

Consultation: illegal practice strategy

March 2014



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Executive summary

1. The purpose of this consultation is to seek views on our proposed approach to addressing the different types of illegal practice defined in the Opticians Act 1989 (the Act). This is in line with our role in protecting and promoting the health and safety of the public.
2. We understand that illegal practice is an area of great interest to many of our stakeholders, and we recognise the importance of effective collaboration as we refine and implement this strategy.
3. The Act creates criminal offences in relation to:
 - 3.1. unlawfully conducting sight tests;
 - 3.2. unlawfully supplying spectacles;
 - 3.3. unlawfully fitting contact lenses;
 - 3.4. unlawfully supplying prescription contact lenses;
 - 3.5. unlawfully supplying zero-powered contact lenses; and
 - 3.6. misuse of protected title.
4. Our current approach to dealing with illegal practice involves handling complaints in line with our prosecution protocol, published in June 2011.¹
5. We face a number of difficulties in taking effective enforcement action:
 - 5.1. we have limited powers of investigation and enforcement;
 - 5.2. we face significant challenges in prosecuting online suppliers of contact lenses (both prescription and zero-powered), particularly as many are based overseas; and
 - 5.3. 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.
6. In this proposed strategy we have therefore recognised that we cannot rely just on responding to complaints and considering whether it is feasible to take enforcement action. We need to adopt a more proactive and creative approach, working collaboratively with stakeholders to reduce the harm to the public which illegal practices can cause.
7. We will need to work with professional bodies and optical businesses and, equally importantly, we will need to work with representatives of patients and the public.
8. To assist in reviewing our strategy we commissioned Europe Economics to carry out research into the risks to the public associated with illegal practice.

¹ http://www.optical.org/en/Investigating_complaints/index.cfm

The findings are summarised in section 2, and can be found on the consultations page of our website: <http://www.optical.org/en/get-involved/consultations/index.cfm>

9. We suggest 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, consumer groups and other enforcement bodies, and in doing so, make clear our role and remit; and
 - 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.
10. Taking into account the above principles and the research by Europe Economics, we are proposing an approach based on the following five areas:
 - 10.1. continuing to handle complaints in line with our prosecution protocol for all types of illegal practice;
 - 10.2. collaboration with other enforcement bodies to address high-risk areas of illegal practice;
 - 10.3. guidance for the public on the safe purchase and use of contact lenses (prescription and cosmetic);
 - 10.4. development of a voluntary code of practice on the supply of contact lenses (prescription and cosmetic) online; and
 - 10.5. further research and intelligence-gathering.
11. Future changes to business regulation should enhance our ability to tackle illegal practices by requiring all UK businesses undertaking restricted functions to be registered with us. However, these changes will not be implemented for some time, and many of the proposals contained in this strategy will be of value regardless of any changes to business regulation.

12. The development of our strategy is at an outline stage, and we recognise that our proposal will need to be developed and worked through carefully. Therefore we welcome comments and suggestions on our proposed strategy from all stakeholders. The consultation will run until 3 June 2014.
13. In addition we will seek to arrange meetings and a workshop with key stakeholders, including public and patient groups.
14. Many of the issues and obstacles inherent in dealing with illegal practices will be difficult to overcome, and we will not be able to eliminate entirely the risks to the public. However, by adopting a creative and collaborative approach and by making this area of work an organisational priority, we hope to take a substantial step forward.

Introduction

15. This document seeks the views of stakeholders on our proposed approach to tackling the different types of illegal practice.
16. Section one explains the different types of illegal practice, the constraints we face, and relevant market developments. Section two summarises the key findings of the research we commissioned into the risks to the public. Section three sets out our proposed strategy.
17. We have prepared this consultation with reference to the principles of good regulation²: 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**³ – 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.
18. Included in this document are a number of questions we would like those responding to the consultation to consider.
19. The consultation will run from **3 March 2014** to **3 June 2014** and applies to the whole of the UK.

About us

20. The General Optical Council (GOC) is 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.
21. We are the regulator for the optical professions in the UK. We currently register around 26,000 optometrists, dispensing opticians, student opticians and optical businesses. Our primary legislation is the Opticians Act 1989 (as

² Better Regulation Executive (2000), *Five principles of good regulation*.

³ Added by the PSA (formerly CHRE) (2010), *Right-touch regulation*.

amended) (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

22. 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

23. We welcome all responses to the consultation and we will consider our approach to illegal practice in light of the responses we receive. You can download further copies of this document and the response form from our website, or you can contact us if you would like us to send you copies of these documents.
24. Please contact us to request a copy of this document in an alternative format, or in Welsh.
25. We are consulting for three months, and the deadline for responses to this consultation is **3 June 2014**.
26. Please send your response in writing to:
- Danny Langley
General Optical Council
41 Harley Street
London W1G 8DJ
27. You may also email responses to dlangley@optical.org or send a fax to +44 (0)207 7436 3525. 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 3473 to discuss any reasonable adjustments that would help you to respond.
28. We will publish on our website all non-confidential responses we receive to the consultation, as well as a summary including the decisions we have taken as a result. If you would prefer your responses not to be made public, please indicate this when you respond.

Further information

29. 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.
30. 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 Danny Langley on dlangley@optical.org or 020 7307 3473.

Our commitment to consultation

31. 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.
32. How we consult with our stakeholders is set out in our Consultation Framework, available in the consultation section of our website. Feedback on the consultation process itself would be welcome. If you have any comments then please contact Simon Grier on sgrier@optical.org

Section 1 – Background

Overview of illegal practice

33. The Opticians Act 1989 (the Act) creates a number of criminal offences in relation to activities that are restricted to persons registered with the GOC (or the General Medical Council) and titles that are restricted to persons registered with the GOC.
34. The Act creates the following offences:
 - 34.1. **Misuse of protected title:** it is an offence to use a protected title or to misrepresent registration status with the GOC. An unregistered individual cannot use the titles “optometrist”, “dispensing optician”, “registered optometrist”; an unregistered body corporate cannot use the titles “ophthalmic optician”, “optometrist”, “dispensing optician”, “registered optician”; an unregistered individual or body corporate cannot use the title "optician" unless it would be unreasonable for anyone to think it is registered with the GOC (Section 28 of the Act).
 - 34.2. **Unlawfully conducting sight tests:** sight testing can be conducted only by a registered medical practitioner or registered optometrist, with special provision for students (Section 24 of the Act).
 - 34.3. **Unlawfully supplying spectacles:** if the user is under 16, registered blind or registered partially sighted, spectacles can be supplied only by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician (who must be present at the time of the supply). For other users, anyone can supply spectacles, but there are additional requirements for spectacles with certain prescriptions (Article 3 of the Sale of Optical appliances Order 1984 and Section 27 of the Act).
 - 34.4. **Unlawfully fitting contact lenses:** contact lenses can be fitted only by a registered medical practitioner, registered optometrist or registered dispensing optician who is in possession of an in-date contact lens prescription (Section 25 of the Act).
 - 34.5. **Unlawfully supplying prescription contact lenses:** prescription contact lenses can be supplied by or under the personal supervision of a registered medical practitioner, registered optometrist or registered dispensing optician. They can also be supplied under the general direction of a registered medical practitioner, registered optometrist or registered dispensing optician (who need not be present at the supply), provided that the supplier

first verifies the wearer's in-date specification with the prescriber. If the user is under 16, registered blind or registered partially sighted, prescription lenses can be supplied only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician (Section 27 of the Act).

- 34.6. **Unlawfully supplying cosmetic contact lenses:** zero-powered contact lenses can be supplied only by or under the supervision of a registered medical practitioner, registered optometrist or registered dispensing optician.
35. We have received complaints about a range of illegal practices, including supply of zero-powered lenses, supply of prescription contact lenses, misrepresentation of title and the supply of spectacles.
36. The number of complaints we receive is influenced by a range of factors, not least the extent to which we publicise our role in dealing with illegal practice and encourage complaints. So the level of complaints about a particular practice does not necessarily indicate the level of public concern or the frequency with which it occurs.

Current approach and constraints

37. Our current approach to dealing with illegal practice involves handling complaints in line with our prosecution protocol, published in June 2011.⁴
38. We are of the view that our prosecution protocol continues to provide an effective framework for dealing with illegal practice complaints. This involves dealing with complaints in three stages:
- 38.1. screening – initial screening to ascertain whether the allegation relates to a matter in relation to which it would be appropriate for the GOC to consider bringing criminal proceedings.
 - 38.2. investigation – we investigate the allegation by gathering evidence.
 - 38.3. decision – we determine whether to:
 - 38.3.1. take no action;
 - 38.3.2. obtain an undertaking or take other informal action;
 - 38.3.3. refer the matter to our Fitness to Practise department, another regulator or the police; or
 - 38.3.4. bring a prosecution.
39. In deciding whether to bring a prosecution we must be able to satisfy two tests. There must be:

⁴ http://www.optical.org/en/Investigating_complaints/index.cfm

- 39.1. sufficient evidence for there to be a realistic prospect of conviction (the evidential test); and
 - 39.2. a prosecution must be required to serve the interests of the public (the public interest test).
40. We have found the current approach to be generally effective in dealing with complaints relating to misuse of protected titles. In most cases the individual or company is not aware they are breaking the law, and agree to stop using a protected title or register with us when the law is explained to them.
41. Less formal enforcement action is also generally effective for some other forms of illegal practice, such as illegal spectacle dispensing to under-16s.
42. We have as a result been able to deal effectively with many cases without needing to resort to formal enforcement action.
43. We consider each case on its merits, but many cases relating to cosmetic contact lenses or online sale of prescription lenses brought to our attention fail one or both of the above tests, resulting in a decision not to prosecute.
44. We face a number of other enforcement challenges:
 - 44.1. We do not have statutory prosecution powers but can bring private prosecutions. Other healthcare regulators are in the same position and we do not expect to be given additional powers through the current UK Law Commissions' review.
 - 44.2. We must bring a prosecution within six months of receiving a complaint (unless the offence is continuing), which creates pressure to process complaints quickly in order to decide within six months whether to pursue a prosecution.
 - 44.3. We have limited powers of investigation and enforcement. We do not have the power to require the disclosure of information. This is in contrast with our ability to require the disclosure of information in relation to a registrant's fitness to practise, carry on business or undertake training.
 - 44.4. The offences specified in the Act are summary offences and the maximum penalty the court can impose is £5,000 per offence. In the event that we bring a successful prosecution, the sanction is limited. This means that a successful prosecution might not have a significant deterrent effect either for the guilty party or more widely.
 - 44.5. Our assumption is that the complaints we receive about the supply of cosmetic contact lenses and the supply of prescription and cosmetic contact lenses online represent the 'tip of the iceberg'. Therefore, seeking to prevent illegal practice by taking more proactive enforcement action would require significant additional resource. This is particularly the case in relation to cosmetic

contact lenses as they tend to be sold in a large number of different outlets, including hairdressers, fancy dress shops and joke shops.

- 44.6. We have been advised that there are significant barriers to us taking action against any businesses based outside of the UK. Furthermore, UK law is often stricter than in other countries, meaning that a supplier may be acting within the law in the country where they are based.
- 44.7. In relation to UK-based suppliers, a prosecution may merely result in the supplier moving to a different country and continuing to supply the UK market via the internet.

Market developments

45. We would like to develop our understanding of the size of the online market and the proportion of sales that might be illegal, but it is reasonable to assume that the online market will continue to grow. First, there has been growth in online sales generally. Secondly, the rise in the cost of living is likely to have encouraged more people to seek savings by buying 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.

Legislative change

46. We do not expect to gain additional powers of investigation and enforcement as part of the Law Commissions' ongoing review of the legislation of professional regulators in the UK.
47. Following our review of how optical businesses are regulated, Council has decided that we should seek to register all optical businesses carrying out restricted functions, such as contact lens fitting and dispensing. Such businesses would then have to comply with our code of conduct for businesses and we would be able to take action under our fitness to practise process for breach of the code, rather than having to rely on legal action as is the case with unregistered businesses. However, these changes require new legislation, which will take a number of years. We believe that a new approach to illegal practice is warranted in the meantime.
48. We will continue to monitor the progress of the European Commission proposals to amend the Medical Services Directives, which include a proposal to classify zero-powered contact lenses as medical devices. This would ensure that zero-powered contact lenses are produced to a certain standard and could mean that we see the exit from the market of less reputable suppliers of the kind that will supply any retail outlet. The timescales for any such changes are currently unclear. However, implementation of this change in the classification of zero-powered lenses (assuming it is approved) will certainly take a number of years.

Section 2 – Summary of evidence of risk

49. 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.
50. In producing their research report, 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.
51. Europe Economics also drew on the knowledge of their external advisor Dr Bruce Evans and his long experience in the optometry profession (from a practitioner, academic and legal witness perspective).⁵
52. 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 point out that the risks associated with illegal practice are difficult to identify even for medical experts.
53. The full research report by Europe Economics can be found on the consultation section of our website: <http://www.optical.org/en/get-involved/consultations/index.cfm>
54. Based on the information gathered, Europe Economics make 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.
55. For each type of risk that flows from illegal practice, Europe Economics have assessed the level of harm that would arise and the likelihood of this harm occurring. For example, in relation to the risk of an illegal sight test leading to misdiagnosis they have assessed: the likelihood that this would lead to an adverse event; and the level of harm that would be likely to result from such an adverse event.
56. Figure 1 summarises their findings, drawing on Table 6.1 of the report. The methodology employed draws on the risks inherent in legal optical practice

⁵ Professor Bruce JW Evans BSc, PhD, FCOptom, DipCLP, DipOrth, FAAO, FBCLA is Director of Research at the Institute of Optometry and a Visiting Professor to City University and the London South Bank University. He was awarded Fellowship of the British Contact Lens Association in 2006. He has authored over 200 scientific and professional papers, five books on binocular vision and two on dyslexia and vision, and has given more than 250 invited lectures.

as well as illegal practices to provide a full picture of the 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



57. 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:
- 57.1. misdiagnosis resulting from illegal sight tests, which in the event of an adverse event is likely to lead to the highest level of harm;
 - 57.2. illegal contact lens supply where there is a lack of aftercare advice;
 - 57.3. illegal online supply of contact lenses;
 - 57.4. illegal sale of cosmetic contact lenses; and
 - 57.5. the indirect risks of misuse of title by unregistered practitioners.

Aggregate level of harm

58. In order to develop our strategy, we also need 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). We suggest that we should respond reactively to complaints about practices that occur relatively infrequently and be more proactive in dealing with practices that cumulatively could cause substantial harm.
59. 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 suggest, therefore, that we should continue to deal with these issues in a reactive way.

60. Our assumption is that the illegal supply of cosmetic and prescription contact lenses occur much more frequently than other types of illegal practice. We have commissioned some market research to try to test this assumption, with the survey being carried out in August and September 2013. We 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.
61. 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.
62. 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. First, there has been growth in online retail sales generally. Secondly, the rise in 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.

Section 3 – Proposed illegal practice strategy

63. Our statutory function is to protect, promote and maintain the public's health and safety in the optical sector. We propose that our objective in relation to tackling illegal practice should be to minimise the risks to the public that can result from the illegal practices defined in the Act.
64. We suggest 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, consumer groups and other enforcement bodies, and in doing so, make clear our role and remit; and
 - 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.
65. Our analysis of Europe Economics' research into the likely public harm suggests that the main issues we should focus on are the illegal supply of prescription contact lenses online and the illegal supply of cosmetic contact lenses. These carry a high likelihood of an adverse event and the potential level of harm is high. We understand that these practices are occurring on large scale and so are likely to be causing a substantial amount of aggregate harm. This suggests that we should be proactive in seeking to minimise the harm caused by these practices.
66. Some other types of illegal practice can also cause significant harm. There is a high risk that an illegal sight test could lead to misdiagnosis and this could lead to a very high level of harm. There is also a high risk that misuse of a protected title could lead indirectly to an adverse event and to a high level of harm. However, we do not have evidence to suggest that deliberate breaches or consequent harm is occurring on a large scale. This suggests that we should continue to deal reactively with complaints about such practices in line with our prosecution protocol.

67. Taking this into account, we are proposing an action plan covering the following five areas:
- complaints-handling 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;
 - development of a voluntary code of practice on the supply of contact lenses (prescription and cosmetic) online; and
 - further research and intelligence-gathering.
68. An impact assessment considering this proposed approach and the other options we have considered can be found in section four of this document.
69. We recognise that implementation of some of these proposals may pose certain issues and challenges. We welcome the opportunity to explore these with stakeholders to produce workable, proportionate and effective solutions.

Complaints-handling in line with our prosecution protocol for all types of illegal practice

70. We intend to continue considering complaints about illegal practice in line with our prosecution protocol.⁶
71. As mentioned above, however, it is clear that the application of our protocol will generally lead to a decision not to bring a prosecution in relation to the supply of prescription contact lenses online. We suggest that collaboration to develop authoritative guidance, and potentially a voluntary code of practice, will be more effective in dealing with this issue.
72. For other types of illegal practice, such as misuse of protected title, informal action backed up by the existing threat of prosecution is likely to remain sufficient.

Collaboration with other enforcement bodies on high-risk areas

73. We need to extend our collaboration with other enforcement bodies to tackle areas of illegal practice which pose a high-risk, particularly in relation to the online supply of contact lenses and the supply of cosmetic lenses. Until now we have tended to engage with local trading standards officers in an ad hoc way, working with them to follow-up individual complaints.
74. We intend to engage at a national level to explore how feasible it would be for local trading standards authorities to take a more consistent and co-ordinated approach to dealing with illegal practice. We are also exploring the scope for collaboration with the Medicines and Healthcare products Regulatory Agency (MHRA) as the regulator of contact lenses.

⁶ http://www.optical.org/en/Investigating_complaints/index.cfm

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

75. Europe Economics' research found much evidence to suggest that compliance by contact lens wearers with guidance on the wearing of lenses and appropriate aftercare is patchy at best, even when users purchase their lenses from a reputable supplier. The report suggests it is reasonable to assume that non-compliance is an even greater issue where the user purchases lenses from a supplier who does not provide adequate advice on the use of lenses and the required aftercare. Such lack of compliance directly increases the risk of an adverse event taking place.
76. The report notes that compliance amongst cosmetic lens users is usually worse than those using prescription lenses, and some evidence suggests that the clinical risks posed by cosmetic lenses may also be greater.
77. As lack of compliance appears to be a key factor in the risk of harm inherent in contact lens use (both prescription and cosmetic), we should aim to increase public awareness about the safe purchase and use of contact lenses, and thereby reduce the risk of actual harm.
78. We therefore propose to work with professional bodies, public health bodies, optical businesses, manufacturers and consumer and public interest groups to develop authoritative guidance for the public on the risks associated with contact lenses (prescription and cosmetic) and how they can be avoided. This could focus, for example, on the importance of regular check-ups and appropriate aftercare. As the research from Europe Economics suggests that young people are at higher risk, it may be worth seeking to specifically target this group.
79. The aim would be for all relevant stakeholders to publish the guidance on their websites. We could also provide the guidance in PDF format to download and print out. This would mean it could be given to patients by registrants.
80. We recognise, however, that considerable guidance exists already and propose to build on this rather than starting from scratch. It will also be important to take account of the different ways in which advice can be provided, working for example with manufacturers on the messages that are included with contact lens packaging.

Development of a voluntary code of practice for supply of contact lenses (prescription and cosmetic) online

81. The research undertaken by Europe Economics suggests that the online sale of contact lenses can pose an increased risk of harm. This can apply to legal as well as illegal online sales, as those who purchase contact lenses online appear less likely to attend aftercare appointments. Europe

Economics also found that substitution of contact lenses can pose additional risk, even within the scope of legal supply.⁷

82. They also found that in many instances of online supply, an in-date specification is not verified with the original prescriber and the supply does not take place under the general direction of a registered practitioner.
83. The report suggests that failure to ensure an accurate and up to date specification carries additional risks to the user. The lenses may not fit correctly, thereby increasing the risk of infection. Furthermore, the lack of requirement for an in-date specification removes the incentive for users to visit their eye care practitioner. These visits are important to ensure that the lenses continue to fit and that they are not causing any damage.
84. More generally, this type of supply increases the risk of harm by eliminating the mitigating factors of having a professional fitting and receiving adequate advice on fitting and aftercare.
85. The issues identified suggest that there are clear steps that online suppliers can take to ensure that they comply with the law and reduce the risk of harm posed to their customers. While the main areas of concern relate to illegal online supply, it is likely that there are further steps legal suppliers could take to mitigate some of the risks.
86. We propose, therefore, to work with the profession (including professional bodies, optical businesses and suppliers) to develop a voluntary code of practice on the supply of contact lenses online. This would be designed to address the risks to the public highlighted by Europe Economics' research and help to achieve the policy objectives reflected in the current legal framework. It could draw on guidance published by the GOC, professional bodies and the European Council of Optometry and Optics.
87. It would be important for optical businesses to have an incentive to sign up to the code. This could be achieved by launching the code with a public campaign advising the public to gain peace of mind by purchasing their contact lenses from a signatory to the code.
88. Mystery shopping could be carried out subsequently to test whether suppliers – whether signatories to the code or not – were complying with good practice as reflected in the code. However, we would obviously need to allow sufficient time to enable signatories to comply. Publicising the findings would generate further publicity and help to enable the public to make better informed decisions about where to purchase their contact lenses.
89. We could also explore with suppliers how they might contribute to the code's effectiveness by encouraging businesses they supply to comply with it.
90. In the course of developing the code of practice, it would be possible to identify any areas where the existing legislation might not be in the public

⁷ See pages 22-23 of the Europe Economics report (Annex 2)

interest and potentially make recommendations to Government for legislative change.

91. We have an open mind about the precise role that the GOC should play in developing and implementing a voluntary code of practice. So as well as seeking comments on the merits of pursuing such an approach we would welcome comments on the best way of taking it forward.

Further research and intelligence-gathering

92. The report by Europe Economics identified a number of areas where there is a limited amount of information available, such as on the market for cosmetic contact lenses. We need to conduct further research to both fill the current gaps in available information and better our own understanding.
93. We need to track and better understand:
 - consumer behaviour, including trends in the purchase and use of contact lenses;
 - the market for contact lenses and how it is likely to evolve, including technological developments;
 - the supply chain for contact lenses, including distribution online; and
 - trends in the scale and type of complaints about illegal practice that we receive.
94. We are currently developing our approach to research in line with our strategic objective of improving our evidence base. Better understanding the above areas will form part of this work.
95. Further research and intelligence-gathering will also help us to measure and evaluate the success of our proposed strategy. Potential metrics include the level of public knowledge of the risks and the estimated frequency of adverse events occurring.

Reviewing our illegal practice strategy

96. We will continue to monitor and analyse illegal practice, and the above strategy will be revised as necessary to reflect further market or legislative developments.
97. We propose to conduct a review of this strategy two years after it has been implemented.

Section 4 – Impact assessment

Introduction

98. This section of the consultation document assesses the likely impact of the proposed strategy and the other potential options. It has been prepared with reference to the GOC's consultation framework which specifies that an impact assessment should generally be carried out together with a consultation.
99. We have considered the principles of good regulation in developing this consultation and undertaking this initial impact assessment. In our impact assessment, we assess whether each option is proportionate, targeted and transparent. More broadly as a regulator we aim to be consistent, accountable and agile in our approach to regulation and the decisions we make; we have applied these principles throughout the process of developing these options and consulting on them.
100. In this context we interpret agility to mean implementing a system of regulation that is 'future proof' and flexible enough to accommodate relevant developments.
101. Our policy objective is to minimise the risks to the public that can result from the illegal practices defined in the Act. We have identified five options that might enable us to achieve this objective:
- **Option 1** – Continue current approach
 - **Option 2** – Focus on educating the public
 - **Option 3** – Broad approach reflecting different types of illegal practice and the relative risk posed by each one (preferred option)
 - **Option 4** – Focus on achieving legislative change
 - **Option 5** – Shift resources to taking further enforcement action
102. We have considered the likely effects of the options on different categories of stakeholder and on the GOC. We have also considered the impact of these options on the devolved nations. The following categories of groups will potentially be impacted by these proposals:
- Public, including patients
 - Professional bodies
 - Online and High Street vendors of contact lenses, and their suppliers
 - Registrants
103. This section also includes an assessment of whether any of the options raise particular equality, diversity or inclusion issues.
104. This impact assessment is an initial impact assessment and we will finalise it in the light of the consultation responses and the further evidence we gather.

105. We have not included detailed information about financial costs in this section, but have provided an assessment of whether the anticipated costs would be low, medium or high, or whether there would be likely to be a saving.

Methodology

106. There are a number of methodological considerations to take into account when conducting an impact assessment.

Analysing the costs and benefits

107. When consulting on policy options we will include an initial impact assessment which focuses on the 'options stage' as identified by the Department for Business Innovation and Skills 'Impact Assessment Toolkit'. This impact assessment:

- identifies the options that may address the policy challenge;
- includes a qualitative discussion of the costs and benefits associated with each option; and
- makes an initial estimate of the costs and benefits associated with each of the different options to the extent that it is possible or proportionate to do so.

108. Choosing the best option will involve an assessment of the costs and benefits which would flow from the options selected, although this will generally inform rather than determine our decision. There are two main reasons for this. Firstly, fulfilling our statutory duties may involve taking account of issues that would fall outside a narrow consideration of costs and benefits. Secondly, it will often be difficult to quantify all the costs and benefits, in which case, it may be hard to identify which option has the highest net benefit and choose an option solely on that basis.⁸

109. We will describe the costs and benefits qualitatively, making clear who bears the costs and who receives the benefits. Benefits in particular can be hard to quantify as they tend to be more uncertain and are often spread across many members of the public.

110. In analysing costs and benefits we will apply the principle of proportionality, which means it will often be proportionate to focus on the most significant costs and benefits rather than costs and benefits which are relatively minor.

111. It is also important to consider the risks relating to particular options, such as the risk that the intended impact would not be achieved or would be delayed by problems with implementation. An option which has a high net benefit, but which carries a high risk, might be less attractive than a lower risk option which has a lower net benefit. The degree of risk will be influenced by the

⁸ The option with the highest net benefit provides the most benefit, taking into account the costs. If two options have the same net benefit but one has much higher costs, it is likely that we would choose the one with lower costs.

likelihood of it occurring and the extent to which it may be possible to mitigate the risk.

112. A related issue is that of possible unintended consequences. In selecting and assessing the different options, our aim will be to think widely about the possible impacts, taking account of possible knock-on effects across the optical sector. By doing so, we will seek to minimise any unintended consequences. But it is important to be alive to the possibility that they may occur.
113. We should also consider the risk of non-compliance with our decision. Our assessment of the costs and benefits that would flow from an option should therefore be based on a realistic level of likely compliance. This will involve exploring the incentives to comply, whether compliance will be practically possible and the costs of enforcement.
114. The distributional impacts which the different options would have should also be taken into account. A distributional impact is an impact which is transferred rather than being additional, for example, a policy might benefit vulnerable patients at the expense of other patients, while the net benefit remains the same. Clearly this would be a relevant consideration even though it would not be revealed by a narrow analysis of the costs and benefits.

Counterfactual

115. An important part of the analysis is identifying the extent to which the options will bring about additional costs and benefits compared with what would otherwise take place. This is achieved by developing a counterfactual, which is a benchmark situation against which to measure the impact of regulatory changes. The counterfactual seeks to take into account both the current situation and likely future developments.

Costs

116. The magnitude and nature of the costs will vary according to each option. We will undertake further analysis to calculate the costs more precisely.
117. The main types of costs associated with the options relate to:
 - costs incurred by the GOC and the professions for production and publication of consumer information, implementation costs for any policy changes, and potential costs for legal advice; and
 - cost to external bodies for complying with any new guidance, and potential costs for enforcement bodies.

Benefits

118. The benefits of the options will result from addressing the specific risks identified. Our analysis is focused on how effective each option is in addressing these risks. Benefits could fall into the following categories:

- increased levels of health and safety for patients and members of the public;
- complaints about illegal practice are dealt with in a more timely and effective way;
- greater public awareness of the risks posed by different types of illegal practice;
- reduction in occurrence of illegal practices; and
- increased confidence among the public and the professions in the system of regulation.

Wider impacts

119. We also consider the wider impacts of the options. These include:

- weaknesses of the policy options that may increase the costs or reduce the benefits;
- the risk of additional negative consequences arising;
- wider advantages or disadvantages that may occur; and
- the extent to which the options are in line with the principles of good regulation.

Option 1: Continue current approach

120. Our current approach is to handle complaints in line with our prosecution protocol. Continuing with this approach would commit us to an essentially reactive response, only taking action when illegal practice is brought to our attention.
121. With some forms of illegal practice, our current approach is broadly effective. An example of this is misrepresentation of title, where we are generally able to take effective action and resolve the issue.
122. With some other forms of illegal practice, however, our prosecution protocol can lead to a decision not to take action as the case fails one or both of the established tests (public interest and likelihood of success). The sale of contact lenses online from outside of the UK and the sale of zero-powered lenses are examples.

Costs

123. This option would not involve any extra costs for the GOC or external bodies. However, additional resource might be required to deal with the existing and future illegal practice caseload.

Benefits

124. This option would be the easiest to implement as it would not involve new activities, although difficulties would remain in dealing with certain cases.
125. The existing approach provides a clear framework for the GOC to take action against illegal practice.

Wider impacts

126. This option does not reflect the differences between the various types of illegal practice, and so would reduce the potential benefits of taking action.

Summary

127. Although this option is the most straightforward, it would only be effective in dealing with certain types of illegal practice and would not be effective in tackling some of the other areas of high risk identified by Europe Economics.

Costs	Low
Benefits	Low - would not address current issues
Wider impacts	Would only be effective for certain forms of illegal practice where our current approach is broadly effective
Proportionate	No - does not adequately address
Targeted	No - not effective at dealing with illegal practices identified as posing greatest risk
Transparent	Yes – based on publically available protocol

Option 2: Focus on educating the public

128. The report by Europe Economics suggests that the key driver of harm for two high-risk areas of illegal practice (illegal online sale of contact lenses and illegal sale of cosmetic lenses) is lack of compliance with guidance on how to safely use the products purchased.

129. This suggests that raising awareness should play a large role in reducing public harm.

Costs

130. This option would incur moderate to high costs for producing, publishing and distributing consumer information, depending on the approach taken.

Benefits

131. By raising awareness amongst the public of how to safely buy and use products such as contact lenses we could steer people away from illegal suppliers and help reduce the risk of harm through reckless use.

Wider impacts

132. Although this approach would likely help reduce harm from illegal practice, it would do little to prevent illegal practice actually occurring. Focusing entirely on raising awareness is therefore unlikely to yield broader benefits.

133. Additionally, the benefits described above may not be fully realised as the publication of new guidance is unlikely to prove newsworthy outside of the optical press.

Summary

134. Educating the public on the safe purchase and use of contact lenses should form part of our approach to illegal practice. However, on its own it would not do much to address illegal supply itself and would do little to address other forms of illegal practice.

Costs	Medium to high, depending on media used
Benefits	Medium - would increase public awareness of risks associated with contact lenses and steer people away from illegal suppliers
Wider impacts	Would do little to address illegal supply itself and does not address other types of illegal practice
Proportionate	Yes – although wider action would be beneficial
Targeted	Yes – targeted at main driver of harm arising from illegal practice
Transparent	Yes – does not raise transparency issues

Option 3: Broad approach to illegal practice

135. A broad approach to illegal practice should look to employ a range of approaches that reflect the varied nature of illegal practice itself.

136. This would likely involve five main areas of action:

- 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;
- further research and intelligence-gathering.

Costs

137. This option would incur moderate to high costs for producing consumer information materials, developing and launching guidance on online sales. Although at this stage we have not determined how these costs would be distributed between the GOC and other stakeholders.

Benefits

138. Employing a range of tactics and targeting the most high-risk activities would maximise the potential benefit to the public by both raising awareness to reduce potential harm and seeking to prevent illegal practices occurring.

139. By reflecting the varied nature of illegal practices, such an approach is likely to yield greater benefits than focusing on one particular area.

Wider impacts

140. The obstacles to taking enforcement action against companies based overseas but supplying to the UK market are likely to remain issues.

Summary

141. Taking a broad approach to illegal practice will enable us to employ a number of levers to achieve the greatest possible benefits by targeting the most high-risk areas and by recognising the challenges we face in pursuing a more traditional approach based on enforcement alone.

Costs	Moderate to high depending on exact approach
Benefits	High - greater public awareness of risks, and spread of good practice in the online contact lens markets. Potentially more action taken by other enforcement bodies against illegal practices.
Wider impacts	Limitations to what action we can take against overseas companies will remain a challenge

Proportionate	Yes – Could deliver high benefits at reasonable cost
Targeted	Yes – targeted at identified areas of highest risk
Transparent	Yes – does not raise transparency issues

Option 4: Focus on achieving legislative change

142. A further approach would be to examine both the legislative framework covering the supply and fitting of contact lenses and the enforcement powers the GOC has to tackle all types of illegal practice.
143. We have not currently identified what changes would be beneficial and whether there would be a realistic prospect of achieving change.

Costs

144. A reasonable amount of time and money would need to be invested in research and engagement, in addition to costs that would be incurred to implement systems, processes and policies arising from new legislation.
145. Subsequent use of any enforcement powers we would gain would likely incur high legal and resource costs as with option 5, albeit with a potentially greater chance of recovering legal costs following successful action.

Benefits

146. A reformed legislative framework could encourage suppliers and manufacturers to follow good practice, and could give the GOC greater powers to deal with individuals or companies not following the law.

Wider impacts

147. Legislative change is challenging and time-consuming to achieve (as much as 5-10 years, if not longer) and may not even be possible. This would particularly be the case if we were to seek legal changes at an EU or international level to deal with non-UK companies. In the case of revised EU law, suppliers may simply move outside the EU.

Summary

148. We believe that there may be some merit in seeking legislative change. However, the timeframes for such changes would be very long, and thus this option would not yield benefits in the short to medium term.

Costs	High – research, engagement and implementation costs of legislative change
Benefits	Unclear but potentially high - clearer and more effective legislative framework enforcing higher standards, and potentially greater powers for the GOC
Wider impacts	May not be possible to achieve legislative change. Enforcement powers could raise resource requirements
Proportionate	Unclear - would depend on scale of change sought
Targeted	Somewhat - legislation alone will not address all issues
Transparent	Yes - could clarify our powers and resolve legal issues

Option 5: Shift resources to taking further enforcement action

149. Although in most cases we currently decide not to prosecute after considering the case in line with our protocol, we could make a conscious decision to divert resources away from other work and take on a higher level of legal risk in actively seeking to increase the number of prosecutions.

Costs

150. This option would be extremely costly, requiring significant additional resources as well as draining resources from other areas of our work. It would likely remain prohibitively expensive to pursue every case identified, particularly in relation to small suppliers of cosmetic contact lenses.

Benefits

151. This approach would likely result in some successful prosecutions, encouraging certain suppliers or practitioners to change their behaviour. However, this might be temporary (see below).

152. Media coverage of successful prosecutions would help raise public awareness and potentially deter others from carrying out illegal activity, although given the low penalties the deterrent effect may be limited.

Wider impacts

153. This option would likely require a large-scale reallocation of GOC resources, undermining other activities we carry out, and ultimately the high costs would need to be borne by registrants through the registration fees.

154. With online retailers in particular, there is a strong chance that a successful prosecution by the GOC would ultimately result in the retailer moving overseas but continuing to supply in the UK, as has previously occurred.

Summary

155. This option would be highly costly, with success far from guaranteed. We might be able to secure some successful prosecutions, but this would have limited benefits and is not a sustainable long-term solution.

Costs	Very high – legal and financial costs.
Benefits	Limited – may secure some prosecutions, helping raise awareness, and deter others.
Wider impacts	Would require higher fees or resource reallocation. Prosecuted suppliers likely to move overseas. Risk of adverse publicity if prosecutions fail.
Proportionate	No – high cost for questionable benefits.
Targeted	No – does not reflect the varied nature of illegal practice and the drivers of harm identified by research.
Transparent	Uncertain – would depend on being able to define clearly the level of legal risk we are willing to take on

Equality and diversity

156. We have considered whether these options would significantly affect some groups more than others, for example on the basis of their age, ethnicity, gender, gender reassignment, disability, sexual orientation, pregnancy or maternity, marriage / civil partnership or religion / belief. We have not identified any issues which we feel require a full impact assessment. However, we welcome any views on how the proposals under consideration may affect one or more of the above groups.

GOC analysis and conclusion

157. Based on the analysis in the research report from Europe Economics and in this document, we believe that option 3 is the best option to take forward.

158. **Option 3** would enable us to:

- continue to take legal action against individuals or companies where it is in the public interest and where there is a realistic prospect of conviction;
- raise public awareness of the safe purchase and use of contact lenses to reduce the risk of harm posed by illegal supply;
- work with other enforcement bodies to take direct action where feasible against individuals or companies practicing or supplying illegally;
- explore the scope to develop a voluntary code of practice on the online supply of contact lenses that would help the public purchase online more safely; and
- increase our understanding of the market and of illegal practices so we can revise and update our approach as required.

159. **Option 1** is inadequate due to the legal and practical obstacles we face.

160. **Option 2** is worthwhile but is not enough on its own to address the risks.

161. **Option 4** may be worth exploring in the future. However, in the short to medium term seeking legislative change will not yield any benefits.

162. **Option 5** would be likely to incur extremely high costs with a limited prospect of long-term success, and would not target the drivers of risk associated with illegal practice.

163. Although we remain open to the idea of exploring potential changes to the law as a long-term solution, we do not feel that this should be a current priority. We do not expect to receive any additional enforcement powers from the ongoing UK Law Commissions' review of our legislation.

164. Future changes to business regulation should enhance our ability to tackle illegal practices by requiring all UK businesses undertaking restricted functions to be registered with us. However, these changes will not be implemented for some time, and many of the proposals contained in this strategy will be of value regardless of any changes to business regulation.

165. In this proposed strategy we have recognised that we cannot rely just on responding to complaints and considering whether it is feasible to take enforcement action. We need to adopt a more proactive and creative approach, working collaboratively with stakeholders to reduce the harm to the public which illegal practices can cause.
166. We look forward to working closely with stakeholders to develop and implement our strategy.

Section 5 – Implementation

167. Although we will refine and revise our strategy based on the outcome of this consultation, we intend to start work on some of the proposals during the consultation period so that we can move quickly to implement them should Council approve the finalised strategy at its July 2014 meeting.
168. To this end we will undertake to arrange meetings and a workshop with relevant stakeholders to develop revised consumer information materials and to discuss the potential voluntary code of practice for online sale of contact lenses.
169. We will also start to engage with external enforcement bodies to explore the scope for further collaboration to tackle illegal practice, and we will carry out further research to support the development of the strategy.
170. The implementation timescales are subject to further detailed planning and the outcome of this consultation. However, we currently envisage that we will issue updated consumer guidance towards the end of 2014 and that guidance for online sale of contact lenses will be issued in early to mid-2015.
171. A more detailed implementation plan will be presented to Council in July 2014 and made public thereafter.
172. We intend to monitor the impact of this strategy and will evaluate it two years after implementation is complete. By this time we should have a clearer idea of when we can expect changes to business regulation to be in place and how the changes will work in practice. This will put us in a strong position to evaluate our approach and refine it as necessary.

Section 6 – Response form

Please send your responses to Danny Langley no later than **3 June 2014**.

Please include a copy of this cover sheet with this consultation document.
Responses should be sent to:

Danny Langley
General Optical Council
41 Harley Street
LONDON
W1G 8DJ

Email: dlanglely@optical.org

Your details

Name:

Address:

Telephone number:

Email:

Are you replying on behalf of an organisation?

Name of the organisation:

Your position:

Nature of the organisation's work:

Keeping in touch

Because we value your input, we would like to contact you occasionally to let you know when we launch consultations and to invite you to future events. We will not pass your data on to any third party. Please tick here if you do not wish to be contacted in this way about the GOC's consultations:

Please include your contact details so that we can follow up any relevant aspect of your response. Unless you state otherwise (and an automatic disclaimer generated by your IT system will not be taken as such) 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. Please tick here if you are only happy for us to share your responses anonymously:

Questions

- 1 Do you feel that we have suggested the right forms of illegal practice to focus our attention on?
- 2 Given the constraints facing the GOC, do you feel that the proposed strategy represents the most effective and proportionate response to tackling illegal practice?
- 3 Do you have any comments on specific proposals in this strategy and how they might be implemented, e.g. the voluntary code of practice?
- 4 Are there any further measures you believe would help reduce the risk of harm different types of illegal practice pose to the public?
5. Do you have any data or insight you would be willing to share with us about the market for contact lenses (prescription and cosmetic), including the online market?

Closing date for responses is **3 June 2014**

Send to:
Danny Langley
General Optical Council
41 Harley Street
LONDON
W1G 8DJ

Email: dlangley@optical.org