders, we envisage sharing with stakeholders the responsibility for administering the code.
19. In October 2014 we appointed Richard Edwards, an optometrist with significant management experience in the sector and a member of our Companies Committee, to act as a consultant to advise on delivery of the illegal practice strategy.
20. We published a statement in November 2014 confirming our strategy, the appointment of Richard Edwards, Rob Hogan's involvement as Council Champion, and our intention to set up a stakeholder group to oversee the workstreams on developing a code of practice for online suppliers and raising awareness among contact lens wearers of how to buy and wear contact lenses safely. We announced this at a seminar of the British Contact Lens Association (BCLA).
21. We set up two stakeholder groups (see appendices 2 and 3 of the consultation document for a list of members) - a stakeholder steering group and a stakeholder working group. The role of the stakeholder steering group was to develop a code of practice for online contact lens suppliers and advise on options for implementation, with the emphasis being on addressing the risks to the public that can arise from internet supply; and to create an initial proposal and advise on strategies to raise awareness among contact lens wearers of the need to follow aftercare advice and have regular check-ups. We set up a

stakeholder working group (made up of some members of the stakeholder steering group along with other stakeholders) to advise the steering group on the detail of this work.

22. Our stakeholder groups met throughout February to July 2015. We have worked in partnership with our stakeholders to produce a draft of the voluntary code of practice that we intend to consult on. Council considered an initial version of the code of practice at its meeting in May 2015.

Workstream 5: Further research and intelligence-gathering

23. In developing our illegal practice strategy we noted that we would need to conduct further research to fill the gaps in our understanding of how consumers purchase and wear contact lenses. This will enable us to target consumer information effectively and evaluate the impact of the code of practice and efforts to raise consumer awareness.

Analysis

Workstream 1: Continuing to handle complaints in line with our prosecution protocol

24. Following the development of our illegal practice strategy we been reviewing the way we handle complaints, with the aim of ensuring that our processes are aligned with the new strategy, as well as the established prosecution protocol.
25. We have reviewed case management procedures and identified the need to make some adjustments, based on a more methodical and risk based approach. We have drafted some guidance (Annex 3) on the application of the prosecution protocol which will ensure that decision making about illegal practice cases takes place in line with our protocol. We intend to annex this guidance to our prosecution protocol and to begin to use it with immediate effect following the Council meeting. We will evaluate its impact and report back to Council in May 2016.

Workstream 2: Collaboration with other enforcement bodies to address high-risk areas of illegal practice

26. We attended the Trading Standards Institute Conference between 30 June and 2 July 2015. We held discussions with trading standards officers who advised that they would be happy to disseminate information about illegal practice produced by the GOC and to speak to individual suppliers in their local area, but due to resourcing issues and lack of familiarity with the legislation, it is likely that they would look to the GOC to take the lead in illegal practice cases.
27. We continue to liaise with the Medicines and Healthcare products Regulatory Agency (MHRA) and have involved them in the membership of our stakeholder working group, which will particularly helpful when we develop guidance for members of the public on the safe purchase and use of contact lenses.

28. We will continue to collaborate with any other enforcement bodies that are relevant (e.g. General Pharmaceutical Council) in relation to our illegal practice cases and raising awareness of the legislation among, for example, pharmacists selling cosmetic lenses without realising they should be sold only under the supervision of an optometrist etc.

Workstream 3: Guidance for the public on the safe purchase and use of contact lenses

29. The stakeholder working group has started to develop guidance for the public, based on current information leaflets provided by the British Contact Lens Association (BCLA). We intend to have this ready in time for the launch of the code of practice as it is our current intention to point members of the public to those suppliers that have signed up to the code of practice when buying contact lenses online.
30. A key challenge in this area will be how to disseminate the guidance and we recognise that we will need collaboration with stakeholders and consumer groups, marketing expertise and research to help us to target the guidance.

Workstream 4: Development of a voluntary code of practice

31. Since February 2015 the stakeholder working group has been developing and refining a voluntary code of practice for the online supply of contact lenses, under the direction of the stakeholder steering group. The main objective is to improve the practice of online suppliers who are not complying with UK legislation to provide information and advice to ensure that, as far as possible, customers are having regular after appointments and eye examinations. In particular, we want to develop a code of practice that addresses the risks identified in the Europe Economics (2013) research into illegal practice including areas such as substitution of contact lenses and that can potentially be signed up to by business registrants based in the UK who do have to comply with UK law.
32. The approach to developing the code of practice is outlined in section 2 of the consultation document (Annex 1). The document also explains how the code of practice could be implemented and evaluated, and contains the latest version of the code of practice. Council may wish to note the issues surrounding zero powered contact lenses and substitution in particular, as well as the discussions around whether the code of practice could apply to all contact lens suppliers, not just those providing online services.
33. We are now seeking Council's approval to consult on the draft code of practice between 3 August and 12 October 2015. We would normally consult for 12 weeks. However, in this case we are proposing to shorten the consultation time by approximately two weeks to allow for us to bring the results of the

consultation to the Council meeting in November 2015, rather than delaying until the Council meeting in February 2016. We feel that this would be appropriate as we have already carried out a 12 week consultation on our proposed illegal practice strategy allowing stakeholders to consider the Europe Economics research and comment on our proposed strategy; this consultation focuses more narrowly on the implementation of one aspect of the strategy.

34. As part of this workstream we have been considering the legislation relating to the sale and supply of contact lenses. This could link in to our work programme on legislative reform, which will include how we can implement our new system of business regulation.
35. This workstream also has links with the standards review project, in particular the intention to produce guidance for our registrants on the legal requirements contained in our legislation.

Workstream 5: Further research and intelligence-gathering

36. We intend to commission some research to provide us with data to establish a benchmark upon which to evaluate the impact of the code of practice. This will involve surveying contact lens wearers to ask about their behaviour and to see how findings vary on where they buy their contact lenses. The research will likely include where and how often members of the public buy their contact lenses, how often they attend eye examination and contact lens check-ups with an eye care practitioner, and awareness and compliance with contact lens aftercare advice. The research will also seek to understand reasons for buying contact lenses online and what might make those that do not currently buy online interested in doing so.
37. The research will also establish a profile of contact lens wearers, particularly those that buy online, and help us to target our consumer information messages using the most appropriate communication methods.

Impacts

38. Likely impact of the proposed illegal practice strategy:
 - 38.1 Reserves – there will be costs involved in implementing the strategy through, for example, setting up the code of practice and raising public awareness. We intend to minimise the costs to the GOC through collaboration with stakeholders, but will need to quantify the costs more precisely following the consultation and discussions with stakeholders about how the code will be administered;
 - 38.2 Budget – we have funds for research and consultancy in the budget for 2015/16;
 - 38.3 Resources – none;
 - 38.4 Equality and diversity – none; and

38.5 Human Rights Act – none.

Devolved Nations

39. We do not believe that the proposed strategy has any specific implications for the devolved nations, but we will continue to engage with stakeholders in all four nations as we implement our proposals and will respond to any issues that may subsequently arise. However, we note that there is no process for private prosecutions in Scotland, which limits the options for formal legal action.

Communications

40. This is an area of great interest to many of our stakeholders, and many of these have already indicated to us that they are very keen to engage with any proposals on how to deal with illegal practice.
41. To this end, we have ensured that our key stakeholders are represented on our stakeholder steering and working groups.
42. We will consult on the draft voluntary code of practice for online contact lens supply between August and October 2015. We will continue to engage with our stakeholders throughout this process, including online suppliers of contact lenses.
43. The stakeholder working group has been involved in developing our engagement plan in respect of the code of practice.
44. The optical press are also likely to take an interest, and at certain times of the year (particularly around Halloween) the issue of cosmetic contact lenses can attract national media attention.
45. We note the concerns of individual registrants in respect of illegal practice and online contact lens supply and will communicate with them directly e.g. through our regular bulletin.

Recommendations

46. Council is asked to **note** our update on the implementation of the illegal practice strategy and to:
- 46.1 **consider** and **approve** for consultation the draft voluntary code of practice for online contact lens supply (Annex 1), subject to incorporation of any comments it may have;
- 46.2 **consider** and **approve** a consultation period of ten weeks for the voluntary code of practice;
- 46.3 **consider** and **approve** the draft appendix to the protocol for criminal prosecutions (Annex 3); and
- 46.4 **delegate** authority to the Chair and the Chief Executive and Registrar to sign off the final versions of the consultation document and draft

appendix to the protocol for criminal prosecutions incorporating Council's comments.

Timeline for future work

47. The currently envisaged timeline for the code of practice workstream is as follows:

Action	Date
Council meeting to approve code of practice and options for implementation for consultation and provide an update on progress with implementing the strategy generally	29 July 2015
Consultation period	3 August - 12 October 2015
Stakeholder steering group to review outcome of consultation	October 2015
Council discussion on consultation outcome, final voluntary code of practice and implementation	11 November 2015
Publish statement on outcome of consultation	December 2015
Implementation period	Spring 2016

Annexes

Annex 1 – Draft consultation document on the voluntary code of practice for online suppliers (**SEE SEPARATE DOCUMENT**)

Annex 2 – Protocol for criminal prosecutions

Annex 3 – Draft appendix to the protocol for criminal prosecutions

Protocol for criminal prosecutions

This protocol governs the conduct of investigations and the decision on whether to prosecute suspected criminal offences under the Opticians Act 1989, as amended by the Opticians Act 1989 (Amendment) Order 2005 and related legislation ("the Act").

The Overriding Objective

The overriding objective of the General Optical Council ("the GOC") in conducting a criminal investigation or bringing a criminal prosecution is to protect, promote and maintain the health and safety of the public.

Background

Qualifying as an optician, whether as an optometrist or as a dispensing optician, demands a long period of study and practical training. The GOC imposes high standards of education, conduct and performance on the opticians registered with it, and the Act has restricted certain activities, and the use of certain titles, to GOC registrants. 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.

The Council for Healthcare Regulatory Excellence stated in its report 'Protecting the Public from Unregistered Practitioners', published February 2010, that "*Patients and the public recognise health professional titles because they indicate competence and fitness to practise. There is a risk to patient safety and public protection when unqualified people pass themselves off as registered professionals. Health professional regulators have a duty to ensure protection for patients and the public, and tackling title misuse is an important part of this.*"

Statutory Framework

The Act creates criminal offences in relation to (a) Activities that are restricted to persons registered with the GOC or the General Medical Council and (b) Titles that are restricted to persons registered or enrolled with the GOC.

The offences created by the Act are as follows:-

- i. Carrying out a sight test when not a registered optometrist or medical practitioner (an offence under Section 24);
- ii. Fitting contact lenses when not a registered optometrist, dispensing optician or medical practitioner (an offence under Section 25);
- iii. Selling optical appliances (with specific exceptions) or zero powered contact lenses otherwise than under the supervision of a registered optometrist, dispensing optician or medical practitioner (an offence under Section 27);

- iv. Pretending to be a registered optometrist or dispensing optician, or an enrolled optical business, when not entitled (an offence under Section 28).

The GOC does not have statutory prosecution powers, and considers allegations of suspected offences as part of its remit to protect, promote and maintain the health and safety of the public. In addition to offences created by the Act, the GOC may consider other allegations that are relevant to its remit, for example that someone has obtained registration by providing false information or that someone has breached a court order requiring the production of a document requested by the GOC in the course of an enquiry. When considering such allegations, the GOC will endeavour to follow this protocol, with modifications as necessary.

Procedure

The GOC may receive allegations verbally or in writing, and may receive anonymous allegations.

The Registrar must at all stages consider whether to refer the matter for a fitness to practise investigation or to consult or notify another agency in relation to the matter, including external legal advisers, another regulator or the police.

Stage 1: Initial screening

The Registrar (or a person nominated on behalf of the Registrar) must first ascertain whether the allegation relates to a matter for which it would be appropriate for the GOC to consider taking criminal proceedings. The Registrar can inform this decision by obtaining further information from the person who is the subject of the allegation (the suspect), the person who has made the allegation (the informant) and/or a third party.

If the Registrar is of the view that the GOC should not consider issuing criminal proceedings, the Registrar must notify the informant (if known) of this decision and the reasons for the decision.

If the Registrar is of the view that the GOC should consider issuing criminal proceedings, the Registrar must deal with the allegation in accordance with the following paragraphs.

Stage 2: Investigation

The Registrar shall investigate the allegation by gathering evidence, including through the instruction of enquiry agents and external lawyers in appropriate cases.

Stage 3: Decision on Prosecution

Following the investigation, the Registrar shall determine whether to:-

- i. Take no action;

- ii. Obtain an undertaking from the suspect or take other informal action;
- iii. Refer the matter to the GOC's Fitness to Practise department, another regulator, the police or the Crown Office and Procurator Fiscal Service (in Scotland);
- iv. Institute a prosecution (in England & Wales or Northern Ireland).

In deciding whether to prosecute, the Registrar must consider whether there is sufficient evidence for a prosecution (the evidential test) and whether a prosecution is required in the public interest (the public interest test). The Registrar must have regard to current guidance regarding these tests, as contained within this protocol and in the relevant code for public prosecution:-

- In England & Wales, the Code for Crown Prosecutors issued by the Crown Prosecution Service;
- In Scotland, the Prosecution Code issued by the Crown Office and Procurator Fiscal Service;
- In Northern Ireland, the Code for Prosecutors issued by the Public Prosecution Service of Northern Ireland.

The Registrar must at all times have regard to the GOC's overriding objective of protecting, promoting and maintaining the health and safety of the public. This might result in the Registrar deciding that the GOC should not issue proceedings even where the allegations are serious or sensitive.

The Evidential Test

The Registrar may determine to issue criminal proceedings only where there is sufficient evidence for a realistic prospect of conviction against each suspect on each charge.

In assessing the evidence, Registrar must have regard to the following factors:-

- i. Whether it is more likely than not that a properly directed tribunal will be satisfied to the criminal standard of proof that the suspect committed the alleged offence;
- ii. What the suspect's potential defences might be, whether general or specific, and how these defences might affect the prospects of conviction;
- iii. Any potential for any of the evidence to be excluded by the court, whether on the grounds of technical inadmissibility or on legal grounds including abuse of process or breach of the Human Rights Act 1998;

- iv. The reliability of the evidence, including the credibility of the witnesses and any conflict in the evidence;
- v. The possibility of any further evidence becoming available.

The Public Interest Test

Even where there is sufficient evidence for a realistic prospect of conviction, the Registrar may not issue proceedings unless the public interest requires a prosecution.

The question for the Registrar is whether a prosecution is necessary to serve the interests of the public, not whether a prosecution would serve the interests of the optical or other professions. In considering this issue, the Registrar must have regard to all the circumstances of the case, including details of the offence, the circumstances of the suspect and the impact of the offending behaviour on the health and safety of the public. The effect on a profession's commercial interests is not a relevant factor.

The following is a non-exhaustive list of factors that might be relevant to the public interest:

- i. Whether the offending activity is ongoing or has ceased;
- ii. The length of time over which the offending activity continued;
- iii. Whether the offence was committed intentionally or as a result of a mistake or misunderstanding;
- iv. Whether the offending is likely to be continued or repeated;
- v. Whether a member of the public was harmed or put at risk of harm by the offending;
- vi. Whether the person harmed, or put at risk of harm, was vulnerable by reason of age or infirmity;
- vii. Whether a prosecution is likely to have an adverse effect on the victim's physical or mental health;
- viii. Whether the prosecution is likely to have a significant effect on maintaining public confidence in the profession or in deterring others from committing an offence;
- ix. Whether the offending involved a breach of trust or abuse of position;

- x. Whether the suspect has a previous conviction or other adverse finding, including a finding by a regulator;
- xi. Whether the suspect has breached an undertaking to the GOC or another body, or has declined an opportunity to provide an undertaking;
- xii. Whether the suspect was warned prior to committing the offence;
- xiii. Whether the suspect is likely to be subject to a regulatory investigation, particularly for similar or related activities, whether by the GOC or another regulator;
- xiv. Whether the suspect is likely to be subject to a separate criminal investigation, whether by the police or another prosecuting agency;
- xv. Whether the court is likely to impose no penalty or a nominal penalty.

The above factors are not all of equal importance, and the relative importance of a factor will be determined by the individual circumstances of each case.

In deciding whether the public interest test has been met, the Registrar must make an overall assessment in the light of all the circumstances. A prosecution might be in the public interest even where there are a number of factors pointing against a prosecution; similarly, a prosecution might not be required in the public interest even where there are a number of factors pointing towards prosecution.

Recording the Decision on Whether to Prosecute

The Registrar's decision to prosecute must be recorded in writing as soon as possible, and must be reported to the GOC's Council at the following Council meeting.

The Registrar must maintain a list of all decisions, and provide copies of the list to the Chair of the Council, the Head of the Fitness to Practise department and the Head of the Registrations department.

Action Following the Decision on Whether to Prosecute

Following the decision, the Registrar may:

- i. Write to the suspect, including asking the suspect to cease the alleged activity and desist from continuing or repeating such activity;
- ii. Take other informal action, including asking the suspect for an undertaking;
- iii. Notify the informant (if known) and any other parties of the decision;
- iv. Report the matter to another agency;

- v. Conduct such further investigation as might be appropriate;
- vi. Institute a prosecution by laying an information in the Magistrates court.

Delegation and Consultation

The Registrar may delegate any or all of the above functions to the Director of Regulatory Services and/or such other person as the Registrar considers appropriate.

The Registrar or delegate, if not legally qualified, must obtain legal advice from an in-house or external lawyer before making a decision on whether to issue proceedings.

The Registrar or delegate, whether or not legally qualified, may at any stage consult any additional sources, including obtaining specialist legal advice.

A decision that might (in the opinion of the decision maker) have major implications for the GOC, must be made or endorsed by the Registrar and must be notified to the Council Chair as soon as possible.

Further information

For further information, please contact the office of the Registrar, General Optical Council, 41 Harley Street, London, W1G 8DJ (Telephone: 020 7580 3898, Fax: 020 7436 3525).

Approved by the General Optical Council on 19 May 2011

Appendix 1 to the protocol for criminal prosecutions

Purpose

This annex has been produced to assist the Registrar in applying the protocol in line with our current illegal practice strategy.

Background

In 2011, we published a revised *Protocol for criminal prosecutions* (“the protocol”) to govern the conduct of investigations and the decision on whether to prosecute suspected criminal offences under the Opticians Act 1989 (“the Act”).

The protocol set out three procedural stages in managing allegations of illegal practice:

- Stage 1: Initial screening;
- Stage 2: Investigation;
- Stage 3: Decision on prosecution.

In 2013, we began a review of our strategy for tackling illegal practice. After commissioning risk research and conducting a consultation, we developed a multi-pronged approach to reducing harm. We published our revised strategy in 2014.

Following publication of our strategy, we reviewed our processes to ensure that we handle illegal practice complaints in line with our new strategy as well as our protocol.

Introduction

Illegal practice complaints should be approached in a methodical, targeted and risk-focussed way. This approach is in line with our strategy, and also accords with the principles of good regulation: to be agile, transparent, proportionate, consistent and accountable. Legal action is not always proportionate or practical; for example, it might be more effective to raise public awareness of safe practice, issue a suspected offender with a warning or obtain an undertaking to cease and desist from unsafe practice. We can also refer complaints to another organisation better placed to investigate and take enforcement action, including for example trading standards officers or another regulator.

Procedure

Stage 1: Initial screening

We will first apply a threshold test to decide whether it is appropriate for us to act on a complaint. This will result in closure of the following:

- Complaints that do not indicate a breach of the Act (e.g. where the alleged offending occurred outside the United Kingdom or the suspected offender is based abroad);
- Complaints against GOC registrants (which should be managed through our fitness to practise process); and
- Complaints where there is no identifiable suspect.

Stage 2: Investigation

We will investigate all allegations by obtaining sufficient evidence to assess the nature of the complaint.

Our assessment will include consideration of the following factors: reported harm, proportionality, public confidence, targeting and consistency.

i. Reported harm

We will consider bringing a prosecution in all cases of reported harm. This could, for example include a report that someone's vision was damaged as a result of illegally supplied contact lenses.

ii. Proportionality

We will identify and target the issues of greatest risk to public safety. We will consider the risks from the alleged offending and the potential benefits to public safety, in identifying the most appropriate action. For example, it might be more proportionate to work with trading standards officers in managing complaints concerning zero powered contact lenses.

iii. Public confidence

We will consider whether there are particular factors in a case that could significantly influence public confidence in the optical professions. For example, we might be more likely to take action against a suspect who is a registered professional or has a high public profile.

iv. Targeting

Our strategy recognises that we have limited powers of investigation and enforcement. Further, we face significant challenges in taking action against suppliers of contact lenses, particularly as many online suppliers are based overseas. We will target resources on practices that pose the greatest risk to public health and safety, for example someone pretending to be registered after being erased by the GOC's Fitness to Practise panel.

v. *Consistency*

We will aim to adopt a similar approach in comparable circumstances, in order to achieve similar results. This does not mean standardisation of procedure, as each case will be considered on its own merits. We recognise that there are multiple aspects that need to be evaluated and considered in each case.

In all cases, we will write to the suspect outlining the relevant requirements of the Act, consider informal action and liaise with any appropriate external agencies.

Stage 3: Decision [on prosecution]

The protocol sets out the following potential options following investigation:

- i. Take no action;
- ii. Obtain an undertaking from the suspect or take other informal action;
- iii. Refer the matter to the GOC's Fitness to Practise department, another regulator (including trading standards officers), the police or the Crown Office and Procurator Fiscal Service (in Scotland);
- iv. Institute a prosecution (in England and Wales or Northern Ireland).

Options (i), (ii) and (iii) will usually be most appropriate for the following complaints:

- Supplying spectacles to adults;
- Supplying prescription contact lenses to adults; and
- Supplying zero powered contact lenses to adults.

Option (iv) will usually be appropriate only for the following complaints:

- Conducting sight tests;
- Fitting contact lenses;
- Misusing a protected title or pretending to be registered;
- Supplying appliances to children or vulnerable users; and
- Any case of reported harm.

However, all decisions must be made in the light of the overriding objective to protect, promote and maintain the health and safety of the public. This may result in the Registrar determining to take no action or direct a prosecution in relation to any complaint.

Consultation: voluntary code of practice for online supply of contact lenses

August 2015

(front cover with image to be included in final document)

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Executive summary

1. The General Optical Council (GOC) is the regulator for the optical professions in the UK. We currently register around 28,000 optometrists, dispensing opticians, student opticians and optical businesses.
2. This consultation document seeks the views of stakeholders on a voluntary code of practice for online supply of contact lenses ('the code of practice'), which is one workstream of our strategy for dealing with practices that do not comply with UK law.
3. The consultation will run from **3 August 2015** to **12 October 2015** and applies to the whole of the UK. We also welcome responses from individuals and organisations outside the UK with an interest in the issues addressed by the consultation
4. In early 2015 we brought together stakeholders from across the optical sector to help us to develop a voluntary code of practice for the supply of contact lenses online. We worked with them to produce the code of practice which we are now consulting on (see Appendix 1).
5. We consider that the key aim of the code of practice is to promote good practice in contact lens supply online for the protection of the public. It is necessary for us to do this for the reasons outlined below.
 - The existing legislation is inadequate as it does not cover some of the key risks to the public that were identified by our research. We commissioned Europe Economics to carry out a study into the risks associated with practices that do not comply with UK law, including the risks associated with the supply of prescription and zero-powered contact lenses. The report highlighted the risks associated with contact lens wear, which are increased when the supply is not regulated effectively, the higher risks associated with online supply, the risks associated with the supply of zero-powered contact lenses and the substitution of contact lenses.
 - Many online suppliers used by consumers in the UK operate outside of the UK and do not therefore have to comply with UK law – it is therefore not possible to prosecute these suppliers.
 - The code of practice could encourage online suppliers operating outside of the UK to adopt good practice for the benefit of the public.
 - We can encourage online suppliers operating within the UK to adopt good practice above and beyond the legislation e.g. in areas such as substitution.
 - Consumers who buy contact lenses online are less likely to have regular eye examinations and aftercare appointments, meaning that eye care practitioners lose out. The code of practice should encourage these consumers to see their eye care practitioner more regularly.

6. A code of practice would normally operate above and beyond the legislation, however, if the code of practice simply repeated the current legislation, online suppliers operating outside the UK would not be willing to sign up to the code as it would require a change in their working practices that would mean incurring additional costs and potentially losing customers. If the code were only applicable to businesses who are already complying with UK legislation, we would not be protecting those members of the public who will likely continue to buy from non-UK based suppliers.
7. It therefore seems preferable to focus on making buying contact lenses online safer for those members of the public who are buying from suppliers who are not complying UK legislation. In view of this, we consider it appropriate to implement a code of practice that it will be possible for online suppliers operating outside the UK to sign up to, as it will mean that they will be committing to good practice even if they are not required to comply with UK legislation.
8. The stakeholder groups noted the difficulties with the existing legislation for UK businesses who are complying with it, particularly around the requirement to verify a copy of a contact lens specification as it takes time to arrange verification and there is no requirement in the legislation for the eye care practitioner who wrote the specification to confirm the specification details. We will continue to consider amendments to the legislation, but legislative change is a long-term matter that requires the support of Government and Parliamentary time.
9. We see the code of practice as a living document, capable of change over time as either the legislation and/or good practice develops. This is a first step towards improving the practice of online suppliers operating outside UK legislation who we cannot compel to comply. We hope to see whoever takes responsibility for sponsoring the code developing it over time.
10. We consider the benefits of the code of practice to be as follows:
 - it will protect the public by:
 - improving the practice of those online suppliers signing up to the code that are not subject to UK legislation;
 - promoting safe and effective use of contact lenses;
 - encouraging online customer to have more regular eye examinations and aftercare appointments; and
 - it will emphasise the registrant's pivotal role by consistently referring the customer back to an eye care practitioner for regular eye examinations and aftercare appointments.
11. The public will benefit from the fact that the code of practice will require signatories to adopt good practice in the supply of contact lenses, based on the

evidence of the risks to the public, notwithstanding that suppliers based outside the UK are not required to comply with UK legislation.

12. Those signing up to the code will benefit by increased customer loyalty and public confidence in their brand through publicity attached to the logo.
13. The code of practice will require a body to accredit suppliers, monitor compliance, deal with complaints, design a logo and set-up and run a website. The GOC sees its role as to act as a catalyst to bring together stakeholders and develop a shared view of what constitutes good practice in the online supply of contact lenses. Having led the work to develop the code of practice with our stakeholders, we intend to hand over responsibility for the implementation at an appropriate point.
14. This consultation will end on 12 October 2015. We will analyse responses and take the feedback to our Council meeting on 29 November 2015, together with a revised version of the code of practice ready for sign off and implementation. In the meantime, we will continue discussions with stakeholders to establish how best the code should be administered.
15. We will also continue to develop guidance for the public on the safe purchase and wear of contact lenses, in collaboration with our stakeholders. We intend to have this ready in time for the launch of the code of practice in order to be able to point out to consumers considering buying lenses online the benefits of buying them from signatories to the code.
16. We would like the code of practice and guidance for the public to be launched in spring 2016, although this is obviously subject to the outcome of the consultation and our discussions with stakeholders about how the code will be administered.
17. We will also be commissioning some research to help us establish a benchmark against which to evaluate the impact of the code of practice and consumer guidance. The research will also establish a profile of contact lens wearers, particularly those that buy online, and help us to target our consumer information messages and consider appropriate communication methods.

Introduction

18. This document seeks the views of stakeholders on a voluntary code of practice for online supply of contact lenses ('the code of practice'), which is one workstream of our illegal practice strategy.
19. Section one explains the background to the consultation and our illegal practice strategy. Section two summarises our approach to developing the code of practice with our stakeholders. Section three outlined the options for implementing the code of practice.
20. We have prepared this consultation with reference to the principles of good regulation¹: proportionate, targeted, consistent, transparent, accountable and agile. We have interpreted these as follows:
 - **Proportionate** – we will identify and target the issues of greatest risk to public safety. We will seek to remove unnecessary bureaucracy.
 - **Targeted** – we will ensure that our activity is focused on the areas of greatest risk, or where there is most benefit to public safety.
 - **Consistent** – we will work in collaboration with UK health regulatory bodies and other partners to develop consistent and complementary policies and procedures.
 - **Transparent** – we will explain and publicise decisions, and make public, wherever possible, Council information, activities and proceedings. We will make roles and responsibilities clear.
 - **Accountable** – we will seek, and respond to, the views of stakeholders and partners. We will consider and review the consequences of our actions through evaluation.
 - **Agile**² – we will anticipate change and take timely action. We will ensure that we can respond to changes in the optical sector and improvements in technology.
21. Included in this document are a number of questions we would like those responding to the consultation to consider.
22. The consultation will run from **3 August 2015** to **12 October 2015** and applies to the whole of the UK.

About us

23. We are one of 12 organisations in the UK known as health and social care regulators. These organisations oversee the health and social care professions by regulating individual professionals.
24. We are the regulator for the optical professions in the UK. We currently register around 28,000 optometrists, dispensing opticians, student opticians and optical businesses. Our primary legislation is the Opticians Act 1989 (as amended)

¹ Better Regulation Executive (2000), *Five principles of good regulation*.

² Added by the PSA (formerly CHRE) (2010), *Right-touch regulation*.

(‘the Act’), and we also have a series of related rules that describe how we carry out our statutory functions. Our legislation can be found on our website at http://www.optical.org/en/about_us/legislation/index.cfm

25. The GOC has four main functions:
- setting standards for optical education and training, performance and conduct;
 - approving qualifications leading to registration;
 - maintaining a register of those who are qualified and fit to practise, train or carry on business as optometrists and dispensing opticians; and
 - investigating and acting where registrants’ fitness to practise, train or carry on business is impaired.

How to respond

26. We welcome all responses to the consultation. We will consider the voluntary code of practice in light of the responses we receive. You can respond by using the online response form on our website, which can be accessed through the following link: **LINK TO BE INSERTED**
27. The deadline for responses to this consultation is **12 October 2015**.
28. We are consulting for ten weeks to allow for us to bring the results of the consultation to the Council meeting in November 2015, rather than delaying until the Council meeting in February 2016.
29. You will have the option for your response to remain anonymous, by completing the appropriate section of the consultation response form. We would however encourage named responses where possible. We would particularly like to be able to identify responses from representative organisations so that we can reflect in our analysis that the response is on behalf of members/stakeholders rather than an individual response.
30. The data presented in our analysis will be summarised and supported by direct quotes from some of the responses received. These quotes will either be attributed to a named respondent or anonymised, depending on your preference as indicated in the consultation response form.
31. Alongside the analysis, we intend to publish the individual responses that we have received, unless you have indicated that your response is to remain private.
32. All data submitted will be stored securely and in accordance with data protection principles.
33. If you are unable to submit a response using our online response then further details of how to submit your written feedback are given in the response form attached to the end of this document.

34. We do not usually accept responses by telephone or in person. We normally ask that consultation responses are made in writing to ensure that we can accurately record what the respondent would like to say. However, if you are unable to provide your response in writing please contact us on +44 (0)20 7307 3923 to discuss any reasonable adjustments that would help you to respond.

Further information

35. Where possible, please provide evidence to support your response. If you are a representative group, it would be helpful if you could include a summary of the people and organisations that you represent.
36. A copy of this consultation has been sent to a large number of stakeholder groups representing our registrants, the public, patients, partner organisations and other groups. If you have any queries about the consultation please contact Marie Bunby on mbunby@optical.org or 020 7307 3923.

Our commitment to consultation

37. We believe it is important that the people affected by our work have a say in how we deliver it. We believe it is vital to consult all the groups with an interest in the GOC: patients, the public, our registrants, optical organisations, healthcare organisations, employers, other regulators, staff and other stakeholders.
38. How we consult with our stakeholders is set out in our Consultation Framework, available in the consultation section of our website.

Section 1 – Background

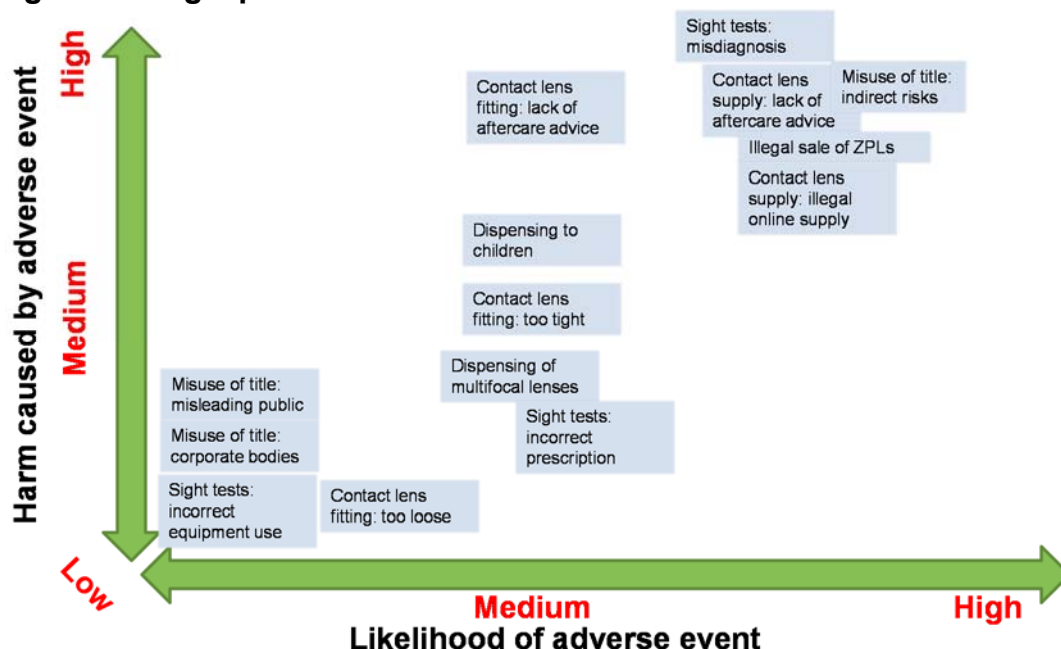
Illegal practice strategy

39. In 2013 we began a review of our strategy for tackling illegal practice. Illegal practice is defined as criminal offences under the Opticians Act 1989 (the Act). The Act creates criminal offences in relation to:
- unlawfully conducting sight tests;
 - unlawfully supplying spectacles;
 - unlawfully fitting contact lenses;
 - unlawfully supplying prescription contact lenses;
 - unlawfully supplying zero-powered contact lenses; and
 - misuse of protected title.
40. In 2013 we commissioned Europe Economics to carry out a study into the risks associated with illegal practice. They examined both the likelihood of an adverse event occurring as a result of each type of illegal practice, and the likely harm that would arise from the adverse event.
41. In producing their research report³, Europe Economics drew on published evidence wherever possible, compiled through a comprehensive review of peer-reviewed articles from medical journals. They obtained additional information from interviews and questionnaires addressed to a wide range of professional optical bodies, and analysis of data held by the GOC. The robustness of non-academic information can vary, and this is discussed throughout the report as and where relevant.
42. The purpose of the work was to provide a technical analysis of the potential health and safety risks posed by different types of illegal practice. Europe Economics did not therefore include feedback from patient or consumer groups and pointed out that the risks associated with illegal practice are difficult to identify even for medical experts.
43. The full research report by Europe Economics can be found on the consultation section of our website (<https://www.optical.org/en/get-involved/consultations/past-consultations.cfm#2014>).
44. Based on the information gathered, Europe Economics made recommendations on the practice areas (whether legal or illegal) that carry the greatest risk to public health and safety. They have also identified the areas where there is insufficient information to assess the risk.
45. For each type of risk that flows from illegal practice, Europe Economics assessed the level of harm that would arise and the likelihood of this harm occurring. Figure 1 summarises their findings, drawing on table 6.1 of the report. The methodology employed draws on the risks inherent in legal optical

³ Europe Economics (2013), *Health Risk Assessment of Illegal Optical Practice: Final report for the General Optical Council*

practice as well as illegal practices to present the additional risks for a member of the public dealing with an illegal supplier or practitioner, hence the inclusion of risks such as loose or tight-fitting contact lenses which are not in themselves an example of illegal practice.

Figure 1: Illegal practice matrix



46. The risk areas flowing from illegal practice that present the highest level of risk to the public are shown in the top right-hand corner of the matrix:

- misdiagnosis resulting from illegal sight tests, which in the event of an adverse event is likely to lead to the highest level of harm;
- illegal contact lens supply where there is a lack of aftercare advice;
- illegal online supply of contact lenses;
- illegal sale of cosmetic contact lenses⁴; and
- the indirect risks of misuse of title by unregistered practitioners.

Summary of Europe Economics' research on contact lens supply

Clinical risks associated with contact lens wear include:

- infection (e.g. keratitis);
- corneal ulcers;
- general contact lens wear derived from a reduced amount of oxygen to the cornea; and
- complications such as corneal abrasions, haemorrhage and conjunctivitis.

“There are a number of studies that directly link eye infections among contact lens

⁴ Referred to as ZPLs (zero powered contact lenses) in figure 1.

wearers with poor patient hygiene and compliance with wear instructions, usually as a result of poor compliance with the registered practitioner's instructions."

Risk factors for infections in contact lens wearers include:

- the use of tap water during lens care;
- swimming while wearing contact lenses;
- use of ineffective lens care solutions;
- failure to follow lens care instructions; and
- wearing contact lenses overnight.

Additional clinical risks associated with zero-powered (or cosmetic) contact lenses based on opinions of experts:

- less likely to be made from the latest materials that maximise oxygen flow;
- may contain dyes that could leak into the eye; and
- typically produced and distributed on a 'one size fits all' basis and therefore not tailored, leading to inappropriate fit in some instances, increasing the risk of complications.

Zero-powered contact lenses are more likely to be shared among friends and purchased from unlicensed vendors. Wearers are less likely to comply with good contact lens hygiene practices and less likely to have a proper fitting and/or follow aftercare advice.

Risks related to contact lens supply are *'failure to provide adequate information about wear and risk factors to patients'*. One study suggested that those who buy contact lenses online are more likely to miss aftercare appointments. A US study found that those who bought their contact lenses online were more likely to do so without a prescription, although the study was not able to look at complication rates compared with those who did not buy their contact lenses online. A European report compared data across sales with and without a prescription and concluded that *'data showed that the unregulated sale of all contact lenses is associated with a statistically significant higher rate of incidents than the regulated sale'*.⁵

Substitution was also identified as an area of concern in relation to those who buy online, particularly in relation to substitution carried out by a non-eye care professional who is not under the supervision or general direction of an appropriately qualified GOC registrant or registered medical practitioner. Concern centred around:

- material of the lens;
- shape and size of the lens;
- brand of the lens; and
- the associated wear requirements.

Please refer to the Europe Economics report for more detail.

⁵ See page 39 of Europe Economics (2013), *Health Risk Assessment of Illegal Optical Practice: Final report for the General Optical Council*

47. We also needed to consider the aggregate level of harm caused by each type of illegal practice (i.e. the frequency with which they occur as well as the severity of any possible adverse event).
48. Based on the evidence, our assumption is that types of illegal practice such as the deliberate misuse of protected title or illegal sight-testing occur relatively infrequently. We suggested, therefore, that we should continue to deal with these issues in a reactive way.
49. We commissioned some market research⁶ to try to test our assumption that the illegal supply of cosmetic and prescription contact lenses occur much more frequently than other types of illegal practice. The survey was carried out in August and September 2013. The research found that 14 per cent of patients who wear prescription contact lenses buy them online. Based on the latest population data from the Office of National Statistics, this suggests that around 715,000 people in the UK buy prescription contact lenses online. Based on our discussions with the professions, we believe that a significant proportion of these people would have used a supplier that does not comply with UK law.
50. As part of our recent research into public perceptions of the optical professions⁷, we found that 21 per cent of people who wore contact lenses purchased them over the internet.
51. We have not yet established a reliable estimate of the total number of people in the UK who buy cosmetic lenses or how frequently they wear them, but it is reasonable to assume that users of cosmetic lenses tend to wear these far less frequently than users of prescription lenses. The market for cosmetic lenses in revenue terms is therefore likely to be significantly smaller than the market for prescription lenses, although research suggests there is a higher risk of individuals suffering an adverse event.
52. More generally, we need to develop our understanding of the size of the online market for contact lenses (prescription and cosmetic) and the proportion of sales that might be illegal, but it is reasonable to assume that the online market will continue to grow for the following reasons. First, there has been growth in online retail sales generally. Secondly, pressure on the cost of living is likely to have encouraged more people to seek savings by buying contact lenses online. Thirdly, the market for contact lenses is expanding as a result of product innovation that has made it possible for more people to wear contact lenses.

Consultation on our illegal practice strategy

53. We launched a consultation on our strategy for tackling illegal practice between March and June 2014. During the consultation we sought views on our proposed approach to addressing the different types of illegal practice. Illegal

⁶ YouGov (2013), *Opticians 2013*, London: YouGov Plc

⁷ Insert reference to ComRes report

practice is an area of great interest to many of our stakeholders and we were keen to collaborate with them.

54. In our consultation document, we explained our current approach to dealing with illegal practice (handling complaints in line with our prosecution protocol, published in June 2011⁸) and the difficulties we faced in taking effective enforcement action as follows:
- we have limited powers of investigation and enforcement;
 - we face significant challenges in prosecuting online suppliers of contact lenses (both prescription and zero-powered), particularly as many are based overseas; and
 - we do not have the resources to deal with the large numbers of people engaged in certain types of illegal practice, such as businesses supplying zero-powered contact lenses.
55. We proposed a strategy that recognised that we cannot rely on reacting to complaints and considering whether it is feasible to take enforcement action. We needed to adopt a more proactive, multi-pronged approach, working collaboratively with stakeholders to reduce the harm to the public which illegal practices can cause.
56. We proposed that our strategy should be guided by the following principles:
- It should encompass all the types of illegal practice covered by the Act.
 - We should adopt a differentiated approach, recognising that a ‘one size fits all’ approach to tackling the different types of illegal practice would not be effective.
 - We should use a range of levers, taking into account businesses’ incentives, focusing on what will achieve the best outcomes for the public.
 - We should base our strategy on the evidence of the risks to the public presented by the different types of illegal practice.
 - We should use our resources in a targeted way, focusing on the types of illegal practice that cause the greatest public harm.
 - We should take into account the aggregate level of harm caused by particular types of illegal practice as well as the harm that can be caused in individual cases.
 - We should collaborate with other organisations, including professional bodies, businesses, consumer groups and other enforcement bodies, and in doing so, make clear our role and remit.
 - We should recognise that we do not have the resources or powers to tackle all these issues alone and that we will need to work through others, acting as a catalyst and co-ordinating activity.

⁸ http://www.optical.org/en/Investigating_complaints/index.cfm

57. Taking into account the above principles and the research by Europe Economics, we proposed an approach based on the following five areas:
- continuing to handle complaints in line with our prosecution protocol for all types of illegal practice;
 - collaboration with other enforcement bodies to address high-risk areas of illegal practice;
 - guidance for the public on the safe purchase and use of contact lenses (prescription and cosmetic);
 - development of a voluntary code of practice on the supply of contact lenses (prescription and cosmetic) online; and
 - further research and intelligence-gathering.
58. During the consultation period we held a public stakeholder event, meetings with a number of our key stakeholders and met with some of the GOC's advisory committees⁹. We also received 32 written responses to the consultation. We analysed the responses and published a statement on 17 November 2014 on the outcome of the consultation (for the full statement see <http://www.optical.org/en/Registration/the-register/reviewing-our-approach-to-regulation.cfm>). The conclusions we reached are outlined in the following excerpt from the statement.

Conclusions from the GOC's illegal practice strategy consultation

- We concluded that our preferred approach represented the best approach to tackling illegal practice. Most stakeholders concurred that this option was the best approach, and while stakeholders differed slightly in which elements of the approach they felt were most important, we felt this further emphasised the importance of taking a variety of measures.
- We recognised that many stakeholders felt that substitution of contact lenses¹⁰ and paediatric dispensing had not been given enough weight in our analysis. Although substitution does not constitute illegal practice, our research suggests that certain types of substitution can pose risks to the public and we will therefore seek to take this issue into account as we develop the proposed code of practice and activities to raise public awareness.
- In relation to paediatric dispensing, the research by Europe Economics does not suggest this is a widespread problem. However, we understand that there is stakeholder concern about the quality of paediatric dispensing, particularly where this is carried out under supervision. We would tend to view the quality of dispensing under supervision as a fitness to practise issue rather than illegal

⁹ The Companies Committee and Standards Committee.

¹⁰ There is a clear requirement in section 27 of the Act that a patient be given a contact lens specification that would enable the lens to be "replicated" and that any third party supplier must receive the original specification or verify the accuracy of a copy of the specification. However, there is no specific requirement for the supplier to supply only in accordance with that specification.

practice. We will consider this issue in the course of our standards review, looking, for example, at whether there is a need for improved guidance on supervision.

- We noted that many stakeholders feel that changes in the law were required. We received suggestions to both tighten the law in certain areas (for example, substitution) and to alter the law so as not to unreasonably hamper legal practices (for example, revisiting the current law on verification). We noted these suggestions. It must be stressed, however, that changing the law is a matter for Government and tends to be a slow process requiring a robust evidence base. We also need to bear in mind that changing the law is effective only if it can be enforced properly. In relation to the online supply of contact lenses, we would still face the issue of supply from overseas businesses that are not bound by UK law, meaning that changing the law would be only a partial solution. Therefore, we remained of the view that we should take action now to promote a voluntary code of practice for online contact lens supply. As well as helping to protect consumers by promoting good practice, developing a consensus about what good practice is would provide a helpful basis for seeking legislative change, notwithstanding the fact that this would only form part of the solution.
- While we believed that we should pursue the idea of a voluntary code of practice for online contact lens retailers, we noted that opinion was divided between those who felt the code should be entirely or largely GOC-run, those who felt that it should operate independently from us, and those who did not believe that it is worth doing. We will continue to engage closely with stakeholders to agree the way forward.
- We did not believe that it would be helpful at this stage to expand the scope of the online code to spectacle sales. Our research suggests that this is a lower-risk area than online contact lens sales, and we believe that trying to address both at the same time would introduce additional complexity and add delay. However, we will review this position once the code of practice for contact lenses has been established and in the light of any further evidence of risks to the public.
- We emphasised that as part of our multi-pronged strategy we would still deal with complaints in line with our prosecution protocol and take enforcement action where there is sufficient evidence and where it would be in the public interest. For example, we will consider very closely any complaints of illegal supply to children.
- We welcomed the enthusiasm and ambition shown by many stakeholders when considering our proposal to focus on raising public awareness. If we are to make the more ambitious suggestions a reality, we will require the active collaboration of the professional bodies, manufacturers and retailers, as well as

individual practitioners.

- In relation to awareness raising, we also took on board the concerns raised by some in the contact lens industry (both practitioners and manufacturers) that we must balance information about how to wear contact lenses safely with the need to avoid unnecessarily worrying the public about the risks.
- We agreed with those who urged us to involve Trading Standards in enforcement action against zero-powered contact lens sales in particular. We are committed to working with Trading Standards and providing advice and guidance. We are engaging with them at a national level to explore what action they might be able to take and how best to share information. We are hopeful that they can be persuaded to take a more proactive approach, although priorities are determined at a local level. Our engagement with individual Trading Standards Officers suggests that they are interested in the issue, but many tend to assume that the task of tackling anything which is an offence under the Opticians Act falls solely on us.

Working with stakeholders to develop the voluntary code of practice

59. In our statement we committed to working with stakeholders to develop detailed proposals for the voluntary code of practice and the development of public guidance.
60. We approached Richard Edwards, an optometrist with significant management experience in the sector and a member of our Companies Committee, to act as a consultant to advise on the development of a code of practice. We established a steering group made up of our key stakeholders (see appendix 2 for a list of members), chaired by Rob Hogan (GOC Council member and Council Champion for this project), in order to:
 - advise on the development of a code of practice for online contact lens suppliers and on options for implementation, with the emphasis being on addressing the risks to the public that can arise from internet supply; and
 - create an initial proposal and advise on strategies to raise awareness among contact lens wearers of the need to follow aftercare advice and have regular check-ups.
61. We also put together a working group made up of key stakeholders (see appendix 3 for a list of members) to draft the code of practice, chaired by Richard Edwards. This working group reported back to the steering group on a regular basis and brought key issues to their attention.
62. The process of developing the code of practice is outlined in the next section.

Section 2 – Developing the voluntary code of practice for online supply of contact lenses

64. This section outlines the legal requirements for online sales of contact lenses and explains the process that we went through with our stakeholders to develop the voluntary code of practice. In particular, we have detailed our thinking on aftercare, compliance with legislation, substitution and zero-powered contact lenses. We have also outlined what we see as the benefits of the code.
65. The draft code of practice, which incorporates explanatory notes to further explain the points in the code, is attached at appendix 1.

Legal requirements for online sales of prescription and zero-powered contact lenses

66. The legal requirements for online sales of prescription contact lenses are set out at Article 3 of the Sale of Optical Appliances Order 1984 and Section 27 of the Opticians Act 1989. In summary:
- online sales of prescription contact lenses must be under the general direction of a registered medical practitioner, optometrist or dispensing optician (i.e. a clinician must be responsible for the sale procedures);
 - the intended user must not be aged under 16 years or registered blind/partially sighted;
 - the seller must receive (i) the original specification, or (ii) a copy of the specification, or (iii) an electronic order containing the specification;
 - if the seller has not received the original specification, he must verify the copy or electronic specification details with the prescriber i.e. he must receive details of the prescriber;
 - the specification must be in date;
 - the seller must be reasonably satisfied that the lenses are for the person named in the specification; and
 - the seller must make arrangements for the user to receive reasonable after care.
67. Section 27 of the Opticians Act 1989 also provides that zero-powered contact lenses can be sold only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician. Our new standards of practice¹¹ will define supervision as the registrant having to be on the premises and able to intervene.

Voluntary code of practice

68. We consider that the key aim of the code of practice is to promote best practice in contact lens supply online for the protection of the public. It is necessary for us to do this because:

¹¹ This is subject to Council approving the new standards of practice on 29 July 2015.

- the existing legislation is inadequate as it does not cover some of the key risks that were identified by the Europe Economics research into risks, for example, substitution of contact lenses;
 - many online suppliers used by consumers in the UK operate outside of the UK and do not therefore have to comply with UK law – it is therefore not possible to prosecute these suppliers;
 - a code of practice could encourage online suppliers operating outside of the UK to adopt good practice for the benefit of the public; and
 - we can encourage online suppliers operating within the UK to adopt good practice above and beyond the legislation e.g. in areas such as substitution.
69. The stakeholder groups noted that the code of practice should not take as its starting point the existing legislation. First, suppliers based outside the UK do not have to comply with the UK legislation. Secondly, there are barriers to suppliers complying with the legal requirements. In particular, the stakeholder working group understands that the great majority of patients are not given their contact lens specification by their contact lens practitioner and has expressed the view that this may be in part because of the uncertainty in the legislation around what constitutes the end of a contact lens fitting. Unless and until this changes, online suppliers will not be able to comply with the legislation because they cannot ask a customer to provide the information contained with their contact lens specification if the customer does not have it.
70. A code of practice would normally operate above and beyond the legislation, however, if the code of practice simply repeated the current legislation, online suppliers operating outside the UK would not be willing to sign up to the code as it would require a change in their working practices (i.e. obtaining and verifying a contact lens specification) that would mean incurring additional costs and potentially losing customers. If the code were only applicable to businesses who are already complying with UK legislation, we would not be protecting those members of the public who will likely continue to buy from non-UK based suppliers.
71. While there will be a consumer awareness campaign to sit alongside the introduction of the code of practice, the GOC and its stakeholders have limited resources and it will be difficult to reach all consumers who are buying contact lenses online. We know from anecdotal evidence that even when customers are advised of the reasons for a UK online supplier having to obtain and verify a contact lens specification, many customers are not willing to wait the time that this would take and instead order online from a non-UK supplier.
72. It therefore seems preferable to find a middle ground between replicating the existing legislation and making buying contact lenses online safer for those members of the public who are buying from suppliers who are not complying UK legislation. In view of this, we consider it appropriate to implement a code of

practice that it will be possible for online suppliers operating outside the UK to sign up to, as it will mean that they will be committing to good practice even if they are not required to comply with UK legislation.

73. The stakeholder groups noted the difficulties with the existing legislation for UK businesses who are complying with it, particularly around the requirement to verify a copy of a specification as it takes time to arrange verification and there is no requirement in the legislation for the optometrist or contact lens optician who wrote the specification to confirm the specification details. As noted on page 12, we will continue to consider amendments to the legislation, but legislative change is a long-term matter that requires the support of Government and Parliamentary time.
74. We see the code of practice as a living document, capable of change over time as either the legislation and/or good practice develops. This is a first step towards improving the practice of online suppliers operating outside the UK who do not have to comply with UK legislation. We hope to see whoever takes responsibility for sponsoring the code developing it over time.

Aftercare

75. The stakeholder groups noted that the key to protecting the public when buying contact lenses online is to provide them with aftercare advice on the safe and effective use of contact lenses, as we are trying to prevent the public from being able to buy contact lenses indefinitely without having seen an eye care practitioner on a regular basis. Therefore, point 1 of the code of practice addresses this by committing the online supplier to provide advice and information to their customers, particularly with regard to emergency situations, and the importance of regular eye examination appointments with their eye care practitioner. Eye care practitioners are also mentioned in several other places in the code of practice and we see this as a key benefit of the code of practice for individual registrants. The code refers to guidance from the British Contact Lens Association (BCLA).

Compliance with legislation and providing complaints mechanisms

76. The stakeholder groups also felt that it was important for the code of practice to include a commitment for online suppliers to comply with relevant consumer protection legislation and ensure that their customers have access to a complaints procedure and advice on what to do if they are not satisfied with the outcome of their complaint. It was also considered important that suppliers should comply with the relevant legislation wherever they are based. Points 2 and 3 of the code address these areas.

Customer assurance

77. The stakeholder groups felt that it would be important for online suppliers to seek confirmation from their customers in a number of areas to ensure that the customer could provide assurance in relation to their age, sight impairment, that

they are not ordering on behalf of someone else, that they attend regular aftercare appointments and will comply with aftercare advice, that they are order contact lenses that have been prescribed by an eye care practitioner, that they have accurately submitted their contact lens details and that they are not ordering a quantity of lenses that will take them significantly beyond the expiry date in their contact lens specification (if it is available to them). Point 4 of the code addresses this customer assurance.

78. It was recognised that there will be some customers who make declarations that are not true. We cannot do anything about those customers who might decide to obtain contact lenses on the basis of mis-information, but we can seek to raise awareness about the safe use and wear of contact lenses, and ask online suppliers to provide advice and information to customers which will help them to understand why it is important to provide accurate information.

Substitution

79. The stakeholder groups recognised the importance of addressing substitution of contact lenses in the code (point 5), given the research findings from Europe Economics (2013)¹² that substitution can pose a risk of harm (related to poor fit and infection), particularly if it occurs online where a patient cannot be checked.
80. The code commits the online supplier to directing a customer back to their eye care practitioner except in certain circumstances where substitution may be appropriate, for example, on the advice of the manufacturer of the lens being substituted. The code of practice also addresses the issue of ‘own-labelling’ of contact lenses, for example, where a supplier re-labels a manufacturer’s brand under their own labelling.
81. Point 6 of the code deals with the possibility of marketing emails to customers effectively leading to ‘self-substitution’ where a customer selects a new lens without having seen an eye care practitioner for a fitting.

Zero-powered contact lenses

82. The legal position in respect of zero-powered contact lenses is clear – the Opticians Act 1989 requires the sale of zero-powered contact lenses to be ‘by or under the supervision of’ a registrant or registered medical practitioner, which means that they need to be present on the premises and able to intervene. We considered simply including a reference to zero-powered contact lenses in the code with the effect that they would be treated in the same way as powered contact lenses. However, we did not consider this to be appropriate as the code needs to be suitable for business registrants to sign up to, and therefore cannot imply that non-compliance with the law is acceptable.

¹² Europe Economics (2013), *Health Risk Assessment of Illegal Optical Practice: Final report for the General Optical Council*, pp 21-23

83. The Europe Economics (2013) research found that zero-powered contact lenses have the same risk profile as prescription contact lenses, as the main underlying causes of risk with contact lens wear are patient behaviour and compliance with wear and hygiene, which is common across both types of lenses. It was also found that:
- opinion of clinical experts and professional bodies suggests that zero-powered contact lenses may pose a higher clinical risk as they are less likely to be made from the latest materials that maximise oxygen flow to the cornea, and may also contain dyes that could leak into the eye;
 - clinical experts maintain that zero-powered contact lenses are typically produced and distributed on a 'one size fits all' basis, and not tailored in any way to the specific needs of wearers – experts have cautioned that these lenses will therefore not fit properly in some instances, thus increasing the risk of ocular complications;
 - zero-powered contact lenses are often supplied illegally by stores such as pharmacies, fancy dress shops, hairdressers etc – this means that people buying from these stores are not getting the advice they need about inserting and removing the lenses, or advice about appropriate wear and hygiene behaviour, including the importance of regular eye examinations; and
 - complaints to the GOC regarding illegal supply of zero-powered contact lenses included five cases where actual harm was reported including temporary vision loss, eye infections, and scratching, staining and swelling of the eye.
84. In view of the above, the stakeholder groups felt that the code should include a commitment from suppliers to comply with UK legislation in this area and therefore not sell zero-powered contact lenses online, in order to sufficiently protect the public in a key area of risk. This is addressed in the final point of the code (point 7).

Code of practice for all contact lens suppliers

85. We considered whether the code of practice could be made applicable for all contact lens suppliers to sign up to, not just those providing online services. The benefits of this approach would be:
- it would be less confusing for patients who would simply need to look for the logo when buying contact lenses (not just when buying online); and
 - it could be beneficial for individual registrants who own their own practices/partnerships or owners of small/medium chains to attract customers.
86. However, this does not seem appropriate at the current time as:
- this is not in line with what the GOC published in its illegal practice statement;

- the terms of reference for our stakeholder groups were to draft a code of practice for *online* contact lens supply, with the emphasis on addressing the risks to the public that can arise from internet supply;
- one of the highest risks identified with contact lens wear in the Europe Economics (2013) risk research¹³ was in relation to illegal practice associated within online contact supply (although it is worth noting that another risk judged only slightly lower was lack of aftercare advice in contact lens supply, which could be applicable in all contact lens supply, but arguably more likely to apply in circumstances where the supply is online/postal); and
- the costs and time associated with administering a code of practice that applied to all suppliers of contact lenses would be significantly increased e.g. it is estimated that there are approximately 6,000 optical businesses in the UK, most of which are likely to supply contact lenses.

87. We could consider this in the future once the code of practice is operational and we have been able to evaluate its impact, but this would mean re-launching guidance for consumers.

Benefits of the code of practice

88. We consider the benefits of the code of practice to be as follows:

- it will protect the public by:
 - improving the practice of those online suppliers signing up to the code that are not subject to UK legislation;
 - promoting safe and effective use of contact lenses;
 - encouraging online customers to have more regular eye examinations and aftercare appointments; and
- it will emphasise the registrant's pivotal role by consistently referring the customer back to an eye care practitioner for regular eye examinations and aftercare appointments.

89. The public will benefit from the fact that the code of practice will require signatories to adopt good practice in the supply of contact lenses, based on the evidence of the risks to the public, notwithstanding that suppliers based outside the UK are not required to comply with UK legislation.

90. Those signing up to the code will benefit by increased customer loyalty and public confidence in their brand through publicity attached to the logo.

Impact assessment

91. In our March 2014 consultation on our illegal practice strategy¹⁴, we carried out an impact assessment in relation to implementing a code of practice as part of

¹³ Ibid.

¹⁴ Available on our website at: <https://www.optical.org/en/get-involved/consultations/past-consultations.cfm#2014>

our strategy. Please refer to pages 26 and 27 of the 2014 consultation document for further information. The consultation responses did not identify any further impacts.

Section 3 – Options for implementing the code of practice

Monitoring the code of practice

92. The code of practice will require a body to accredit suppliers, monitor compliance, deal with complaints, design a logo and set-up and run a website.
93. At our public consultation event for our illegal practice strategy we set out three options for how the code might work in practice. These were a code run by the GOC, a code run by the industry and an independently-run code overseen by a group made up of various professional and industry organisations (including the GOC). There was no support for an industry-run code and equal support for the two other options.
94. We indicated in our November 2014 *Statement on the outcome of the consultation on our illegal practice strategy*, that our preference would be for a model that is independently-run with GOC involvement in an oversight capacity alongside other bodies. This would help to differentiate between the GOC's role as the statutory regulator responsible for enforcing UK legislation in relation to the supply of contact lenses and the GOC's role in acting as a catalyst for the development of, and helping to oversee, a voluntary code of practice. This would help to mitigate the concern raised in response to the consultation that if an organisation was a signatory to a code run by the GOC, the public might assume that it was complying with UK law even if it was based overseas and therefore not required to do so.
95. Our stakeholder groups agreed that it would not be appropriate for the GOC to implement and monitor the code of practice as a body on its own. It was felt that the code should be arms-length from the GOC, as the GOC is responsible for enforcing the legislation and the code goes beyond this in some areas and not as far as in others.
96. The GOC sees its role as to act as a catalyst to bring together stakeholders and develop a shared view of what constitutes good practice in the online supply of contact lenses. Having led the work to develop the code of practice with our stakeholders, we intend to hand over to the sector at an appropriate point to take forward the detailed implementation.
97. Our stakeholder groups were advised that voluntary codes of practice are usually linked to trade associations. However, there is no trade association specifically for online suppliers and it was felt that there was not currently an appropriate optical body that could take this on. Therefore, two possible options were considered:
- a small group of optical body representatives (and potentially consumer representatives too) coming together to monitor compliance with the code – this group could meet periodically to discuss, for example, application for accreditation and deal with any instances of non-compliance by existing signatories;

- a small group of optical body representatives (and potentially consumer representatives) tendering for an external body to administer the code, including monitoring compliance (in much the same way as the GOC tendered for the optical consumer complaints service).
98. There would need to be an incentive for online suppliers to continue to comply with the code. Mystery shopping could be carried out and the results published on an annual basis. This would promote public confidence in, and awareness of, the code and help to enable the public to make better informed decisions about where to purchase their contact lenses.
99. We will continue to explore with stakeholders what options there might be for monitoring the code.

Logo and website

100. Our stakeholder groups considered that the use of a logo would be important so that customers can identify who has signed up to the code and the value of looking for a supplier displaying the logo can be promoted through guidance to the public. We envisage that clicking on the online logo will take the customer to a website which lists the organisations that are currently signed up to the code and provides information on how compliance is monitored. The website will contain information about the code of practice as well as guidance for the public on the safe purchase and wear of contact lenses. We expect the guidance to come in different forms, for example, downloadable information leaflets, on-screen advice including written instructions as well as videos showing insertion and removal of contact lenses, and aftercare advice.
101. The stakeholder groups suggested that the logo should only be used by suppliers on their website, and not in any shop-fronts as this would be unfair to registrants who do not currently provide contact lenses online. This is addressed in the explanatory notes in the code of practice.
102. In the longer term, the code could be developed towards being a Trading Standards Institute (TSI) approved scheme. This might not be possible initially as the process for approval is likely to take a period of years, but we have sought to make the code compatible with TSI scheme principles.

Costs

103. It is difficult to work out precisely how much it would cost to fund the voluntary code of practice given that it is not yet possible to know how many online suppliers are likely to sign up. Based on our current understanding of the online contact lens supply market, we anticipate around 10-12 organisations might sign up to the code. If this is the case, it is unlikely that there would be a large cost in administering it.
104. We would expect the code to be paid for largely by the signatories of the code.

Section 4 – Next steps

Implementing the code of practice

105. This consultation will end on 12 October 2015. We will analyse responses and take the feedback to our Council meeting on 29 November 2015, together with a revised version of the code of practice ready for sign off and implementation.
106. In the meantime, we will continue discussions with stakeholders to establish how best the code should be administered.
107. We will also continue to develop guidance for the public on the safe purchase and wear of contact lenses, in collaboration with our stakeholders. We intend to have this ready in time for the launch of the code of practice in order to be able to point out to consumers considering buying lenses online the benefits of buying them from signatories to the code.
108. We would like the code of practice and guidance for the public to be launched in spring 2016, although this is obviously subject to the outcome of the consultation and our discussions with stakeholders about how the code will be administered.

Evaluating the impact of the code of practice

109. In our November 2014 *Statement on the outcome of the consultation on our illegal practice strategy* we explained that one of the workstreams of our illegal practice strategy would be to carry out further research and intelligence gathering.
110. We intend to commission some consumer research to provide us with data to establish a benchmark against which to evaluate the impact of the code of practice and consumer guidance. This will involve surveying contact lens wearers to ask about their behaviour and to see how findings vary depending on where they buy their contact lenses. The research is likely to explain where and how often members of the public buy their contact lenses, how often they attend eye examination and contact lens check-ups with an eye care practitioner, and awareness and compliance with contact lens aftercare advice. The research will also seek to understand reasons for buying contact lenses online and what might make those that do not currently buy online interested in doing so.
111. The research will also establish a profile of contact lens wearers, particularly those that buy online, and help us to target our consumer information messages and consider appropriate communication methods.

Section 5 – Response form

How to respond

The simplest way to provide a response is through our online consultation response form, which can be accessed here: www.optical.org/en/utilities/standards-response-form.cfm

If you are unable to submit your feedback online, then please use the form below to submit your written feedback by 12 October 2015.

This form should be emailed or posted to:

Marie Bunby
General Optical Council
41 Harley Street
LONDON
W1G 8DJ

Email: mbunby@optical.org

If you are unable to provide your response in writing or you require the consultation form in a different format, please contact us on +44 (0)20 7307 3473 to discuss reasonable adjustments that would help you to respond.

Publication of consultation responses

Unless you state otherwise we will assume you are happy for us to publish your response, including your name, and to share it with other appropriate bodies and stakeholders. We would however encourage named responses where possible and particularly from representative organisations so that we can reflect that the response is on behalf of members / stakeholders rather than an individual response.

Please tick here if you are only happy for us to share your responses anonymously:

Your name or the name of your organisation:

Which category of respondent best describes you?

- Member of the public
- Optical patient
- Optometrist
- Dispensing optician
- Student – optometry
- Student – dispensing
- Optical business (supply contact lenses online)

- Optical business (does not supply contact lenses online)
- Online supplier of contact lenses
- Contact lens manufacturer
- Education or training provider
- Optical professional body
- Other optical employer
- Healthcare regulator
- Other (please specify below)

Questions

We have a number of structured questions below. You do not have to answer all of the questions when responding – please feel free to respond just to the questions you feel are relevant to you. There are opportunities within the document to provide your specific comments on both the framework for standards and the standards themselves.

1. Do you support the code of practice for the online supply of contact lenses?

- Yes No

Please give your reasons below:

2. Does the code of practice make it clear what would be expected from online suppliers who signed up to it?

- Yes No

Please give your reasons below:

3. Is the code of practice clear and accessible?

- Yes No

Please give your reasons below:

4. Is there anything missing, incorrect or unclear in the code of practice?

- Yes No

Please give your reasons below:

5. Are there any barriers to implementing the code of practice?

- Yes No

Please give your reasons below:

6. Do you agree with the approach taken in the code of practice to zero-powered contact lenses?

- Yes No

Please give your reasons below:

7. Overall, do you expect that the code of practice will be beneficial to, and have a positive impact on, the protection of the public who buy contact lenses online?

- Yes No

Please give your reasons below:

8. Are there any aspects of the code of practice that could have an adverse or negative impact on certain groups of patients, optometrists, dispensing opticians, online businesses without a high street presence, high street businesses without an online presence, businesses with both an online and high street presence, manufacturers of contact lenses or any other groups?

- Yes No

Please give your reasons below:

9. Are there any areas of the code of practice that could discriminate against stakeholders with specific characteristics? Please consider sex, age, race, religion or belief, disability, sexual orientation, gender reassignment, pregnancy or maternity, caring responsibilities or any other characteristics.

- Yes No

Please give your reasons below:

10. Do you have any other comments that you wish to make on the code of practice?

Please specify below:

More about you

The GOC strives to be as diverse as the public it protects and welcomes consultation responses from everyone, regardless of age, disability, gender reassignment, race, religion or belief, ethnicity, sex, sexual orientation, marriage and civil partnership, pregnancy and maternity. We monitor the diversity of all the individuals who respond to our consultations to ensure that we have heard from a diverse range of people and that we can identify where further engagement or consultation may be required. To help us to monitor this, please complete the following questions if you feel comfortable to do so. Providing this information is optional, but we would be grateful for your co-operation. Information provided will be treated in the strictest confidence under the Data Protection Act 1998 and will be used for monitoring purposes only. No information in this section will be published or used in any way which allows any individuals to be identified.

Age

- 16-24
- 25-34
- 35-44
- 45-54
- 55-64
- 65+
- Prefer not to say

Disability

Do you consider yourself disabled?

- Yes – please specify _____
- No
- Prefer not to say

[The Equality Act 2010 defines disability as a physical or mental impairment which has a substantial long-term effect on a person's ability to carry out normal day to day activities.]

Gender

- Female
- Male
- Prefer not to say

My gender identity is different from the gender I was assigned at birth

- Yes
- No

I describe my gender identity as _____

Sexual orientation

- Bisexual
- Gay man
- Gay woman/lesbian
- Heterosexual
- Other
- Prefer not to say

Marital status

- Civil partnership
- Divorced/legally dissolved same-sex civil partnership
- Married
- Partner
- Separated
- Single
- Not stated
- Prefer not to say

Maternity leave

Are you pregnant, on maternity leave, or returning from maternity leave?

- Yes
- No
- Prefer not to say

Ethnic origin

- Prefer not to say

White

- English / Welsh / Scottish / Northern Irish / British
- Irish
- Gypsy or Irish Traveller
- Any other white background – please specify _____

Mixed / multiple ethnic groups

- White and Black Caribbean
- White and Black African
- White and Asian
- Any other mixed / multiple ethnic background – please specify _____

Asian / Asian British

- Indian
- Pakistani
- Bangladeshi
- Chinese
- Any other Asian background – please specify _____

Black / African / Caribbean / Black British

- African
- Caribbean
- Any other Black / African / Caribbean background – please specify _____

Other ethnic group

- Arab
- Any other ethnic group – please specify _____

Religion/Belief

- No religion
- Buddhist
- Christian
- Hindu
- Jewish
- Muslim
- Sikh
- Any other religion / faith – please specify _____
- Prefer not to say

Appendix 1

Code of practice for the online supply of contact lenses

Purpose

Contact lenses can positively change the lives of millions of wearers as a safe and effective way to correct eyesight. Developments in contact lens materials and design continue to bring ever-advancing benefits to wearers.

The purpose of this code of practice is to protect the eye health of those members of the public who purchase their contact lenses online and to promote safe contact lens wear, by improving advice and information provided to the customer and encouraging regular visits to an eye care practitioner.

Signatories to this code of practice commit to promote the safe and effective online provision of contact lenses.

The code reflects the views of a range of experts from across the optical sector and consumer representatives on what constitutes current good practice in the supply of contact lenses online. It also takes account of the risks associated with contact lens supply identified in research undertaken by Europe Economics (2013)¹⁵.

Code of practice

All suppliers signing up to the code of practice will commit to the following:

- 1) We will provide advice and information to our customers about safe and effective use of contact lenses (in line with agreed guidance¹⁶ published on the website of the code of practice sponsor) including advising the customer to follow the advice of their eye care practitioner, with particular reference to advice on emergency situations and a reminder of the importance of aftercare and eye examination appointments.
- 2) We will comply with this code of practice as well as all domestic and international legislation that applies to the country where we are based, including consumer protection legislation. In particular, we will ensure that all lenses supplied are genuine and not counterfeit.

¹⁵ Europe Economics (2013), *Health Risk Assessment of Illegal Optical Practice: Final report for the General Optical Council*.

¹⁶ This guidance will be developed by the stakeholder working group and approved by the stakeholder steering group. It will draw on existing guidance produced by the British Contact Lens Association and other professional bodies such as the College of Optometrists and the Association of British Dispensing Opticians.

- 3) We will provide customers with advice about how to complain to us about a service or product and what they can do if they are not satisfied with the outcome of the complaint.
- 4) We will only sell contact lenses online or over the telephone to a customer who has provided assurance that he/she:
 - a. is 16 years of age or over;
 - b. is not registered sight impaired¹⁷;
 - c. is ordering contact lenses for themselves or, if ordering contact lenses on behalf of someone else (e.g. someone who is not able to use a computer or someone who does not have a debit/credit card), is assured that that person has been fitted with the contact lenses being requested by an eye care practitioner;
 - d. attends aftercare appointments on a regular basis as directed by their eye care practitioner;
 - e. will follow the contact lens advice given by their eye care practitioner, the manufacturer of the contact lenses and the online supplier of the contact lenses, for example, advice on emergency situations;
 - f. is ordering contact lenses prescribed by an eye care practitioner within the last two years;
 - g. has accurately submitted the contact lens details as prescribed by their eye care practitioner; and
 - h. is ordering a quantity of contact lenses that does not amount to more than two years' supply.
- 5) We will supply only the exact contact lenses that have been requested by the customer (provided that they have given the assurances in point 4 above). In the event that the requested contact lens is not available, we will direct the customer back to their eye care practitioner for further advice unless one of the following circumstances applies:
 - a. the original manufacturer of the prescribed contact lens has endorsed an alternative without the need for a further fitting;
 - b. where an own-label contact lens has been prescribed and the supplier is able to supply the manufacturer-branded contact lens that is the same as the own-label contact lens;
 - c. where a manufacturer-branded contact lens has been prescribed and the supplier is able to supply the own-label contact lens that is the same as the manufacturer-branded contact lens; or

¹⁷ 'Registered sight impaired' means a person who has registered with their local social service's register. Registration is voluntary and requires the person to have been certified by an ophthalmologist (known as a Certificate of Vision Impairment (CVI) in England and Wales, an A655 in Northern Ireland and a BP1 in Scotland).

- d. where a request is made for a tinted version of the same contact lens that has been prescribed (provided that the tint has been added by the same manufacturer) (or an alternative contact lens that it is permissible to supply in accordance with 5a, b or c above).
- 6) When informing customers about a new or alternative range of contact lenses, we will advise them to consult an eye care practitioner to be fitted for the new contact lenses before placing an order (unless point 5 of the code of practice applies).
- 7) We will not sell zero-powered contact lenses (the rationale for this being that the Opticians Act 1989 provides that zero-powered contact lenses may only be sold by or under the supervision¹⁸ of a registered medical practitioner, a registered optometrist or a registered dispensing optician).

Explanatory notes

The code takes into account the legislative framework governing the supply of contact lenses, but also reflects the fact that good practice should evolve in line with technological advances, changes in consumer behaviour and the development of new delivery channels, notably online supply.

The logo for the *Code of practice for the online supply of contact lenses* will be used to assure customers that contact lenses will be supplied in accordance with the above best practice and may be withdrawn if any material breach of this code is proven. Online suppliers signing up to the code will be given permission to use a logo on their website to promote their business to customers. Mystery shopping will be carried out on a regular basis to ensure that the online supplier is complying with the points and explanatory notes specified in this code. If any evidence is found to suggest that there has been a material breach of the code, the use of the logo will be suspended pending investigation. If the breach is proven, use of the logo will be withdrawn until the breach can be rectified or on a permanent basis should the breach be considered to be serious.

The code reflects the following principles:

- All contact lens wearers should have aftercare appointments at appropriate intervals in line with the recommendation of the eye care practitioner who fitted their contact lenses.
- Aftercare appointments enable eye care practitioners to:
 - remind and advise contact lens wearers how to use their contact lenses safely;

¹⁸ The GOC's standards of practice defines supervision as being on the premises and in a position to intervene. [NB The inclusion of this footnote is subject to Council approving the final version of new standards of practice at its meeting on 29 July 2015.]

- check the health of the eye and ensure that the contact lenses remain suitable to wear; and
- advise contact lens wearers about product developments from which they may benefit.

Guidance for the numbered points in the code of practice is provided below.

- 1) *We will provide advice and information to our customers about safe and effective use of contact lenses (in line with agreed guidance¹⁹ published on the website of the code of practice sponsor) including advising the customer to follow the advice of their eye care practitioner, with particular reference to advice on emergency situations and a reminder of the importance of aftercare and eye examination appointments.*

Online suppliers should ensure that they provide advice and information to their customers about safe and effective use of contact lenses, including advising the customer to follow the advice of their eye care practitioner, with particular reference to emergency advice and reminders about the importance of aftercare and eye examination appointments. We would suggest referring the customer to guidance provided on the code of practice sponsor's website in this regard.

- 2) *We will comply with this code of practice as well as all domestic and international legislation that applies to the country where we are based, including consumer protection legislation. In particular, we will ensure that all lenses supplied are genuine and not counterfeit.*

Online suppliers should ensure that they are aware of all relevant legal obligations when selling to their customers, regardless of the legal jurisdiction applicable to their operations. In the UK the following consumer protection legislation applies: the Consumer Protection from Unfair Trading Regulations 2008, Consumer Contracts (Information, Cancellation and Additional Charges) Regulations 2013, Unfair Terms in Consumer Contracts Regulations 1999, Sale of Goods Act 1979 and Supply of Goods and Services Act 1982 and the Data Protection Act 1998. The Unfair Terms in Consumer Contracts Regulations 1999, Sale of Goods Act 1979 and Supply of Goods and Services Act 1982 will be replaced by the Consumer Rights Act 2015 in October 2015.

- 3) *We will provide customers with advice about how to complain to us about a service or product and what they can do if they are not satisfied with the outcome of the complaint.*

¹⁹ This guidance will be developed by the stakeholder working group and approved by the stakeholder steering group. It will draw on existing guidance produced by the British Contact Lens Association and other professional bodies such as the College of Optometrists and the Association of British Dispensing Opticians.

Online suppliers should make information about their complaints process available to customers, including what a customer can do if they are not satisfied.

- 4) *We will only sell contact lenses to a customer who has provided assurance that he/she:*
- a. *is 16 years of age or over;*
 - b. *is not registered visually impaired;*
 - c. *is ordering contact lenses for themselves or, if ordering contact lenses on behalf of someone else (e.g. someone who is not able to use a computer or someone who does not have a debit/credit card), is assured that that person has been fitted for the contact lenses being requested by an eye care practitioner;*
 - d. *attends aftercare appointments on a regular basis as directed by their eye care practitioner;*
 - e. *will follow the contact lens advice given by their eye care practitioner, the manufacturer of the contact lenses and the online supplier of the contact lenses, for example, advice on emergency situations;*
 - f. *is ordering contact lenses prescribed by an eye care practitioner within the last two years;*
 - g. *has accurately submitted the contact lens details as prescribed by their eye care practitioner; and*
 - h. *is ordering a quantity of contact lenses that does not amount to more than two years' supply.*

Contact lenses should not be provided to the under 16s or visually impaired and therefore we require online suppliers to seek this assurance from the customer. We also require them to seek assurance (via a tick-box approach) that the customer is ordering contact lenses for themselves, or if on behalf of someone else that person has been fitted for the contact lenses being requested, attends regular appointments with an eye care practitioner, will follow contact lens advice given by their prescribing eye care practitioner and the online supplier (particularly in emergencies), that they are only requesting contact lenses prescribed by an eye care practitioner and have accurately submitted those details. Customers are also required to provide confirmation that they are not ordering a quantity of contact lenses that will exceed the expiry date in their contact lens specification (if available).

- 5) *We will supply only the exact contact lenses that have been requested by the customer (provided that they have given the assurances in point 4 above). In the event that the requested contact lens is not available, we will direct the customer back to their eye care practitioner for further advice unless one of the following circumstances applies:*
- a. *the original manufacturer of the prescribed contact lens has endorsed an alternative (via a fit-match study) without the need for a further fitting;*

- b. *where an own-label contact lens has been prescribed and the supplier is able to supply the manufacturer-branded contact lens that is the same as the own-label contact lens;*
- c. *where a manufacturer-branded contact lens has been prescribed and the supplier is able to supply the own-label contact lens that is the same as manufacturer-branded contact lens; or*
- d. *where a request is made for a tinted version of the same contact lens that has been prescribed (or an alternative contact lens that it is permissible to supply in accordance with 5a, b or c above).*

Contact lenses should only be substituted in accordance with the guidance provided above. Points 5b and 5c of the code relate to situations where a contact lens is exactly the same product (that is, exactly the same material) but has been branded by both the manufacturer and supplier, meaning that the product has two different names.

- 6) *When informing customers about a new or alternative range of contact lenses, we will advise them to consult an eye care practitioner to be fitted for the new contact lenses before placing an order (unless point 5 of the code of practice applies).*

We recognise that suppliers will wish to inform their customers about product developments. However, we expect suppliers to advise customers to ensure that they see an eye care practitioner for a contact lens fitting before placing an order.

- 7) *We will not sell zero-powered contact lenses (the rationale for this being that the Opticians Act 1989 provides that zero-powered contact lenses may only be sold by or under the supervision²⁰ of a registered medical practitioner, a registered optometrist or a registered dispensing optician).*

The Opticians Act 1989 provides that zero-powered contact lenses may only be sold by or under the supervision of a registered medical practitioner, a registered optometrist or a registered dispensing optician. Supervision has been interpreted to mean on the premises and in a position to intervene. It would therefore not be appropriate for online suppliers to sell zero-powered contact lenses online or over the telephone.

²⁰ The GOC's standards of practice defines supervision as being on the premises and in a position to intervene. [NB The inclusion of this footnote is subject to Council approving the final version of new standards of practice at its meeting on 29 July 2015.]

Appendix 2

Membership of stakeholder steering group on contact lens supply

- Gordon Ashworth – Director of Consumer Policy at the Competition and Markets Authority
- Peter Black – President of the Association of British Dispensing Opticians (ABDO)
- Gill Brown – Chief Executive of Healthwatch Lancashire (consumer representative)
- Kamlesh Chauhan – Immediate Past President of the College of Optometrists and Director of THE VISION CARE INSTITUTE®, Europe, Middle East & Africa at Johnson & Johnson Medical Ltd
- Chris Cherry – Delivery Manager at Healthwatch East Riding of Yorkshire (consumer representative)
- Cheryl Donnelly – Chief Executive Officer of the British Contact Lens Association (BCLA)
- Mitesh Patel – founder of Lenstore (online contact lens supplier), Digital Strategy Director at Vision Express and member of the GOC Companies Committee
- Simon Rodwell – Secretary General of the Association of Contact Lens Manufacturers (ACLM)
- Claire Slade – member of the Federation of Ophthalmic and Dispensing Opticians (FODO) and GOC Companies Committee and Registration Committee, Superintendent Optometrist at Asda
- Kevin Thompson – member of Council of the Association of Optometrists (AOP) and GOC Companies Committee
- Alistair Bridge – Director of Strategy at the GOC
- Marie Bunby – Policy Manager at the GOC
- Richard Edwards – independent consultant and member of the GOC Companies Committee
- Rob Hogan – Council Member of the GOC and Member of the Board of Trustees of the College of Optometrists

NB Rob Darracott, Chief Executive Officer of Pharmacy Voice, attended the first meeting of the steering group in an advisory capacity.

Phil Morgan, Professor of Optometry and Director of Eurolens Research at The University of Manchester, was previously a member of the group and attended the first steering group meeting.

Appendix 3

Membership of stakeholder working group on voluntary code of practice for online suppliers and consumer awareness

- Gordon Ashworth – Director of Consumer Policy at the Competition and Markets Authority
- Jonathon Bench – Head of Professional Affairs, UK and Ireland at Alcon Laboratories Inc (contact lens manufacturer)
- Cheryl Donnelly – Chief Executive Officer of the British Contact Lens Association (BCLA)
- Kayleigh Dunn – Head of Professional Services at Lenstore (online contact lens supplier)
- Giles Edmonds – Director of Products and Professional Advancement (UK and ROI) at Specsavers (as of May 2015)
- Simon Rodwell – Secretary General of the Association of Contact Lens Manufacturers (ACLM)
- Claire Slade – member of the Federation of Ophthalmic and Dispensing Opticians (FODO) and GOC Companies Committee and Registration Committee, Superintendent Optometrist at Asda (as of May 2015)
- Alistair Bridge – Director of Strategy at the GOC
- Marie Bunby – Policy Manager at the GOC
- Richard Edwards – independent consultant and member of the GOC Companies Committee
- Rosie Glazebrook – GOC Council member (as of May 2015)

Phil Morgan, Professor of Optometry and Director of Eurolens Research at The University of Manchester, was previously a member of the group and attended the first working group meeting.